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Review Article

Systematic Review of the Chronic Care Model in Chronic Obstructive Pulmonary Disease Prevention and Management

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ABSTRACT

Background Implementation of the chronic care model (CCM) has been shown to be an effective preventative strategy to improve outcomes in diabetes mellitus, depression, and congestive heart failure, but data are lacking regarding the effectiveness of this model in preventing complications in patients with chronic obstructive pulmonary disease.

Methods We searched the MEDLINE, CINAHL, and Cochrane databases from inception to August 2005 and included English-language articles that enrolled adults with chronic obstructive pulmonary disease and (1) contained intervention(s) with CCM component(s), (2) included a comparison group or measures at 2 points (before/after), and (3) had relevant outcomes. Two reviewers independently extracted data.

Results Symptoms, quality of life, lung function, and functional status were not significantly different between the intervention and control groups. However, pooled relative risks (95% confidence intervals) for emergency/unscheduled visits and hospitalizations for the group that received at least 2 CCM components were 0.58 (0.42-0.79) and 0.78 (0.66-0.94), respectively. The weighted mean difference (95% confidence

interval) for hospital stay was –2.51 (–3.40 to –1.61) days shorter for the group that received 2 or more components. There were no significant differences for those receiving only 1 CCM component.

Conclusions Limited published data exist evaluating the efficacy of CCM components in chronic obstructive pulmonary disease management. However, pooled data demonstrated that patients with chronic obstructive pulmonary disease who received interventions with 2 or more CCM components had lower rates of hospitalizations and emergency/unscheduled visits and a shorter length of stay compared with control groups. The results of this review highlight the need for well-designed trials in this population.

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Chronic obstructive pulmonary disease (COPD) affects about 30 million Americans, represents the fourth leading cause of death, and costs $37.2 billion annually.[1-3] Acute exacerbations of COPD (AECOPD) often require hospitalization and result in significant morbidity. In 2000, COPD and AECOPD were responsible for 8 million outpatient visits, 1.5 million emergency department (ED) visits, more than 725 000 hospitalizations, and nearly 120 000 deaths.[1] Pharmacotherapy has been shown to reduce AECOPD episodes by approximately 22% to 26%.[4]

Because COPD and other chronic illnesses represent an inordinate burden to health care resources, attention is often allocated to acute disease treatment as opposed to possibly more efficacious and cost-effective means of exacerbation prevention.[5] For example, COPD management is often tailored to treating AECOPD episodes, while minimal effort is expended to educate patients or health care systems about preventing exacerbations. This may lead to inappropriate resource use. Accentuating the disconnect between current health care systems and "ideal" care that may be attainable for chronic illness management, the Institute of Medicine has noted that "the current care systems cannot do the job," "trying harder will not work," but "changing care systems will."[6(p4),7] Therefore, a multidisciplinary organized approach to preventative COPD management is needed.

The chronic care model (CCM) has been a proposed solution to improve management, prevention of complications, and outcomes in patients with chronic diseases.[8] This model identifies essential elements that encourage high-quality chronic disease care.[5, 8-10] These elements involve the community and health system and include self-management support, delivery system design, decision support, and clinical information systems. The model fosters productive interactions between informed patients who actively participate in their care and experienced providers (nurses, physicians, respiratory therapists, pharmacists, etc), resulting in a broadly applicable, higher quality, and possibly more cost-effective patient care environment. Systematic reviews and clinical studies[11-12] have demonstrated that implementing the CCM components in patients with chronic diseases, such as diabetes mellitus, depression, asthma, and congestive heart failure, is associated with significantly improved outcomes. However, little is known about the effects of implementing this model in patients with COPD, because the CCM has not been systematically evaluated in this population. Therefore, we set out to conduct a systematic review and meta-analysis of the literature to determine the following: (1) which CCM components have been implemented in patients with COPD and (2) what combination of CCM components is associated with improved outcomes.

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LITERATURE SEARCH

We identified English-language articles in adults from the following databases: MEDLINE (1966-August 2005, week 1), CINAHL (1982-August 2005, week 1), and Cochrane (second quarter, 2005). Search terms were *disease management*, *case management*, *chronic disease*, *self-care*, *self-management*, or *patient education* and *lung diseases*, *obstructive*, *chronic obstructive pulmonary disease*, *COPD*, *chronic obstructive airway disease*, *COAD, chronic obstructive lung disease*, *COLD*, *emphysema*, or *chronic bronchitis*. We further augmented this search by (1) reviewing references of the identified articles and reviews, (2) hand searching abstracts from national conferences from January 1995 to May 2005, and (3) communicating with experts.

STUDY SELECTION AND DATA EXTRACTION

Two reviewers (S.G.A. and J.A.P.) independently selected studies for inclusion, with the following predetermined criteria: (1) contained intervention(s) with at least 1 CCM component, (2) included a control or comparison group or at least 1 outcome measured at 2 points (before/after), and (3) had relevant outcome(s) (ie, knowledge, dyspnea, quality of life [QOL], lung function, performance-based test [eg, 6-minute walk test], health care use [eg, emergency/unscheduled visits, hospitalizations, or length of stay {LOS}], clinical end point [eg, mortality or number of AECOPD], or cost). Agreement was examined, and disagreements were resolved by consensus. We excluded articles designed to evaluate the impact of specific therapeutic measures, such as oral or inhaled bronchodilator therapy, pulmonary rehabilitation, and supplemental oxygen therapy, because these therapies are considered to be "standard of care" and are beyond the scope of this review. Two reviewers (S.G.A. and P.K.S.) independently (1) extracted data on a standardized abstraction form created for this study and (2) applied the US Preventive Services Task Force rating for each randomized controlled trial (RCT). We categorized the interventions based on the CCM components (Table 1).

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Table 1. Interventions Categorized Into the Components of the Chronic Care Model

STATISTICAL ANALYSIS

Outcome results were entered into a spreadsheet (Excel; Microsoft, Redmond, Wash) and were imported into statistical software (Stata, version 8).[13] We performed statistical analyses only on RCTs. For each group of outcomes, such as functional status and performance measures, studies were grouped by category and either a relative risk (RR) or a mean difference was computed. In the instances in which outcomes were assessed using similar measures by at least 3 RCTs, outcome results were pooled after adjusting for study size and precision. Estimates were obtained for fixed- and random-effects models. For consistency, we report only the random-effect estimates. We used the I^2 statistic[14] and the Cochran Q statistic[15] to assess study heterogeneity. We also recomputed pooled estimates with and without studies that produced extreme results. An I^2

statistic of 50% or greater indicates that substantial heterogeneity exists among study estimates. We used the Mantel-Haenszel method to compute random-effect estimates for RRs and the DerSimonian and Laird[16] method to compute random-effect estimates for weighted mean or standardized mean differences when the studies were heterogeneous. Funnel plots were inspected for evidence of publication bias.

RESULTS

TRIAL RETRIEVAL

The search identified 534 titles that, when independently assessed by 2 reviewers, resulted in 82 potentially relevant articles and an additional 3 nonduplicate articles from references, national conferences, and experts (Figure). Only 32 studies reported in 37 articles[3, 17-52] were suitable for full abstraction and review. These studies were clinically heterogeneous, used many different interventions, and measured various outcomes[53-54] (Table 2).

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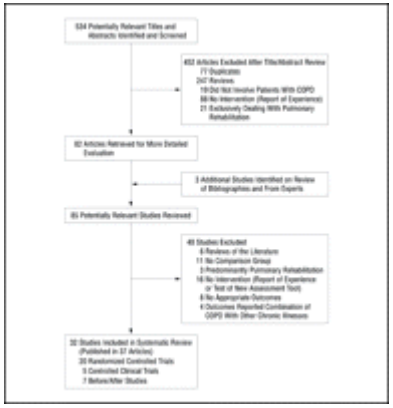

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Figure. Study flow diagram. COPD indicates chronic obstructive pulmonary disease.

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Table 2. Characteristics of Studies Included in a Systematic Review of Components of the Chronic Care Model in Patients With COPD

STUDY DESIGNS

Of 32 studies, 20 included in this systematic review were RCTs.[17, 20-26,28, 31-41] Table 2 summarizes study population characteristics, interventions, methodological quality, and outcome measures of these studies.[54] Only 1 study[39] randomized physicians rather than patients. Of 20 RCTs, 14 involved interventions that addressed only 1 CCM component, predominantly self-management.[17, 20-26,28, 31-32,37, 40-41] Table 3 summarizes the CCM components addressed with each study intervention.

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Table 3. Individual Components of the Chronic Illness Care Model for Each Study*

METHODOLOGICAL QUALITY OF INCLUDED STUDIES

Because blinding is impossible in educational/behavioral studies, no studies were double blinded. We evaluated if outcome assessors were blinded to treatment allocation, in addition to all other US Preventive Services Task Force criteria for each RCT.[55] Only 1 study[34] met all criteria for "good" quality. Four trials[20, 35, 39-40] had 1 or more methodological problems, but did not have a fatal flaw and were, therefore, rated as "fair." In contrast, 15 of 20 RCTs had 1 or more fatal flaws and were of "poor" quality (eTable 1).[17, 21-26,28, 31-33,36-38,41]

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eTable 1. Quality of Included Randomized, Controlled Studies*

TYPES OF INTERVENTIONS

Various interventions were evaluated in these studies (Table 2 and Table 3). All but 4 studies[37, 43, 49, 52] included interventions of self-management (Table 3). Eighteen studies[3, 17, 20, 23-24,26, 31, 33-34,36, 38-41,45-46,50-51] targeted individual patients, 6 studies[25, 32, 35, 42, 47-48] targeted groups, and 4 studies[21-22,28, 44] provided interventions to individuals and groups. The intervention duration varied among studies: from 15 minutes[21] to more than 80 hours[32] (mean, 9.5 hours; median, 7.25 hours) (Table 2). In addition, follow-up length ranged from 6 weeks[48] to 2 years[44, 50] (mean, 10 months; median, 12 months) (Table 2). Ten studies[17, 26, 28, 31-32,34-36,39, 46] excluded patients with significant cardiac disease (congestive heart failure and/or ischemic heart disease).

STATISTICAL HETEROGENEITY

We observed less statistical heterogeneity among studies than expected given the degree of clinical heterogeneity. Modest statistical heterogeneity was observed for multicomponent interventions reporting data on hospitalization (I^2 = 39.3%), but self-management studies reporting data on anxiety (I^2 = 63.4%) and the 6-minute walk test (I^2 = 93.1%) were heterogeneous. Given relative interstudy homogeneity for most of our outcomes, the results of the fixed- and random-effects models are nearly identical, so the results of the more conservative random-effects models are presented.

OUTCOMES OF DATA SYNTHESIS

Knowledge

Participants' knowledge significantly improved in the intervention group in 4 RCTs[21, 32-33,36] and 1 controlled cohort trial (CCT),[44] and was not significantly different from the control group in 4 studies.[17, 22-23,41] However, only 1 study[32] used a standardized instrument.[54]

Dyspnea

Pooled results from 3 RCTs[17, 25, 31] that used the Borg dyspnea scale demonstrated a statistically significant, but clinically insignificant, improvement in dyspnea (mean change, –0.63; 95% confidence interval [CI], –1.09 to –0.18). The other 4 studies[39, 41, 45, 48] used other dyspnea scales, but were without significant differences between groups.

Quality of Life

Ten RCTs[17, 20, 23-26,28, 31-32,40] included interventions with only 1 CCM component and used multiple disease-specific and general QOL measures; therefore, pooling results was not possible for most of these studies (Table 2). Two trials[31, 40] demonstrated clinically and statistically significant improvements in QOL, but the remaining 8 studies[17, 20, 23-26,28, 32] did not. Six RCTs[33-36,38-39] included interventions with 2 or more CCM components, and 4[33-35,38] measured the St George's Respiratory Questionnaire at baseline and follow-up. Pooled results did not demonstrate statistically significant differences in St George's Respiratory Questionnaire scores between intervention and control groups (eTable 2).

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eTable 2. Intervention Differences in Change in St George's Respiratory Questionnaire Scores Among RCTs*

Pooled results of the 3 RCTs[24-25,32] that included only a self-management component did not demonstrate significant improvement in anxiety or depression in the intervention groups (eTable 3). However, in the CCT by Neff et al,[45] the intervention group had significantly fewer depressive

symptoms.

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eTable 3. Intervention Differences in Changes in Standardized Anxiety and Depression Measures

Lung Function

Six RCTs[24, 26, 28, 32, 37, 39] evaluated a common measurement of lung function (change in forced expiratory volume in 1 second, percentage of the predicted value). The pooled results from the 5 studies[24, 26, 28, 32, 37] that evaluated only 1 component did not demonstrate significant change in forced expiratory volume in 1 second, percentage of the predicted value (eTable 4). However, the 1 study[39] that evaluated all 4 CCM components demonstrated a mean change in forced expiratory volume in 1 second of 7.50, percentage of the predicted value, between the intervention and control groups.

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eTable 4. Intervention Differences in Mean Change in FEV_1 Values*

Performance-Based Measures

Of 5 studies[24-25,31, 35, 39] that evaluated performance measures, 4[24-25,31, 35] used the 6-minute walk test. Overall, the pooled results from the 3 studies[24-25,31] that included only the self-management CCM component demonstrated no significant improvement in the 6-minute walk test: mean (95% CI) of 84.36 (–82.15 to 250.87). The 2 studies[35, 39] with multiple CCM components did not demonstrate significant improvements in any tested performance measures.

Mortality

Three RCTs[35-36,39] that evaluated mortality involved multiple CCM components, and 4 RCTs[23-24,37, 41] included only 1 component. Pooled results did not demonstrate differences in mortality for any intervention (Table 4).

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Table 4. Relative Risk of Mortality Among Intervention Patients Relative to Control Patients*

Health Care Use

ED / Unscheduled Visits. The pooled results of the 3 RCTs[33-34,36] that implemented multiple CCM components and reported ED/unscheduled visits demonstrated a significant reduction in these visits (RR [95% CI], 0.58 [0.42-0.79]) in the intervention groups compared with controls (Table 5). These 3 trials (1) involved 2,[33] 5,[36] and 8[34] sessions with a nurse who taught self-management skills, (2) provided advanced access to care, (3) used guideline-based care, and (4) included communications between the nurse and the subject's physician. The trial by Bourbeau and colleagues[34] also included an action plan, individualized for each subject in the intervention group.

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Table 5. Relative Risk of Emergency Department/Unscheduled Visits for Intervention Patients Relative to Control Patients*

This pattern (of lower ED/unscheduled visits in the intervention group of studies that included multiple CCM components) was also present in studies with other designs (1 CCT[45] and 3 before/ after studies[3, 49, 51]). The 1 study of only 1 CCM component (self-management) that reported ED/unscheduled visits was an RCT,[17] and did not demonstrate a significant difference between groups (Table 5).

Hospitalizations. Seven RCTs (3 trials[17, 23-24] with 1 CCM component and 4[33-34,36, 39] with multiple components) reported hospitalizations in a manner that could be pooled (Table 6). The RR for hospitalization was not significantly different between the intervention and control groups in the studies[17, 23-24] that involved only 1 CCM component (Table 6). In contrast, the pooled results of the 4 RCTs[33-34,36, 39] that implemented multiple CCM components demonstrated significant reductions in hospitalizations in the intervention groups (RR [95% CI], 0.78 [0.66-0.94]). Three of these trials[33-34,36] are the same trials listed previously in the "ED/Unscheduled Visits" subsection of this section. The fourth trial[39] implemented all CCM components (as listed in Table 1).

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Table 6. Relative Risk of Hospitalization for Intervention Patients Relative to Control Patients*

Five other RCTs[20, 37-38,40-41] reported hospitalizations in various ways that could not be pooled (eg, rehospitalizations, mean hospitalizations per patient per month, and combined with ED visits). Four of these RCTs involved only 1 CCM component, and 2 trials[37, 41] demonstrated significant reductions in hospitalizations of the intervention groups, while the other 2 studies[20, 40] reported no significant differences. The results of 2 CCTs involving multiple CCM components were split: one[45] demonstrated lower respiratory-related rehospitalizations in the intervention group, while the other[46] reported no significant differences. All 4 before/after design studies[3, 49-51] involving multiple CCM components demonstrated significant reductions in hospitalizations in the intervention groups.

Mean Hospital LOS. Four RCTs[23-24,28, 37] that involved 1 CCM component demonstrated no significant differences in mean hospital LOS between intervention and control groups. However, the pooled results of 2 RCTs[34, 36] that involved multiple CCM components demonstrated significantly shorter hospital LOS for the intervention groups (weighted mean difference, –2.51 [95% CI, –3.40 to –1.61] days) compared with control groups. The 2 CCTs[45-46] that reported LOS and involved multiple CCM components demonstrated significantly shorter LOS in the intervention compared with control group. Both before/after studies[49, 52] that reported LOS also demonstrated a significant reduction in LOS in the intervention groups.

Cost. Four RCTs[28, 36-37,41] reported cost data in non-US currencies. Three trials[36-37,41] demonstrated a range of 34% to 70% reduction in health care costs in the intervention groups, predominantly because of reduced hospitalizations, and the other trial[28] demonstrated a trend toward reduced cost. The 3 before/after studies[49, 51-52] reporting cost information (in US dollars) demonstrated an 11% to 23% reduction in cost after implementing the intervention.

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Despite the fact that the CCM is a successful preventative strategy in other chronic illnesses, such as diabetes mellitus, congestive heart failure, and asthma, our systematic review demonstrates that there are limited published data evaluating the CCM components in patients with COPD. However, our review of available data suggests that an effective preventative strategy to reduce health care use (unscheduled/emergency center visits, number of hospitalizations, and hospital LOS) for patients with COPD is to implement 2 or more CCM components. The trials that resulted in reduced health care use provided the following: (1) an extensive self-management program[33-34,36, 39] with an individualized action plan[34, 39]; (2) "advanced" access to care, which consisted of a knowledgeable health care provider[33-34,36, 39]; (3) guideline-based therapy[34, 39]; and (4) a clinical registry system.[39]

To our knowledge, this systematic review is unique in that it is the first comprehensive evaluation of the utility of CCM components in COPD management. Three other systematic reviews[56-58] on COPD management have evaluated portions of related interventions, but not in the context of the CCM. Monninkhof and colleagues[56] demonstrated that self-management education in patients with COPD did not improve hospitalizations, emergency visits, or lung function, and demonstrated inconclusive results for QOL and COPD symptoms. We believe that our results are entirely consistent with their findings in that studies[17, 20-26,28, 31-32,40-42,44, 47-48] identified for our review that used the self-management component only

also did not show an effect on QOL or use outcomes. Taylor and colleagues[58(p5)] evaluated RCTs of self-management in COPD and also found no differences in QOL at 12 months, lung function, number of exacerbations, or mortality, but they reported that emergency visits "may be reduced." Many studies included in these reviews (and our own review) had incomplete descriptions of interventions, and the self-management interventions were often limited in intensity (half had an intervention duration of <7.25 hours). Known to be efficacious cognitive-behavioral approaches to smoking cessation, medication and oxygen compliance and exercise had limited application in many studies. In addition, only 7 studies included all 3 elements of self-management (education, behavioral changes, and motivation), whereas most studies were aimed at changing only the participants' knowledge of the disease (ie, education alone is known to be necessary, but not sufficient, to change behavior). Another systematic review[57] involved disease management programs in various chronic diseases, including COPD, and was also consistent with our results regarding single-component interventions. Only 7 COPD studies met their inclusion criteria. They pooled results of 3 studies, which included only self-management interventions, and did not demonstrate improved outcomes.[57]

The CCM has been promoted as a unified management package, but there is still conflicting evidence regarding the necessity of implementing the entire package with every chronic illness or whether some components of the model are more effective in some disease states. In a review of studies of diabetes mellitus, congestive heart failure, asthma, and depression, Tsai and colleagues[12] found that even the implementation of a single component was associated with significantly improved clinical and process-of-care outcomes, but not QOL. We suspect that self-management interventions in this review were more powerful (eg, 29% of these studies included depression treatment) and were more likely to have been theory based, including cognitive-behavioral therapy. In contrast, eligible studies for our systematic review for COPD used relatively weak self-management interventions. A large ongoing evaluation of implementing CCM packages, funded by the Robert Wood Johnson Foundation and performed by RAND (available at: http://www.rand.org/health/projects/icice), may contribute to our understanding of the CCM, but none of these focus on COPD.

The limitations of this systematic review are predominately due to the methodological problems of the underlying literature. Our extensive search strategy identified a paucity of published literature evaluating chronic care interventions in patients with COPD. We implemented a similar search strategy to that used for our systematic review in COPD, but replaced the COPD terms with diabetes mellitus terms. In contrast to the 534 titles identified by the COPD search, the diabetes mellitus search yielded 3767 titles. Because of this relative paucity, we included CCTs and before/after intervention studies in our review. We encountered a phenomenon found across the medical intervention literature: before/after studies tended to have more positive results than RCTs.[59-60] However, we only included RCTs in the pooled results, whereas we descriptively summarized the other study design results. Overall, these studies had a high degree of clinical heterogeneity, in terms of types and duration of interventions, settings, measures, length of follow-up, and outcomes. However, some common elements in the heterogeneous interventions demonstrated a favorable effect. In addition, with the limited number of available studies, we could not determine the optimal combination, specific types, and duration of the interventions. However, the 2 trials[34, 39] that included a comprehensive self-management program with an individualized action plan provided advanced access to care, and guideline-based therapy had the most significant effect on reducing health care use in patients with COPD.

The results of this systematic review highlight the need for high-quality and well-designed trials implementing the CCM in patients with COPD and suggest an agenda for future research in this area. Studies with better-defined and more powerful theory-based interventions should be undertaken to identify the most important elements for improving outcomes and preventing complications in patients with COPD. One notable deficiency that was only addressed in 6 studies in our review includes psychiatric illnesses, which are particularly important in patients with

COPD.[61-62] In a recent cross-sectional study,[63] 80% of patients with chronic breathing disorders screened positive for depression, anxiety, or both by the Primary Care Evaluation of Mental Disorders (PRIME MD) questionnaire. Of the subpopulation with COPD, 65% had an anxiety and/or depressive disorder diagnosis confirmed on further testing. Only a minority of those identified with anxiety and/or depression had a diagnosis in their chart, and only 31% were receiving treatment.[63] Similarly, heart disease is common (≤45%) in patients with COPD; yet, concomitant heart disease was an exclusion criterion for 10 studies and was not reported to be in the management plan in any of the studies. The identification and management of these important comorbidities may likely be critical additions to implement a truly comprehensive and "ideal" CCM for COPD. Finally, comparing comprehensive packages with all components vs limited packages will be important to ascertain which elements are most beneficial in COPD. These should include well-designed economic analyses to aid policy makers in decisions regarding widespread implementation of such packages.

In conclusion, the published data evaluating the CCM components in COPD are limited, but suggest that patients with COPD who received interventions with 2 or more CCM components had fewer unscheduled/emergency center visits, fewer hospitalizations, and reduced hospital LOS compared with the control groups. Our findings from this systematic review and the success of similar programs in other chronic diseases highlight the need for well-designed trials implementing multiple components of the CCM to prevent complications and improve outcomes in patients with COPD.

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Additional Information: The online-only eTable 1, eTable 2, eTable 3, and eTable 4 are available.

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