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# Mechanisms Associated with Clinical Improvement in Interventions That Address Health-Related Social Needs: A Mixed-Methods Analysis

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## **Abstract**

Linking individuals to community resources in order to help meet health-related social needs, such as food, medications, or transportation, may improve clinical outcomes. However, little is known about the mechanisms whereby such linkage interventions might improve health. The authors conducted a mixed-methods analysis consisting of outcomes from a prospective cohort study of a linkage intervention and a qualitative analysis of case records from participants. The cohort study included intervention participants who first enrolled between December 2014 and March 2015. Participants were excluded if they could not complete the assessment because of illness or language. The authors examined changes in cost-related medication underuse (CRMU), transportation barriers, and food insecurity (FI). For the qualitative analysis, a random sample of 80 participants was selected for electronic health record review – 40 cases who showed clinical improvement (responders) and 40 cases who did not (nonresponders). Themes were extracted by 3 reviewers guided by the immersion/crystallization approach. For the cohort study, 141 individuals were included; 138 (97.9%) completed follow-up. Comparing baseline to follow-up, there were significant reductions in the prevalence of CRMU (from 44.2% to 39.1%, P = .003) and transportation barriers (from 46.3% to 30.2%, P = .001), but not FI (from 40.4% to 38.2%, P=.73). For the qualitative study, emergent themes that helped differentiate responders and nonresponders included acuity of need, resource availability/access, and adequacy of the resource utilized. CRMU and transportation barriers may be important mechanisms by which linkage interventions improve health-related social needs. Patient-centered themes can help guide intervention improvements.

**Keywords:** population health, social determinants of health, food insecurity, cost-related medication underuse

#### Introduction

INMET HEALTH-RELATED social needs, which include cost-related medication underuse, lack of transportation, and food insecurity (lack of access to nutritious food related to cost) are common in clinical care. These unmet needs have been associated with adverse health outcomes, including worse glycemic control, lower receipt of recommended cancer screening, and more frequent health care utilization.<sup>2-4</sup> For this reason, health-related social needs are increasingly the focus of "linkage" interventions embedded in population health management programs, which seek to link patients to resources located in their communities that will meet their needs.<sup>5</sup> This approach is exemplified by the Centers for Medicare & Medicaid Services' Accountable Health Communities model, <sup>1</sup> and has been supported by studies that show improvement in clinical outcomes with linkage interventions in both pediatric and adult populations.<sup>6,7</sup>

The research group for the present study has previously found that a linkage intervention improved blood pressure

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and cholesterol, along with health-related quality of life, in adult primary care patients. However, that analysis was unable to explain why these changes in clinical outcomes occurred. Proposed mechanisms include enrolling in medication assistance programs to reduce cost-related medication underuse, more reliable transportation allowing for more consistent chronic disease management, or improving access to healthier food via local food pantries. However, studies have not been able to assess whether these proposed mechanisms are consistent with the experience of intervention participants.

Identifying health-related social needs that have available and effective resources may permit broader implementation as part of population health management programs. Further, the connection between presenting needs and clinical outcomes has important implications for program design. If there is a straightforward connection between presenting need, resources for those needs, resolution of the need, and clinical improvement, then focused intervention on a small number of key needs (eg, simply screening for food insecurity) may be most effective and efficient. However, if a presenting need uncovers other, potentially more actionable needs, or resources for one need are fungible and can be used to assist in other areas, then a more comprehensive approach that seeks to holistically understand the individual's social circumstances may be needed.

This study sought to evaluate the mechanisms whereby linkage interventions may improve health using a mixed-methods approach including both a prospective cohort study of program participants with subsequent quantitative analysis, and qualitative analysis of the case records of program participants who both did and did not experience clinical improvement. The research team hypothesized that they would be able to identify specific mechanisms related to improved clinical outcomes.

#### Methods

# Study design

Two complementary designs were used in this study. The first was a prospective cohort study of intervention participants seen in clinics in which the intervention occurred. The second was a qualitative content analysis of the case records of intervention participants, stratified by whether the individual demonstrated clinical improvement in blood pressure (among those with hypertension), low-density lipoprotein cholesterol (among those with an indication for cholesterol lowering), or hemoglobin A1c (among those with diabetes). Further details follow.

# Setting

Participants for this study came from 3 clinics in an academic primary care network in eastern Massachusetts. These clinics had a linkage program to help individuals with health-related social needs. In brief, this program consisted of a paper "screen" for health-related social needs administered at visit check-in. This screening form was then given to the individual's doctor, who referred the individual to the program (located near the clinic). Individuals would then present for an initial visit, where they would work with a patient advocate to understand what each individual's

needs were, and determine what resources were available to help meet those needs, according to the specifics of the individual's situation and preferences. The advocate would maintain contact with the individual, either in person or by telephone, until resolution of the needs, until it was determined the needs could not be resolved, or until the individual chose to discontinue the program.

The Human Research Committee at Partners Health Care approved this study.

### **Participants**

For the cohort study, all intervention participants who first enrolled between December 15, 2014, and March 31, 2015 were eligible. Individuals were followed through July 31, 2015. Participants were excluded if they could not complete the assessment because of a medical issue (eg, dementia) or if they spoke a language other than English or Spanish. For intervention participants, a baseline assessment was conducted around the time of starting the intervention, and, because prior studies found that the usual duration of the intervention was approximately 2 months, a follow-up assessment was made approximately 3 months after the initial assessment.

To examine changes in dietary quality as a result of the intervention, a comparison to individuals not enrolled in the intervention was needed. The research team randomly selected individuals who had been seen in the same clinics at the same time, and similarly conducted an initial assessment and a follow-up interview approximately 3 months later. For both groups, initial and follow-up assessments were conducted by trained interviewers in English or Spanish, either in person (at the clinic site) or over the telephone, at the preference of the participant. Individuals were offered gift cards worth \$10 for the initial interview and \$20 for the follow-up interview.

For the qualitative analysis, a random sample of 80 intervention participants was selected for electronic health record review – 40 cases who showed clinical improvement (responders; meaning that their blood pressure, cholesterol, or hemoglobin A1c decreased after starting the intervention) and 40 cases who did not (nonresponders).

#### Outcomes

For the cohort study, outcomes were assessed using a standard instrument consisting of previously validated items. For health-related social needs, the research team asked about 3 needs that were prevalent in prior studies, plausible drivers of clinical outcomes, and were amenable to improvement via linkage intervention in a relatively short time period: food insecurity (assessed using the 6-item short form of the Food Security Survey Module), cost-related medication underuse (using 4 items derived from the National Health Interview Study), and transportation barriers to medical appointments. All items had a 1-month lookback period, and full versions of the items used are available in the Supplementary Data.

In addition to health-related social needs, the team also investigated whether participation in the intervention was associated with changes in dietary quality, as food assistance is a common need and changes in dietary quality are a major hypothesized mechanism whereby linkage programs may lead to improved clinical outcomes. Dietary quality was assessed using an interviewer-administered Dietary Screener Questionnaire, originally used in the continuous National Health and Nutrition Examination Survey 2009–2010 wave. Because of the additional participant burden a detailed assessment of dietary quality entailed, only a random subset of the overall cohort study was selected for this.

#### Covariates

Demographic information including age, race/ethnicity, sex, health insurance, and education was extracted from the electronic health record using previously validated algorithms. 12

# Quantitative analysis

Because the main interest in this analysis was the experiences of program participants, primary unadjusted analyses are presented so that the analysis does not "adjust away" real differences members of varying demographic groups could experience. For analyses of unmet needs, the research team tested whether the prevalence of unmet needs decreased after program participation using logistic regression with generalized estimating equations to account for repeated measurements. Because it would have been unethical to withhold program referral from those who reported unmet needs during the initial survey, there is no contemporaneous comparison group for this set of analyses (as those who reported unmet needs and were not already in the program were referred to it), and instead individuals serve as their own controls, before and after the intervention.

For the analyses of dietary quality, changes in intervention participants were compared to those in nonparticipants using difference-in-difference analyses, again using generalized estimating equations to account for repeated measures. Because of the multiple categories of dietary change examined, the team accounted for multiple testing by using the q-value approach, which adjusts P values to maintain a false discovery rate of <5%.

A 2-sided *P* value (or q-value) of <0.05 was taken to indicate statistical significance, and all analyses were conducted in SAS Version 9.4 (SAS Institute Inc., Cary, NC).

#### Qualitative analysis

Qualitative analysis proceeded in 2 stages: a data extraction phase and a coding phase. In the extraction phase, case record data were extracted from the patient case notes stored in the case management and resource directory database used by the intervention program (Health Leads REACH<sup>TM</sup>, Boston, MA). Participant case notes are written by program staff immediately following any interaction with a participant, or a collateral source such as a caregiver, to document the content of the interaction. For case report data, all case notes within the time frame of the study were reviewed. Notes were abstracted by a single reviewer (ACH) using a standardized abstraction form that was developed through an iterative process by members of the study team (ACH, HP, and SAB), which included piloting the form on 10 case records that were not included in the study. The abstraction form focused on information regarding the needs experienced by the individual, help provided to meet the needs, adequacy of available resources to meet the needs, barriers to using resources experienced by the individual, whether needs were ultimately met, whether needs changed during the intervention period, and whether there were difficulties in participating in the intervention (see Supplementary Data for abstraction form). The abstractor was masked to whether a participant experienced clinical improvement. The coding phase involved 3 independent reviewers (CAH, HP, and SAB). One reviewer independently reviewed the patient case reports to identify key concepts and themes, with 2 additional reviewers providing validation. The immersion/crystallization method guided the coding process. 14,15 Coding templates were created iteratively as themes emerged from the data to ensure that no key concepts or themes were overlooked. Then a second round of analysis was conducted, during which key quotations were extracted from the case reports and used for illustrative purposes in describing key themes. Validation and trustworthiness were ensured by direct reference to field notes as well as independent and team analyses. All disagreements regarding themes were discussed until consensus was achieved among the 3 reviewers.

#### Results

# Cohort study results

For the cohort study, out of 198 eligible individuals who began the intervention during the study period, 141 (71.2%) enrolled in the study. Of the 141 who enrolled, 138 (97.9%) completed follow-up. Demographics and clinical characteristics of cohort study participants are presented in Table 1. Demographics and clinical characteristics of those who did not enroll were similar to those who enrolled (Supplementary Table S1), except for characteristics related to study exclusion (eg, language, clinical condition).

At the initial assessment, 44.2% reported cost-related medication underuse, 46.3% reported missing a medical appointment because of a transportation barrier, and 40.4% of participants reported food insecurity; 53% of participants reported at least 1 of these needs, 17.7% had 2 needs, and 12.1% had all 3 needs. At follow-up, prevalence of costrelated medication underuse was 39.1%, a significant decrease (P=.003), and prevalence of missed appointments related to transportation barriers was 30.2%, also a significant decrease (P = .001). Food insecurity prevalence was 38.2% at follow-up, a difference that was not significant (P=0.73). The prevalence of all 3 health-related social needs was quite dynamic (Supplementary Table S2). For example, of those who reported food insecurity at baseline, 25.5% (n = 14) were no longer food insecure at follow-up (P < .0001). However, 13.6% (n = 11) of those who were not food insecure at baseline became food insecure during the study period, resulting in little net change in prevalence of food insecurity.

For dietary adherence, 62 randomly selected cohort study members who enrolled in the intervention completed dietary quality assessment, and were compared with 50 individuals from the same clinics who did not participate in the intervention using difference-in-difference analyses. There were significant improvements in the amount of dietary sugar and sugar-sweetened beverages consumed for intervention participants, but no improvements in other areas (Table 2).

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TABLE 1. DEMOGRAPHICS OF COHORT PARTICIPANTS

	N = 141
	% or Mean (SD
Age	59.7 (15.1)
Female	64.9
Race/ethnicity	
Non-Hispanic White	50.4
Non-Hispanic Black	28.4
Hispanic	6.3
Asian/Multi/Other	15.0
Education	
<high diploma<="" school="" td=""><td>12.8</td></high>	12.8
High School Diploma or GED	48.7
>High School Diploma	38.5
Insurance	
Commercial	29.5
Medicare	11.5
Medicaid	50.4
Self-Pay	8.6
Primary Language	
English	90.6
Spanish	7.1
Other	2.3
Charlson comorbidity score	3.6 (2.8)
Body mass index	31.5 (7.9)
History of hypertension	44.7
History of diabetes mellitus	21.3
History of coronary heart disease	15.6
History of congestive heart failure	5.0
History of depression	19.9

GED, general equivalency diploma; SD, standard deviation.

# Qualitative results

Descriptive analysis showed that those who had a clinical response had similar baseline characteristics compared with those who did not have clinical response (Table 3).

In general, an individual's pathway through the intervention was similar for both the group who had a clinical response and the group who did not. The pathway began with a positive screen, followed by an "intake" (the contact made after screening positive for an unmet resource need during which demographic information is collected along

with more detailed information related to the individual's needs). Approximately two thirds of intakes in both groups were completed by telephone after the individual left the clinic rather than in person as part of a clinic visit (one third). Indicators of social isolation were similar in the 2 groups (approximately 1 in 6).

However, 3 themes did emerge with regard to differentiating responders and nonresponders (Table 4 includes illustrative quotes for these themes). The first theme was acuity of need. In general, responders often were referred with an acute clinical need, meaning that a clinician was concerned the individual would experience clinical worsening in the short term if the need was not met. Examples of this included not being able to fill needed prescriptions, see a medical specialist, or attend cardiac rehabilitation.

The second theme involved the availability of and access to the resource landscape. In general, resources were available for most types of need (>90% of needs in both groups), meaning they were at least nominally appropriate for the presenting issue. The major exception to this, however, was housing, for which there often were few resources. After resource availability was determined, the next barrier many individuals faced was access. Barriers to access included having a primary language other than English, comorbid medical conditions (eg, mobility impairments), complexity regarding other life circumstances (eg, lack of childcare, work obligations during operating hours), systematic factors (eg, nonfunctional hyperlinks on websites, out-of-date information). Occasionally, issues such as low patient activation or motivation to access the resource were identified. In general, responders faced fewer barriers than nonresponders. An interesting finding regarding resources was the frequent "nonlinearity" with which individuals could meet needs. For example, an individual who presented with a food need might find the food need improved not by obtaining food-specific resources, but instead by obtaining pharmacy assistance, which would lower monthly medication costs and in turn free up household resources for the food budget. Important differences also were noted in the types of resources used by responders and nonresponders. Responders often were referred to resources that required provider involvement (eg, health care-related resources such as medication assistance programs), which may be related to acuity of needs as already noted.

TABLE 2. CHANGES IN DIETARY INTAKE

	Intervention group (n=62)	Comparison group (n=50)	Absolute change for intervention group	Differential change for intervention group*	q-Value**
	Baseline	Baseline	Follow-up	Follow-up	
Daily added sugar intake (tsp)	11.99	9.88	-1.83	-2.39	0.049
Daily intake of added sugar from sugar sweetened beverages (tsp)	5.69	3.05	-1.97	-2.53	0.04
Daily whole grain intake (ounce equivalent)	0.68	1.02	0.03	-0.06	0.95
Daily dairy intake (cup equivalent)	1.20	1.32	0.08	0.08	0.95
Daily fruit/veg/legume intake (minus french fries) (cup)	2.33	2.66	0.05	0.002	0.99

<sup>\*</sup>Differential change represents the change in the intervention group minus the change in the comparison group.

<sup>\*\*</sup>The q-value represents the P value corrected to have a false discovery rate of 5% to account for multiple comparisons.

TABLE 3. DEMOGRAPHICS FOR QUALITATIVE SAMPLE

	Overall N=80	Responder N=40	Nonresponder N=40	P
	N (%) or mean (SD)	N (%) or mean (SD)	N (%) or mean (SD)	
Age, years	63.19 (11.64)	61.97 (10.36)	64.44 (12.84)	0.35
Female	34 (42.5)	20 (50.0)	14 (35.0)	0.27
Race/Ethnicity				0.67
Non-Hispanic White	43 (53.8)	25 (62.5)	18 (45.0)	
Non-Hispanic Black	20 (25.0)	8 (20.0)	12 (30.0)	
Hispanic	2 (2.5)	1 (2.5)	1 (2.5)	
Asian/Other/Multi	15 (18.8)	6 (15.0)	9 (22.5)	
Education	` '	` '	` ,	0.41
<high diploma<="" school="" td=""><td>28 (35.0)</td><td>12 (30.0)</td><td>16 (40.0)</td><td></td></high>	28 (35.0)	12 (30.0)	16 (40.0)	
High School Diploma	33 (41.2)	15 (37.5)	18 (45.0)	
>High School Diploma	19 (23.8)	13 (32.5)	6 (15.0)	
Insurance				0.35
Commercial	21 (26.2)	10 (25.0)	11 (27.5)	
Medicare	15 (18.8)	5 (12.5)	10 (25.0)	
Medicaid	43 (53.8)	24 (60.0)	19 (47.5)	
Uninsured	1 (1.2)	1 (2.5)	0 (0.0)	
Primary language other than English	14 (17.5)	6 (15.0)	8 (20.0)	0.63
Unmet Needs	3.52 (3.28)	3.70 (3.88)	3.35 (2.59)	0.64
Successful Contacts	10.81 (11.46)	11.93 (10.49)	9.70 (12.38)	0.39

SD, standard deviation.

The third theme is related to the adequacy of and satisfaction with resources. Being a responder often was linked to having adequate resources available. Similarly, nonresponders often were not satisfied with available resources, meaning that they felt the resources would not "solve their problem."

# **Discussion**

Participants in a linkage intervention to improve health-related social needs saw decreases in cost-related medication underuse and transportation barriers, but not food insecurity. There also were small improvements in consumption of added sugars, though the clinical significance of this change is not clear. Access, adequacy, and availability of resources all emerged as important themes among those who did and did not see a clinical response during the intervention. These themes help the research team understand the significant decreases in cost-related medication underuse and transportation barriers observed. Taken together, these findings paint a picture whereby appropriate resources can be used to improve factors such as medication adherence and attendance at clinical appointments, which in turn may result in improvements in clinical biomarkers.

Despite the seemingly direct relationship of need identification to clinical change, the team found that helping individuals meet needs often proceeded in a nonlinear pattern. For example, a presenting need may be met via meeting a separate need that was only subsequently uncovered (eg, following up on a report of food insecurity with a comprehensive interview may uncover a high burden of medication co-pays; helping an individual enroll in a pharmacy assistance program may then free up money for food). This emphasizes the importance of a comprehensive needs assessment, and in thinking creatively about helping individuals make use of fungible resources even when a directly

"on-topic" resource is not available. Importantly, this implies that trying to identify a small set of needs most amenable to intervention, or "highest yield," may prove quixotic. Instead, interventions may benefit from more comprehensive assessments that attempt to find any available resource across a broad set of health-related social needs. Further, the results highlight that attention must be paid to every step of the process. Even when resources were nominally available, barriers to access such as language and timeliness of information were important considerations. The study also highlighted the dynamic social situation of many individuals—as exemplified by changes in food insecurity.

The results of this study are consistent with and expand knowledge regarding linkage interventions. Prior work in both adult and pediatric settings has found that linkage interventions can improve clinical outcomes, including blood pressure, cholesterol, health-related quality of life, and overall child health.<sup>6,7</sup> This study helps explore some of the mechanisms that may underlie this improvement specifically that better medication adherence and better transportation to clinical appointments could result in improved chronic disease management. This study also highlights the central importance of the adequacy of the resource landscape. Although much effort has been directed at determining the best way to identify those with unmet needs and linking them to existing resources, less is known about how to assess the adequacy of the resource landscape in a given area, or how to better shape the resource landscape to meet individuals' needs when existing resources are suboptimal. To address this, more precise ways to measure, define, and identify adequate, accessible, and available resources are needed. 16,17

This study has several implications for further work regarding linkage interventions, and health policy more broadly. Linkage interventions should consider the need for

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Table 4. Illustrative Ouotes

	Table 4. Illustrative Quotes
Theme	Quote
Acuity	
,	"The PCP is concerned as the patient was discharged from the hospital's cardiac rehab program due to transportation issues' Patient also not scheduling with PCP due to co-pay concerns." (responder) "Nurse reported that patient needs resources to obtain his medication and that the patient has memory issues." (responder)
Availabilit	ty and Access
	"Client call[ed] that number and choose option '2' for Spanish. However, she informed the advocate that she had been hung up on each time." (nonresponder)
	"She received the SNAP [Supplemental Nutritional Assistance Program/food stamps] and TAP [Transportation Assistance Program] pass materials in the mail but has not had the energy or time to read them through yet." (nonresponder)
	"That link is useless, I cannot sign up I get broken links. I've tried to sign up for that a year ago and still no luck." (nonresponder)
	"Client has not contacted any of the services the previous advocate has recommended because he said he is a "procrastinator." (nonresponder)
	"Client said he also was able to contact Operation ABLE and will begin a program with them starting next week. Client presented as excited to start." (responder)
	"Advocate checked up with client, who confirmed that he was able to book an appointment [for dental care]." (responder)
Adequacy	and Satisfaction
	"Patient couldn't believe it, that the service referral happened so quickly and someone came last week to lightly clean her home after the HESSCO [Health & Social Services Consortium] referral was made. She was very happy and thankful, elder affairs called right away." (responder)
	"The client also told me that she visited the Cambridge food pantry yesterday, that it was easy to get to and that it helped her a lot." (responder)
	"Patient told his PCP there's food in the house and things are looking better" (responder) "Patient feels as though the employment center asked her to make revisions that weaken her resume."
	(nonresponder) "Patient went to legal aid clinic and she said that she was told to see a young woman right out of college with no

legal knowledge who also behaved extremely rudely and was not helpful at all with her immigration issues."

PCP, primary care provider.

(nonresponder)

navigation and support throughout the entire resource referral process, especially for those whose primary language is not English. This study also highlights the important role of the clinician—particularly with regard to identifying needs that may convey a short-term risk of clinical deterioration. Recognition of this risk may serve as a catalyst that brings to bear a multidisciplinary approach to help patients meet their needs. At the policy level, gaps were found in community-based interpreter support, as well as inadequacy of housing services, which also has been reported elsewhere. <sup>18–20</sup> Integrated eligibility systems, whereby individuals applying for one benefit can enroll in other benefits through a "no wrong door" approach, also may enhance individuals' ability to access resources. Successful linkage interventions rely on having adequate, accessible, and available community resources within a specified geographic location. It is important to acknowledge the limits of linkage interventions if public policy does not make these resources available. Close collaboration between health care providers and governmental and community-based human services organizations also is necessary to ensure that referral resources can adequately meet the health-related social needs of referred individuals, and that increases in referrals do not overwhelm the capacity of human services organizations.

The findings of this study should be considered in light of several limitations. In the quantitative analysis, because of ethical concerns, the research team did not compare those who received the intervention to those with similar unmet needs for whom the intervention was withheld. Therefore, the team cannot draw causal conclusions regarding intervention participation and the improvement observed, as participants may have been liable to see improvements regardless of the intervention. Next, because of the relatively small sample size and large variability of some study outcomes, the study may not have had sufficient power to detect smaller but clinically meaningful changes. In the qualitative work, the team only considered those who did and did not see an improvement in particular cardiometabolic risk factors. There are other important health outcomes, including health-related quality of life, well-being, and mental health, that linkage programs may affect, and it will be important in future studies to understand whether the same themes relate to benefits in those domains. Finally, the team did not have data on aspects of patient activation, a measure of case complexity, or precise measures of personal barriers to accessing resources, such as fear or shame, which will be important to investigate in future studies.

These limitations are balanced by several strengths. The study provides an in-depth and mixed-methods look into an effective linkage intervention, helping to open up the "black box" regarding participation in these programs. Further, the data sources, which combined electronic health records, real-time cases records of intervention participation, and

primary data collection from intervention participants, allow for a richer understanding than any single source alone would.

Linkage interventions are a promising strategy to help patients meet health-related social needs and ultimately improve health. In the quantitative portion of the study, the research team found support for the idea that clinical improvements may result from reductions in cost-related medication underuse and transportation barriers to clinic attendance. Qualitatively, the study emphasized the need to "get right" every component of the complex chain from ascertaining unmet needs, identifying resources, accessing them, and ensuring they are adequate to ultimately help meet the need. Building on this foundation, the team will improve linkage interventions in order to help individuals with unmet health-related social needs overcome barriers to better health.

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# **Author Disclosure Statement**

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#### **Supplementary Material**

Supplementary Data Supplementary Table S1 Supplementary Table S2

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