Title of project: Use of Electronic Health Records for Addressing Overweight and Obesity in Primary Care

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Inclusive Dates of Project: September 1, 2010 – November 30, 2015

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Acknowledgment of Agency Support: This work was supported by a mentored research scientist career development award from the Agency for Healthcare Research and Quality and a pilot and feasibility grant from the Boston Nutrition Obesity Research Center.

Grant Award Number: AHRQ/ K01 HS019789

1. Structured Abstract

Purpose: To develop and evaluate electronic health record (EHR)-based tools for addressing overweight and obesity in primary care.

Scope: EHR-based tools may help providers with the assessment and management of overweight and obesity, but few studies have examined this.

Methods: We developed several new features within the EHR used by primary care practices at Brigham and Women's Hospital (BWH). We then conducted a pragmatic, cluster-randomized controlled trial in 12 BWH primary care practices. We randomized 23 clinical teams ("clinics") within these practices to the intervention group or the control group. The new features were activated for clinics in the intervention group and were not activated for clinics in the control group.

Results: There were 60,244 eligible patients during Phase 1 of the intervention period and 35,665 eligible patients with BMI ≥ 25 kg/m^2 during Phase 2 of the intervention period. During Phase 1, documentation of body mass index (BMI) increased from 93% to 98% among patients in the intervention group and from 94% to 98% among patients in the control group ($p = 0.69$). During Phase 2, diagnosis of overweight or obesity on the problem list increased from 37% to 71% among patients with BMI ≥ 25 in the intervention group, but decreased from 16% to 8% among patients with BMI ≥ 25 in the control group ($p < 0.0001$). However, there were no significant differences in management outcomes or weight change among patients in the intervention and control groups.

Key Words: overweight, obesity, primary care, electronic health record

2. Purpose

Electronic health record (EHR)-based tools may help providers with the assessment and management of overweight and obesity, but few studies have examined this. Therefore, the aims of this study were: 1) to develop a set of EHR-based tools to help primary care providers identify, evaluate, and treat patients who are overweight or obese; and 2) to conduct a cluster-randomized trial to examine the effectiveness of these new EHR-based tools.

3. Scope

Overweight and obesity are problems of tremendous clinical and public health importance. Over 35% of U.S. adults are obese (body mass index, or BMI, ≥ 30 kg/m^2) and another 33% are overweight (BMI 25-29.9 kg/m^2).[1] Overweight and obesity are associated with many serious health conditions, including type 2 diabetes, cardiovascular disease (CVD), and some cancers.[2-5] Even small amounts of weight loss (3-5%) can lead to significant health benefits.[6-11] A variety of weight loss strategies have been shown to be effective,[6,10] and clinical practice guidelines urge providers to screen for overweight and obesity using BMI and to recommend appropriate treatment options.[6,10,12-14] Despite these guidelines, however, primary care providers often fail to identify patients who are overweight or obese or discuss weight management with them.[15-24]

Many providers use EHRs, and adoption of EHRs has been increasing since the Health Information Technology for Economic and Clinical Health (HITECH) Act was introduced in 2009.[25] Reminders and clinical decision support within EHRs can improve compliance with medical practice guidelines for conditions such as hypertension, diabetes, and coronary artery disease.[26-28] Electronic health records also may be able to help providers with assessment and management of overweight and obesity, but few studies have examined this.[29]

4. Methods

Development of EHR-based tools

We developed several new features within the Longitudinal Medical Record (LMR), an internally-developed, certified EHR used by all primary care and outpatient specialty practices at Brigham and Women's Hospital (BWH).[30] We first reviewed clinical practice guidelines on the identification, evaluation, and management of overweight and obesity that had been published by organizations such as the National Institutes of Health (NIH),[6,12] the U.S. Preventive Services Task Force,[13] and the American College of Physicians;[31,32] the 2013 guidelines from the American Heart Association, American College of Cardiology, and The Obesity Society had not yet been published at the time this study was initiated.[10] We then convened an expert panel that included primary care providers, registered dietitians, and information technology specialists, who formulated recommendations for the proposed new features in the LMR. The expert panel's recommendations were reviewed by the LMR Executive Committee and the Clinical Content Committee, which oversee the design and content of the LMR, in order to decide on the final set of features.

At the completion of this process, four new features were developed in the LMR. These were:

1) Reminders to measure height and weight. If a patient had no measure of height and/or no measure of weight in the LMR within the past year, a reminder would appear on the summary screen, asking the provider to enter a height and/or weight for the patient. The LMR automatically calculates BMI from patients' most recent height and weight entries; therefore, any patient with both height and weight should have a BMI.

2) An alert asking providers whether they want to add overweight or obesity to the problem list, for patients with BMI 25-29.9 or ≥ 30 kg/m^2, respectively. The alert would appear as a pop-up screen, and the provider would have the option to add overweight or obesity or to dismiss the alert (Figure 1). This alert was added to an existing clinical alerting system, introduced in May 2010, which was designed to improve the completeness of electronic problem list documentation for 17 other conditions.[33,34]

3) Reminders with tailored management recommendations, based on patients' BMI and other risk factors (e.g., hypertension, hyperlipidemia, type 2 diabetes) included on the problem list or identified from medications or laboratory results.[34] For each patient with BMI ≥ 25, one reminder would appear on the summary screen with a recommendation that was based on the NIH guidelines (Table 1).[12]

4) A Weight Management screen with several features, including tools to help providers assess patients' motivation to lose weight, calculate and set a 6-month weight loss goal, refer patients to other resources (e.g., nutritionist or medically-monitored weight loss program), and access more information (Figure 2).

Study design and setting

After developing and testing the new features in the LMR, we conducted a pragmatic clinical trial within all primary care practices (*n* = 12) affiliated with BWH, an academic medical center in Boston, Massachusetts.[35] These practices are located in both urban and suburban areas across the greater-Boston area, and they serve a racially and socioeconomically diverse population of patients. The 12 practices were divided into 23 clinical areas or teams (hereafter called "clinics") based on pre-existing administrative divisions within some of the practices. For example, one of the larger practices is divided into three suites; each suite has its own set of individual providers (including physicians, nurse practitioners, and physician assistants), who work together as a cohesive unit. Each of these suites was considered to be a separate clinic for the randomization. Providers within a clinic see patients in that clinic only. There are trainees (clinical fellows and residents) in all of the clinics and medical students in some of them.

Randomization and intervention

Prior to randomization, the 23 clinics were grouped into 3 strata: hospital-based clinics (*n* = 10), community-based clinics (*n* = 11), and federally-qualified community health centers (*n* = 2). The clinics within each of these strata were randomly allocated to the control or intervention group using a computer algorithm, with 12 clinics randomized to the control group and 11 to the intervention group (Table 2).

There were several reasons for choosing the clinic as the unit of randomization. First, all decision support within the LMR has to be activated either at the practice level or the clinic level; therefore, it was not possible to randomize individual patients or providers. Our rationale for randomizing clinics, rather than practices, was to achieve a better balance of patient characteristics in the intervention and control groups. For example, at the largest hospital-based practice, approximately 25% of patients are black and 15% are Hispanic; the other hospital-based practices have fewer black and Hispanic patients. If we had randomized practices, this entire practice would have been assigned either to the intervention or the control group. Instead, the five clinics within this practice were randomized individually; two of them were assigned to the intervention group and three to the control group.

The new features were activated for clinics in the intervention arm and were not activated for clinics in the control arm. The original intent was to activate all of the new features at the same time. However, due to other projects that the LMR development team was working on simultaneously, and the fact that the LMR is on a 6-month release cycle, the intervention was implemented in 2 phases; the height and weight reminders went live on December 15, 2011 (Phase 1), and all of the other features went live on June 11, 2012 (Phase 2). Blinding was not possible, given the nature of the intervention.

Before the new features were activated, the Principal Investigator (HJB) conducted a brief presentation for providers at each intervention clinic and circulated a quick reference guide with information about the new features. Although no written information about the new features was distributed to providers in control clinics, the presentations were conducted in regularly-scheduled practice meetings because that was the only time when most providers were available; providers in both intervention and control clinics within a given practice could attend these meetings.

Patients were not made aware of the intervention and did not have to give consent. The study was approved by the Partners Human Research Committee and was registered with ClinicalTrials.gov (NCT01480466).

Study population, data collection, and outcomes

There were different eligibility criteria and outcomes for Phase 1 and Phase 2 of the study. Both phases consisted of a 6-month accrual period, followed by 12 months of follow-up for the relevant outcomes (Figure 3). For Phase 1, the study population included all adult patients (age 20 or older) who had a visit at one of the intervention or control clinics between December 15, 2011 and June 10, 2012. We excluded patients who had visits with providers who saw less than 50 patients during this time period. The main outcome was the proportion of patients with a documented BMI in the LMR within 12 months after their initial visit.

For Phase 2, the study population included all adult patients who had a visit at one of the intervention or control clinics between June 11, 2012 and December 10, 2012 and had a BMI ≥ 25 kg/m^2. Similar to Phase 1, we also excluded patients who had visits with providers who saw less than 50 patients during this time period. The primary outcomes for this phase were 6-month and 12-month weight change. Weight change was calculated as the difference between the patient's weight at the first primary care visit during Phase 2 with BMI ≥ 25 (index visit) and his or her weight at the visit closest to 6 months later (4-8 month window) and closest to 12 months later (9-15 month window). Secondary outcome measures for Phase 2 included the proportion of patients with BMI ≥ 25 who had a diagnosis of overweight or obesity on the problem list; the proportion of patients with BMI ≥ 27 kg/m^2 who had a nutrition counseling visit at BWH; and the proportion of patients with BMI ≥ 27 kg/m^2 who were prescribed weight loss medications, such as orlistat (Xenical or Alli).

Data on these outcomes, as well as other patient characteristics, were collected during routine clinical care and then extracted from coded fields in the LMR or from the BWH scheduling system. Similar data also were extracted for a 6-month pre-intervention period before Phase 1.

Nested substudy

Within the main trial, we also conducted a small substudy among a sample of overweight or obese patients. To be eligible for the substudy, patients had to have a new patient visit or an annual exam during Phase 2, be between ages 20 and 70 at the time of the visit, and speak English. They also had to have a recorded BMI in the past year of 30-50 kg/m^2, or a recorded BMI in the past year of 27-29.9 kg/m^2 along with a diagnosis of type 2 diabetes, hypertension, or hyperlipidemia on their problem list.

Eligible patients were mailed a written survey about their past experiences with weight management, their diet and physical activity, and their motivation and self-efficacy around weight loss. The survey also included questions about their most recent primary care visit, such as whether the provider recommended that they lose weight, helped them to set a specific weight loss goal, or gave them any information or referred them to any resources related to weight management. At the end of the survey, patients were asked whether they would be interested in participating in a 30-minute study visit. If a patient was interested, a research assistant would call to confirm eligibility and then to schedule a study visit for 6 months (± 2 weeks) after the patient's routine primary care visit. At this study visit, a research coordinator would measure the patient's height, weight, and blood pressure, and the patient would complete another survey and have his or her height, weight, and blood pressure measured. Patients had to provide consent for the substudy.

Provider surveys and interviews

We assessed providers' attitudes about management of overweight and obesity on web-based surveys that were sent by email to all primary care providers at the intervention and control clinics.[36] These surveys were sent immediately before Phase 1 of the intervention period and again at the end of Phase 2. The survey at the end of the intervention period included an additional set of questions for providers in the intervention

group, which were designed to assess the usability of the new features in the LMR.[37] At the end of the second survey, providers in the intervention group also were asked whether they would be interested in participating in a 15-minute phone interview to discuss the new features in more detail.

Statistical analysis

All statistical analyses were conducted using SAS version 9.4 (SAS Institute Inc., Cary, NC). We compared changes in documentation of BMI in the LMR from the pre-intervention period to Phase 1 for patients who had visits in the intervention and control clinics, using mixed-effects logistic regression models (SAS PROC GLIMMIX) to account for the within-clinic and within-provider correlation. We used a similar approach to compare changes in diagnosis and management of overweight and obesity from the pre-intervention period to Phase 2 for patients with BMI ≥ 25 kg/m^2 who had visits in the intervention and control clinics. We also compared 6-month and 12-month weight change during Phase 2 for patients with BMI ≥ 25 kg/m^2 who had visits in the intervention and control clinics, using mixed-effects linear regression models (SAS PROC MIXED). In all of our models, we adjusted for patients' demographic characteristics (e.g., age, sex, race/ethnicity) and medical problems (e.g., hypertension, type 2 diabetes, cardiovascular disease).

For the nested substudy, we compared differences in outcomes reported on the mailed surveys and differences in 6-month weight change for patients in the intervention and control clinics. For the provider surveys, we compared changes in attitudes about management of overweight and obesity among providers in the intervention and control clinics.

5. Results

Main Findings

A total of 60,244 eligible patients had visits during Phase 1 of the intervention period (26,481 in the intervention group and 33,763 in the control group), and a total of 35,665 eligible patients with BMI ≥ 25 kg/m^2 had visits during Phase 2 of the intervention period (14,779 in the intervention group and 20,886 in the control group). There were some differences in characteristics of patients in the intervention and control groups (Table 3). For example, there was a higher percentage of female patients in the intervention group than the control group in both phases (68.6% in the intervention group and 60.8% in the control group during Phase 1); this is because there is one women's health clinic, which was randomly allocated to the intervention group. There also was a higher percentage of Hispanic or Latino patients in the intervention group than the control group in both phases (19.2% in the intervention group and 11.7% in the control group during Phase 1), because there is one Spanish clinic, which was allocated to the intervention group. Patients in the intervention group were also slightly older and were more likely to have other medical problems (including hypertension, high cholesterol, type 2 diabetes, and cancer) compared to patients in the control group.

Changes in documentation of height, weight, and BMI in the LMR during Phase 1 are shown in Table 4. There were small increases in documentation of BMI from the pre-intervention period to Phase 1 in both the intervention and control groups (from 93% to 98% among patients in the intervention group and from 94% to 98% among patients in the control group), but the difference between groups was not significant ($p = 0.75$). The increase in documentation of BMI was entirely due to increased documentation of height; there were no changes in documentation of weight in either group.

Changes in diagnosis and management of overweight and obesity during Phase 2 among patients with BMI ≥ 25 kg/m^2 are shown in Table 5. From the pre-intervention period to Phase 2, diagnosis of overweight or obesity on the problem list increased from 36% to 71% among patients in the intervention group, but decreased from 16% to 8% among patients in the control group ($p < 0.0001$). Among patients with BMI ≥ 27 kg/m^2, there were no significant differences between groups in changes in the percentages of patients who had a nutrition counseling visit or were prescribed weight loss medication.

Weight change over 6 months and 12 months for eligible patients with BMI ≥ 25 kg/m^2 who had visits during Phase 2 are shown in Table 6. There were no significant differences in weight change between the

groups. Mean 6-month weight change was -0.25 pounds for patients in the intervention group and -0.14 pounds for patients in the control group, and mean 12-month weight change was -0.94 pounds for patients in the intervention group and -0.73 pounds for patients in the control group (p = 0.47 for effect of the intervention over time). The mean percent weight change over 12 months was -0.38% for patients in the intervention group and -0.37% for patients in the control group (p = 0.89 for effect of the intervention over time.)

Among 590 overweight or obese patients who completed a mailed survey after their primary care visit during Phase 2 (response rate = 25%), 60.7% of patients in the intervention group compared to 53.9% of patients in the control group reported that their provider recommended that they lose weight (p = 0.03), and 17.5% of patients in the intervention group compared to 13.3% of patients in the control group said that their provider helped them set a specific weight loss goal (p = 0.05). However, among 172 patients who completed both the mailed survey and attended a study visit 6 months later, there were no significant differences in weight change between groups (mean 6-month weight change = 0.92 pounds in the intervention group and 0.29 pounds in the control group, p = 0.24).

There were 84 providers who completed the pre-intervention survey and 86 providers who completed the post-intervention survey (response rate = 49%). There were no significant changes in providers' attitudes about management of overweight and obesity, although providers in the intervention group reported greater increases in their confidence in counseling patients about weight (from 68.1% to 81.6% among providers in the intervention group and from 72.2% to 73.0% among providers in the control group). On the post-intervention survey, most providers reported that they would like more help creating weight loss plans for their patients (77.6% and 89.2% in the intervention and control groups, respectively). Among providers in the intervention group, 28.6% reported that the recommendations about management of overweight and obesity were useful, and 14.3% felt that the new features in the LMR improved the quality of care. In addition, 45.7% reported that the new features were very cumbersome to use.

During the phone interviews, providers mentioned that most patients are aware that overweight and obesity are important health issues, but many barriers make weight management difficult within primary care. They found some aspects of the new LMR tools helpful; for example, they reported that the height reminder, calculation of the weight loss goal, and referral tools were useful. Providers also suggested some improvements to the tools; for example, they reported that the current system was disruptive to workflow and could be improved if fewer "clicks" were required to get through the system and if there were fewer reminders every time they accessed a patient's record.

Discussion

Many studies have shown that providers under-identify overweight and obese patients and fail to counsel them about weight management.[15-24] Reminders, alerts, and clinical decision support within EHRs could help primary care providers address overweight and obesity with their patients. Our findings suggest that EHR-based tools can lead to substantial improvements in the diagnosis of overweight and obesity, although there were no significant differences in management outcomes or weight change between patients in the intervention and control groups.

Few previous studies have examined the effects of EHR-based tools on the identification, evaluation, and treatment of overweight and obesity in adults.[29] Among the studies that have been done, most have focused only on increasing identification of overweight and obesity and have not included additional features to assist providers with management, such as patient-specific recommendations or tools for referring patients to other resources. Moreover, almost all of the studies have focused only on provider performance outcomes and have not examined effects on patient outcomes, such as changes in weight, diet, and physical activity. Our study addressed these gaps by adding several features to assist providers with management and by assessing a variety of patient outcomes, such as weight change over 6 and 12 months.

One of the most important lessons from this study is that it can be challenging to develop and implement an intervention within an existing EHR without major changes to the EHR architecture or clinical

workflow. We needed to seek buy-in and obtain approval from several different groups, including the primary care practice leaders and the LMR Executive Committee; this process can take a substantial amount of time. Furthermore, researchers must be realistic about what can be accomplished in the context of routine clinical practice. Our expert panel originally requested some changes to the LMR that could not be incorporated, and the new features were less comprehensive than originally anticipated; this may have weakened the effect of the intervention.

There also are some unique methodological issues that are involved with this kind of pragmatic trial. As mentioned, it was not possible to randomize at the level of the individual patient or provider. We decided to randomize clinics instead of practices to try to make the intervention and control groups more comparable and, thus, to minimize confounding; however, some patient characteristics still were not balanced. In addition, the main disadvantage of randomizing clinics is that there is potential for contamination, since individual providers in intervention and control clinics may be within the same practices and could discuss management of overweight of obesity. This also could have led to attenuation in the estimated effect of the intervention.

Finally, using the EHR as the primary source of data is advantageous from the standpoint of cost and logistics, but it also has its own set of limitations. In clinical practice, many patients do not come in for visits at regular intervals, which results in missing data and the potential for selection bias. In addition, some of the outcomes of interest may not be well-documented in the EHR. Therefore, investigators must give careful thought as to how missing data will be handled in the design and the analysis. We plan to use multiple imputation in future analyses in order to address this.

Conclusions and Implications

These findings suggest that EHR-based tools can lead to substantial improvements in the diagnosis of overweight and obesity, although there were no significant difference in weight change. Future studies should focus on creating and evaluating other scalable, low-cost solutions to help address overweight and obesity in the primary care setting.

6. List of Publications and Products

Publications

Baer HJ, Cho I, Walmer RA, et al. Using electronic health records to address overweight and obesity: a systematic review. Am J Prev Med 2013;45:494-500.

Baer HJ, Karson AS, Soukup JR, et al. Documentation and diagnosis of overweight and obesity in electronic health records of adult primary care patients. JAMA Intern Med 2013;173:1648-52.

Baer HJ, Wee CC, DeVito K, et al. Design of a cluster-randomized trial of electronic health record-based tools to address overweight and obesity in primary care. Clin Trials 2015; 12: 374-83.

Abstracts

Baer HJ, Williams DH, Wee CC, et al. Use of electronic health records for addressing overweight and obesity in primary care: preliminary results from a cluster-randomized controlled trial. The 30th Annual Meeting of The Obesity Society, Atlanta, GA, November 2013 (recipient of Poster of Excellence Award from Health Services Research Section).

Devito KM, Wee CC, Bates DW, et al. Primary care providers' attitudes about use of electronic health records for addressing overweight and obesity. The 31st Annual Meeting of The Obesity Society, Boston, MA, November 2014 (recipient of Poster of Excellence Award from Health Services Research Section).

Baer HJ, Wee CC, Orav EJ, et al. Use of electronic health records for addressing overweight and obesity in primary care: results from a cluster-randomized controlled trial. Society for General Internal Medicine Annual Meeting, Hollywood, FL, May 2016 (selected for oral presentation).

Invited presentations

2012 Use of Electronic Health Records for Addressing Overweight and Obesity in Primary Care / Obesity and Health Behavior Research Seminar Series
Division of General Medicine and Primary Care, Beth Israel Deaconess Medical Center, Boston, MA

2013 Development and Implementation of Tools within Electronic Health Records for Addressing Overweight and Obesity in Primary Care: The ETOOL Study / Monthly Research Conference
Division of General Internal Medicine and Primary Care, Brigham and Women's Hospital

2013 Use of Electronic Health Records for Addressing Overweight and Obesity in Primary Care / Annual Symposium
Boston Nutrition Obesity Research Center, Boston University School of Medicine

2014 Use of Electronic Health Records for Management of Overweight and Obesity in Primary Care/ Invited Lecture
31st Annual Meeting of The Obesity Society, Boston, MA