TITLE PAGE

Title: Computer-‑‑Supported Management of Medical-‑‑Legal Issues Impacting Child Health

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STRUCTURED ABSTRACT

Purpose: To determine whether integrating medical---legal issue (MLI) screening tool and decision support protocol into an existing computerized clinical decision support system (CDSS) would help physicians identify and address MLI in an effective and satisfactory manner.

Scope: This randomized controlled study was conducted in five urban community health centers, focusing o   three common MLI including food insecurity, utility insecurity and two types of housing insecurity (housing instability and substandard housing).

Methods: Aim 1 --- expand and modify an existing CDSS to assist with the identification and management of MLI that have the potential to adversely impact child health. Aim 2 --- evaluate the intervention's effect o   the identification and mitigation of MLI by evaluating rates of MLI identification via pre/post chart abstraction, and evaluating actions taken by physicians and caregivers to mitigate identified MLI via caregiver interview. Aim 3 --- evaluate physician and caregiver comfort with, and acceptance of, the intervention via survey and interview. Aim 4 --- evaluate its impact on healthcare utilization by comparing the utilization of intervention patients to control patients.

Results: Descriptive findings included in report; qualitative and quantitative analyses in progress.

Key Words: Medical Legal Partnership, Social Determinants of Health, Computerized Clinical Decision Support

PURPOSE

This study inserted medical---legal issue screening tool and tailored decision support protocol into the regular health care delivery process of an existing computerized clinical decision support system, the Child Health Improvement through Computer Automation (CHICA) system. In designing this process, we hypothesized that our innovative use of the CHICA computerized decision support system to identify and address medical---legal issues in a consistent, appropriate and effective way would help diminish the barriers that physicians often cite when questioned about identifying medical---legal issues and taking steps to help address them. We also hypothesized that the proposed intervention would directly benefit our target populations, and serve as a model for other communities, by increasing the rate of medical--- legal issue identification; increasing and improving the delivery of appropriate physician counseling and referral processes when medical---legal issues are identified; increasing and improving the rate at which patient caregivers take positive steps to mitigate medical---legal issues when identified; increasing physician comfort with medical---legal issue identification and counseling; and decreasing system costs based upon effective medical---legal issue resolution.

The specific aims of this study were to first to expand and modify the CHICA system to assist pediatricians with the identification and management of four common medical---legal problems (unmet food needs, unmet utility needs, and unmet housing needs including both housing insecurity and substandard housing conditions) that have the potential to adversely impact child health (**Aim 1**). We then sought to evaluate the effect of the CHICA medical---legal module on the identification and mitigation of medical---legal problems in five pediatric practices by evaluating rates of medical---legal issue identification via pre/post chart abstraction, and evaluating actions taken by physicians and patient caregivers (as reported in caregiver interviews) to mitigate identified medical---legal issues (**Aim 2**). We also set forth to evaluate physician and patient caregiver satisfaction with the CHICA medical---legal module by evaluating physician comfort with medical---legal issue identification and acceptance of the CHICA medical---legal module via physician survey, and evaluating patient caregiver perceptions (as reported in caregiver interviews) about physicians' handling of medical---legal issues and the CHICA medical---legal module process (**Aim 3**). Lastly, we planned to evaluate the impact of the CHICA medical--- legal module on healthcare utilization by comparing the healthcare utilization of patients in our intervention population to patients in our control population (**Aim 4**).

SCOPE

<u>Background/Context</u> It has previously been shown that health outcomes are closely related to degrees of social and economic disadvantage, and that interventions addressing social determinants of health may help mitigate adverse health outcomes. One such intervention is Medical Legal Partnership (MLP), a health care delivery model that seeks to improve the health and wellbeing of vulnerable populations by identifying social problems that may ultimately impede health and contribute to existing disparities, and incorporating legal service providers into the health care team to help facilitate solutions. The American Academy of Pediatrics and the American Medical Association have recognized the importance of such collaborations, and specifically encouraged the development of working partnerships between medical and legal providers.

Although there exist a wide variety of social conditions that may benefit from MLP intervention, three common areas of unmet need involve household food insecurity, energy insecurity and housing insecurity. Food insecurity occurs when a family does not consistently have access to enough food to ensure an active and healthy life for all household members. Energy (or utility) insecurity occurs when

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families struggle to regulate the temperature of their homes and operate lighting and appliances while simultaneously maintaining enough money for other necessities such as rent, food and clothing. Housing insecurity has been defined by the Department of Health and Human Services as high housing costs in proportion to income, overcrowding, homelessness, poor housing quality, and unstable neighborhoods.

Setting: This study was conducted in five urban community health centers that are part of the Eskenazi Health safety net hospital system in Indianapolis, Indiana.

Participants:

Eligible patient subjects for this study included children 24 months or younger that presented at one of the five participating clinic sites during the study period.

Eligible caregiver subjects for this study included caregivers (≥ 1 years of age) of children 24 months or younger that presented at one of the five participating clinic sites during the study period.

Eligible physician subjects for this study included all physicians, including residents, practicing in the targeted clinic sites.

METHODS

Study Design This was randomized controlled study. Three clinic sites operated as an intervention group and two operated as a control group. While the unit of randomization was the primary care clinic site, the unit of analysis was individual subjects. Allocation of clinics to intervention or control group involved a pseudo---randomization scheme in which the clinics were ranked by the number of physicians staffing the clinic. One of the two largest clinics was randomized to the intervention group and the other to the control group, and subsequent clinics were alternately assigned to intervention and control such that each clinic could be matched to its most similarly sized clinic (or clinics).

Intervention clinics had access to the CHICA system and the full MLP module (as described below). The control clinics had access to the CHICA system and modified version of the MLP module that included the screening questions described below and alerted pediatricians to positive screens, but did not provide follow---up prompts or informational handouts. Pediatricians instead were prompted to follow standard methods of care.

Intervention: The Child Health Improvement through Computer Automation (CHICA) system is a pediatric primary care computer based clinical decision support system first deployed in 2004 and described in detail in a number of existing publications. CHICA, which currently provides decision support for a wide range of preventive and disease management services, is used to screen families for potential health problems in the clinic waiting room with a prescreening form (PSF) that includes 20 questions selected by CHICA based o age---appropriate clinical guidelines and data already contained in the patient's electronic health record. All PSF questions are displayed and answered on an electronic tablet that can be toggled between English and Spanish. Upon completion, PSF responses are immediately coded into the CHICA database. Based on these responses, and other data contained in the patient's EHR, CHICA then produces a scannable paper physician worksheet (PWS) that includes six tailored alerts. Each alert includes up to six check boxes with which physicians can document how they respond to the alert. After the clinical encounter, the PWS is optically scanned back into CHICA, and

check---box responses are recorded as coded observations. These observations are then used to pre--- populate physician notes in the EHR.

Aim 1 of this study resulted in the design, build, testing and deployment (in Year 2 o December 4, 2014) of a new module for the CHICA system that has the capacity to electronically identify health---harming legal and social needs, improve the delivery of appropriate physician counseling during primary care physician encounters, and streamline access to legal and social service professionals when complementary remedies are required. A detailed article describing the interdisciplinary process of designing and implementing the Child Health Improvement through Computer Automation Medical   Legal Partnership (CHICA MLP) module was published in the *Journal of Interprofessional Care* in November of 2015. For the purpose of understanding the results contained in this report, it is important to know that the CHICA MLP module includes screening questions related to unmet food needs, unmet utility needs, and unmet housing needs including both housing insecurity and substandard housing conditions. Questions were derived from established screening instruments and local ordinances, and then revised by a panel of local and national MLP experts to specifically target actionable needs that could be addressed by the family with the help of a physician, social worker, and/or attorney.

Table 1: Unmet Legal Need Screening Questions

Unmet Food Needs
In the past year, have you ever worried that your food might run out before you have enough money to buy more?
In the past month, have you gotten a letter telling you that you are not able to get food stamps even though you think you should be able to get them?
Unmet Utility Needs
In the past year, has your utility company turned off (or threatened to turn off) your power or gas?
In the past year, have you had no heat when you needed it because you couldn't pay your bill?
Unmet Housing Needs – Housing Instability
In the past year, have you ever fallen behind on your rent or been told you'll be evicted?
In the past year, have you had to move more than once, live in a crowded house or apartment, or live with another family for money reasons?
In the past two weeks, have you gotten a letter telling you that you are going to be evicted from your rental home or apartment?
Unmet Housing Needs – Substandard Housing
Do you rent your house or apartment and worry that your landlord doesn't keep the property safe or clean enough?
Do you rent your house or apartment and worry that the appliances (stove, fridge, etc.), electrical, plumbing, sewage, heating or cooling systems aren't working right?

Data Sources/Collection/Measures and Limitations:

Patient Chart Reviews For patient subjects we conducted pre---intervention chart reviews early in Year 2 pursuant to Aim 2 to see how often medical---legal issues were identified in each of the four focus areas. We randomly selected charts meeting the ≤24 month age criteria from all five clinic sites and   determined the frequency with which each of the four categories of issues was identified using an electronic Chart Abstraction Guideline tool. Locations where the issue was documented within the chart, and actions taken by the physician as noted in the chart, were also recorded. Pediatric Research

Network (PResNet) staff entered chart abstraction data directly into the PResNet database and the results were pooled for intervention and control. In Years 3 and 4, we pulled same number of charts from the intervention and control groups and again counted the frequency of issue identification in the same manner.

- Medical---Legal Issue Identification: Since our study was a cluster---randomized trial, the analysis plan took the clustering effect into consideration. To fully account for characteristics that may have been unbalanced across clusters, while also accounting for our small number of clusters, we ultimately elected to model this dichotomous variable using logistic regression analysis with random clinic effects to accommodate the potential dependence of responses from subjects within the same clinic. Fixed covariates were to include the time of chart review (pre/post), as well as age, gender, race, ethnicity and insurance type.

Caregiver Interviews For <u>Aims 2 and 3</u> potential caregiver subjects were asked to participate in a 5---20 minute interview regarding the intervention process, their satisfaction with it and any measures they had taken to mitigate identified medical---legal issues. Approximately 10% of all interviews were audio--- recorded for quality control purposes. PResNet staff were responsible for obtaining verbal informed consent and conducting the interviews beginning in Year 2, entering data into the PResNet database, and reporting these data to study investigators. Interview questions pertained to the perceived existence of medical---legal problem; the receipt of verbal counseling; the receipt of written information; the receipt of a legal/social work referral; utilization of the information received; perceived resolution of the medical---legal problem; and satisfaction and comfort with the process. Most questions had limited response options, while some (such as those related to satisfaction) allowed for both a dichotomous response and a free text response. See Figure 1 for an example of an interview flowchart (flowcharts were designed for all four types of unmet legal need and then used as templates for programming the electronic interview script and corresponding electronic data management tool).

Figure 1: Interview Flowchart: Unmet Housing Needs – Substandard Housing
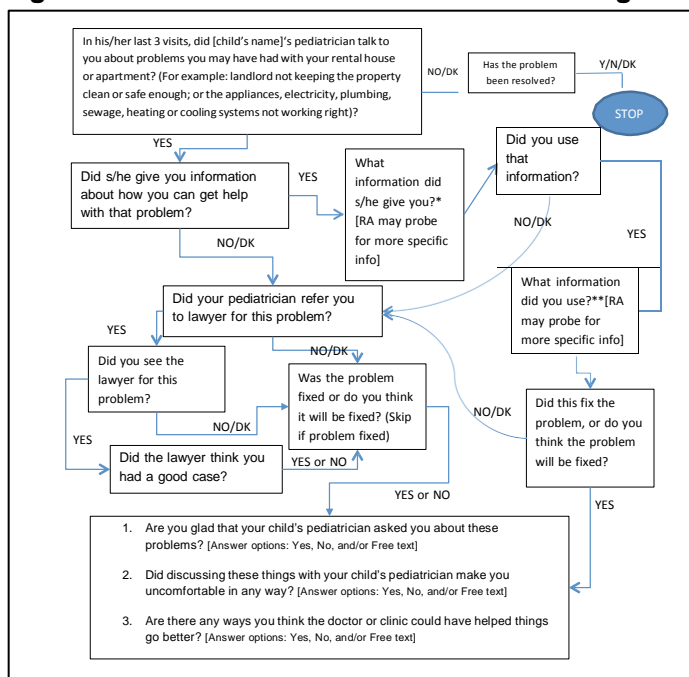
- Actions Taken by Caregivers and Physicians (as Reported by Caregivers): To examine how subjects in the intervention and control clinics differed in terms of rates of action taken to mitigate identified issues (i.e., whether a child received social work/legal referral), we are employing logistic regression analyses with random clinic effects and controlling for subject--- level characteristics by including these variables in the model.

- Caregiver Satisfaction: To examine how subjects in the intervention and control clinics differed in terms of satisfaction with the MLP intervention, we are engaging a mixed methods approach. For questions with limited response options, we are again employing similar model to that articulated above. For qualitative responses, content analysis will be used to analyze and condense the reports into mutually exclusive and substantially exhaustive topics. Two independent investigators will then identify independent coding categories, which will be validated between the investigators. After categories have been established, responses will be re---analyzed to select text that illustrates points of convergence and divergence.

Physician Surveys All CHICA---using physicians practicing in the targeted clinic sites were eligible to participate in the <u>Aim 3 </u>physician satisfaction study by default. Quantitative survey instruments addressing physician comfort with medical---legal issue identification and mitigation, acceptance of the medical---legal module, and estimated time spent resolving medical---legal issues were hand---delivered to physicians by PResNet staff and verbal informed consent was requested in Years 2 (pre) and 3 (post). Surveys included 20 likert---style questions regarding satisfaction, and 7 demographic questions regarding gender, clinic, years in practice (if post---residency), residency year (if in residency), primary specialty, number of patients seen per week, and % time spent in clinic. Surveys required approximately 10---15 minutes to complete. PResNet staff were responsible for data entry and reporting of all data to study investigators.

- Physician Satisfaction: Physicians' overall satisfaction with the medical---legal module is being obtained by summing up the scores from the 20 Likert---style questions included in pre--- and post--- intervention surveys. The mixed effect regression model will be employed to examine the treatment effect while controlling for potential confounders. The difference in the overall satisfaction level before and after the treatment will be modeled as a dependent variable. The model will include a clinic---specific random effect to correlate physicians in the same clinic. The treatment indicator, as well as other physician and clinic characteristics, will be included as fixed effects.

Patient Healthcare Utilization Queries To complete Aim 4, we had proposed pulling Medicaid claims data for children seen in both the intervention and control sites. Unfortunately, Indiana's Office of Medicaid Policy and Planning (OMPP) changed their claims processing for vendor and data systems. As a result, we lost access to the claims data. In order to complete Aim 4, we instead obtained electronic health record data from the Indiana Network for Patient Care (INPC) operated by the Regenstrief Institute, Inc. The INPC is a repository of EHR data from hospitals throughout Indiana, captured through the only statewide health information exchange in the US. This data source has the disadvantage of not containing the dollar amounts of paid claims. However, because it captures data from all patients, not just those covered by Medicaid, it allowed us to evaluate all patients in the cohort rather than just a subset.

- Healthcare Utilization: The procedures we followed closely paralleled those in our original proposal. We obtained medical record numbers for all patients seen in both the intervention

and control sites who were also in the age range to be included in the MLP intervention. These medical records were then passed to the Regenstrief Institute for matching in the INPC, and corresponding data all clinical encounters and prescriptions were returned. The encounters were manually separated into outpatient visits, inpatient visits, and emergency/urgent care visits. Prescriptions were manually categorized as "vaccines and other preventive measures," "over the counter medications," and "medications requiring a prescription. Counts of each of these categories of utilization will be used as dependent variables in statistical models, examining the impact of the MLP CHICA module on overall utilization in the clinics. To account for the clustering of patients within clinics, we have elected to use generalized estimating equations (GEE) for all regression analyses.

RESULTS

Findings Related to Unmet Legal Need Identification in CHICA Data In Year 2 of the grant, we ran a preliminary analysis using data from 2151 caregivers of patients ≤ 24 months of age receiving care at any one of five our study sites using CHICA who answered at least one MLP PSF screening question between December 4, 2013 and June 11, 2014 (the first six months post---launch). Findings from this analysis were presented in poster format at the Pediatric Academic Societies Annual Meeting, San Diego, CA, in April 2015. See Table 2 for characteristics of this population.

Table 2: Preliminary Findings Related to Unmet Legal Need Identification

VARIABLES	(%)
Sociodemographic (N=2151)	
Gender	
Male	108 (50.3)
Femal	106 (49.7)
Race/Ethnicity	
Black	99 (46.1)
Hispanic/Latin	59 (27.8)
o White	17 (7.9)
Other	39 (18.1)
Medicaid	
Insurance Yes	181 (84.3)
No	14 (6.9)
Missin	18 (8.8)
Language	
English	159 (74.3)
Spanis	55 (25.7)
Report of Unmet Legal Needs	
Unmet Food Needs (N=2127)	**35 (16.7)**
Denial of SNAP Benefits (N=2112)	15 (7.2)
Not Enough Money for Food (N=1944)	26 (13.7)
Unmet Utility Needs (N=2148)	**18 (8.7)**
Threatened/Actual Utility Shut Off (N=2126)	16 (7.7)
No Heat When Needed (N=2000)	5 (2.8)
Unmet Housing Needs – Substandard Housing (N=2095)	**29 (14.1)**
Rental Property Not Clean/Safe (N=1474)	10 (7.4)

Non---Working Rental Property Appliances/Systems (N=2083)	24	(11.9)
Unmet Housing Needs – Housing Instability (N=2013)	**23**	**(11.8)**
Fallen Behind on Rent/Threat of Eviction (N=1461)	8	(6.1)
Frequent Moving/Crowding/Multiple Families (N=2004)	16	(8.2)
Receipt of Eviction Letter (N=1750)	3	(2.2)
Number of Unmet Legal Needs Reported		
0	144	(67.1)
1	45	(21.1)
2	15	(7.4)
3	7	(3.5)
4	1	(0.9)

Findings Related to Unmet Legal Need Identification in Pre/Post Chart Data: In contrast to the extent of unmet legal needs being self---reported by patient caregivers on their PSF forms, as described above, our examination of chart review data (which captures physician acknowledgement of unmet legal needs in the patient's chart) reveals a very different, but equally important, outcome. Patient characteristics and rates of issue documentation were compared pre--- and post---intervention by means of Fisher's exact or chi---squared tests. Contrary to expectation, counts of documented medical---legal needs in the charts were too small to allow for the proposed modeling. Our sample included 142 pre---intervention charts (67 intervention/75 control) and 122 post---intervention charts (51 intervention/71 control). Across all four types of medical---legal need, there was evidence that physicians documented such needs in the charts of only 4 patients pre---intervention and 9 patients post---intervention. We are in the process of reviewing our analyses and writing a manuscript that will describe the discrepancy between rates of medical---legal need as identified by caregivers on the PSF form and rates of medical---legal need as identified by physicians in patient charts, and discuss potential clinical implications of these findings.

Findings Related to Actions Taken by Caregivers and Physicians (as Reported by Caregivers) and Caregiver Satisfaction: total of 58 eligible caregivers (352 intervention/230 control) completed the initial interview. Of those, 197 subjects (118 intervention/79 control) answered questions related to unmet housing needs specific to substandard housing; 134 subjects (89 intervention/45 control) answered questions related to unmet housing needs specific to housing instability; 11 subjects (75 intervention/43 control) answered questions related to unmet utility needs; and 292 subjects (138 intervention/94 control) answered questions related to unmet food needs. Descriptive analyses showed that among those interviewed from intervention sites, the proportion reporting that their physician spoke to them about the various issues they screened positive for ranged from 40---48% by issue type. In control sites, the proportions ranged from 33---58% by issue type. For those that spoke to their physicians about their issues, the proportion in intervention sites reporting that they were also given written information about how to get help ranged from 72---82% by issue type, and the proportion reporting the same in control sites ranged from 64---81% by issue type. We are currently reviewing the full dataset and working with our biostatistician team to complete the proposed logistic regression analyses with random clinic effects, controlling for subject---level characteristics. Qualitative data (e.g., free text responses to questions about caregiver comfort and satisfaction with the issue identification and intervention process) are also being extracted for coding and analysis. Pending review of the final results, we anticipate reporting outcomes in 1---2 peer reviewed publications.

Findings Related to Physician Satisfaction: Our sample includes 45 physicians (including residents) who completed the survey pre--- and post---intervention. We have completed the

proposed analyses and are currently writing a manuscript describing the outcomes of this portion of our study. This manuscript will be submitted for peer---reviewed publication by the end of the year.

Findings Related to Healthcare Utilization Our sample consisted of 3913 patients seen during the intervention period in three intervention and two control clinics. Among all patients, there were 6209 outpatient visits, 5511 inpatient stays (including newborn), and 3398 emergency/urgent visits.
Physicians prescribed over the counter medications 29,863 times. There were 37,469 vaccines and other preventive measures administered, and 70,766 prescription medications. The GEE analyses are currently in the hands of our biostatisticians. We expect Aim 4 to lead to one additional peer---reviewed   publication.

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