# A Cluster Randomized Trial of a Personalized Multi-Condition Risk Assessment in Primary Care

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## Abstract

**Introduction**—Personal risk for multiple conditions should be assessed in primary care. This study evaluated whether collection of risk factors to generate electronic health record (EHR)-linked health risk appraisal (HRA) for coronary heart disease, diabetes, breast cancer, and colorectal cancer was associated with improved patient–provider communication, risk assessment, and plans for breast cancer screening.

**Methods**—This pragmatic trial recruited adults with upcoming visits to 11 primary care practices during 2013–2014 (N=3,703). Pre-visit, intervention patients completed a risk factor and perception assessment and received an HRA; coded risk factor data were sent to the EHR. Post-visit, intervention patients reported risk perception. Pre-visit, control patients only completed the

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risk perception assessment; post-visit they also completed the risk factor assessment and received the HRA. No data were sent to the EHR for controls. Accuracy/improvement of self-perceived risk was assessed by comparing self-perceived to calculated risk.

**Results**—The intervention was associated with improvement of patient–provider communication of changes to improve health (78.5% vs 74.1%, AOR=1.67, 99% CI=1.07, 2.60). There was a similar trend for discussion of risk (54.1% vs 45.5%, AOR=1.34, 95% CI=0.97, 1.85). The intervention was associated with greater improvement in accuracy of self-perceived risk for diabetes (16.0% vs 12.6%, *p*=0.006) and colorectal cancer (27.9% vs 17.2%, *p*<0.001) with a similar trend for coronary heart disease and breast cancer. There were no changes in plans for breast cancer screening.

**Conclusions**—Patient-reported risk factors and EHR-linked multi-condition HRAs in primary care can modestly improve communication and promote accuracy of self-perceived risk.

## Introduction

Family health history and lifestyle contribute to risk of developing chronic diseases like diabetes, coronary heart disease, and cancer.[1,2] Systematic assessment of this information may facilitate early identification of patients at greatest risk, promote informed decision making,[3] and address barriers to risk assessment in practice.[4,5] Use of health risk appraisals (HRAs) in primary care may promote accurate risk assessment, motivate health promotion and behavior change, and facilitate population management,[6,7] particularly as recommendations for screening and prevention become more personalized.[8]

Electronic health records (EHRs) offer opportunities to overcome barriers to collection and synthesis of these data by integrating HRAs with EHRs. Patient Risk Evaluation and Prevention (PREP) collected family health history and lifestyle risk factors from primary care patients and produced a personalized HRA for coronary heart disease, diabetes, breast cancer (for women), and colorectal cancer. The goal was to examine whether generating an HRA for patients prior to a visit, with data transmission to an EHR for provider use, improved patient–provider communication, more accurate self-perceived risk assessment, and plans for breast cancer screening.

## Methods

The PREP study was a pragmatic cluster RCT of adults receiving care in 11 practices affiliated with the Brigham and Women's Primary Care Practice Network. The protocol was IRB-approved and registered at Clinicaltrials.gov (NCT01468675).

### Study Population

Eligible patients were aged 30–75 years, had an annual or new patient visit, and spoke English or Spanish. Patients were excluded who did not have a phone or e-mail address.

Randomization occurred at the practice level, with recruitment May 2013–November 2014. Patients could participate by web (55.8%) or automated phone survey (44.2%). Pre-visit assessment in the intervention group included questions to generate an HRA and self-

perceived risk for each condition (Table 1). The HRA was mailed before the primary care provider (PCP) visit. Coded, health level-7 (HL7)-compliant risk factor data were sent to the EHR for use in documentation and decision support. PCPs received a data alert e-mail the morning of the visit and an icon appeared on their daily schedule next to the patient's name (Appendix A). Two to 4 weeks post-visit, intervention patients re-assessed self-perceived risk. Pre-visit, control patients only completed the risk perception assessment; post-visit they also completed the risk factor assessment and received the HRA. No data were sent to the EHR for the control group.

Your Health Snapshot is a self-administered HRA derived from validated algorithms of Your Disease Risk (www.yourdiseaserisk.wustl.edu; Appendix B).[9,10]

### Outcome Measures

Outcome assessment included:

1. whether at their last PCP visit they talked about risk of developing diseases in the future, changes to improve health, and speaking to a genetic counselor (only for high-risk individuals);

2. improvement in accuracy of self-perceived versus calculated risk for individuals with inaccurate risk perception before the visit (both self-perceived and calculated risks were categorized as "average," including below average or average versus "high" risk. Self-perceived risk was considered inaccurate if self-perceived risk did not match calculated risk. Improvement in accuracy was defined as accurate self-perceived risk post-visit if it had been inaccurate pre-visit); and

3. whether women aged 40 years talked with their PCP about getting a mammogram in the next year.

### Statistical Analysis

Logistic regression models with generalized estimating equations clustered on clinic, adjusted for age and patient characteristics that differed between the intervention and control groups. Statistical significance at $p<0.01$ accounted for multiple comparisons.

## Results

Contact was attempted with 31,223 individuals (Appendix C). Sample demographics are shown in Table 2.

Intervention was associated with a trend toward patients reporting greater likelihood to have discussed risk of developing a disease with their PCP (54.1% vs 45.5%, AOR=1.34, 99% CI=0.97, 1.85) and was significantly associated with discussion of changes to improve their health (78.5% vs 74.1%, AOR=1.67, 95% CI=1.07, 2.60) (Table 3). Discussion of referral to a genetic counselor among those at high risk did not differ between intervention and control groups.

Intervention was associated with greater improvement in accuracy of self-perceived risk following the PCP visit for diabetes (16.0% vs 12.6%, AOR=1.31, 95% CI=1.02, 1.69) and colorectal cancer (27.9% vs 17.2%, AOR=1.83, 95% CI=1.25, 2.68), with a similar trend for coronary heart disease (23.1% vs 18.3%, AOR=1.29, 95% CI=0.95, 1.75) and breast cancer (21.0% vs 15.9%, AOR=1.39, 95% CI=0.97, 2.00) (Table 3).

Women were fairly adherent with mammography screening (68.3% had documented screening in the prior year). Intervention was not associated with plans to receive a mammogram in the coming year among women aged 40–75 years or among subgroups aged 40–49 or 50–75 years. A trend toward greater discussion of whether a woman should receive a mammogram was observed for controls (85.7% vs 88.7%, AOR=0.77, 95% CI=0.57, 1.03).

## Discussion

Systematic, pre-visit use of a multi-condition, EHR-integrated HRA in primary care has the potential to modestly improve patient–provider communication and patient understanding of personal health risk, by linking patient-provided information with their healthcare team and providing personalized education, reminders, and health tips.[6,7] No evidence was generated for changes in discussion of plans for mammography, perhaps because this population was fairly adherent with mammography at baseline.

Though the literature is mixed on HRA effectiveness in primary care,[6,7,11] this study is one of the few to examine an HRA integrated with an EHR. The approach was also "holistic," addressing risk across several common conditions. The approach is a strength for primary care, particularly because several factors convey risk for more than one condition, although this approach may dilute disease-specific messages. My Wellness Portal is a web-based personal health record that supports the delivery of preventive health services and includes a patient wellness plan and reminds patients about recommended preventive services, but is not integrated with decision support in an EHR; this personal health record was associated with improved timely receipt of preventive services.[12] A pragmatic trial of a free-standing, breast cancer–focused risk assessment tool in primary care found improvements in discussion of breast cancer risk and also speaking with a genetic counselor.[13] Several platforms assess risk based on family history alone.[14,15] A pragmatic trial of web-based Family Healthware was associated with improvements in risk perception, and modest increases in self-reported physical activity and fruit and vegetable intake, but a reduced likelihood of receiving cholesterol screening.[16]

### Limitations

Although PREP only reached 20% of potentially eligible individuals, implementation as part of a care plan could have higher participation. Even small effects can lead to substantive health improvement at the population level. Despite limitations, the PREP design informs the effectiveness of using patient-reported outcomes in primary care. Longer follow-up is needed to assess the impact of this HRA on health behaviors, and use of services.

## Conclusions

Integration of HRAs with EHRs offer the potential to improve the impact of HRAs. Access to a web-based portal, where patients could examine the effect of changes in lifestyle on risk, may promote behavior change, particularly if linked to assistance programs.[17] Several trends in primary care, including population management,[18] offer potential for greater integration of HRAs to promote healthier lifestyles, and personalized screening and management.

The widespread dissemination of EHRs that utilize a personal health record offers the potential to broaden population-based risk assessment, and promote communication and risk perceptions that may lead to more-personalized health prevention.

## Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

## Acknowledgments

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**Table 1**

Study Flow

| Intervention | Control |
|---|---|
| **Assessment 4 weeks before primary care provider (PCP) visit** | |
| • Collection of risk factors and calculation of risk | |
| • Self-perceived risk | • Self-perceived risk only |
| • Health risk appraisal (HRA) with personalized recommendations sent to patient | • No risk HRA to patient |
| • Coded risk factor data sent to PCP | • No coded risk factor data to PCP |
| **PCP visit** | |
| **Assessment 2 to 4 weeks after PCP visit** | |
| | • Collection of risk factors and calculation of risk |
| • Self-perceived risk | • Self-perceived risk |
| • Outcome Assessment | • Outcome assessment |
| | • HRA with personalized recommendations sent to patient |
| | • No coded risk factor data to PCP |

**Table 2**

Study Population

| Characteristics | Intervention N (%) | Control N (%) | p-value |
|---|---|---|---|
| N | 1,699 | 2,004 | |
| Median age, years | 55 | 56 | 0.18 |
| Sex | | | |
| Female | 1,338 (78.8) | 1,415 (70.6) | **<0.0001** |
| Race/ethnicity | | | |
| White | 1,418 (83.5) | 1,675 (83.6) | 0.78 |
| Black | 79 (4.7) | 82 (4.1) | |
| Latino | 91 (5.4) | 105 (5.2) | |
| Other/unknown | 111 (6.5) | 142 (7.1) | |
| Married | 1,101 (64.8) | 1,456 (72.7) | **<0.0001** |
| Insurance | | | |
| Private | 1,231 (72.5) | 1,435 (71.6) | 0.7995 |
| Medicare | 358 (21.1) | 430 (21.5) | |
| Medicaid/uninsured | 110 (6.4) | 139 (6.9) | |
| BMI category | | | |
| Normal/underweight | 751 (44.3) | 725 (36.3) | **<0.0001** |
| Overweight | 541 (31.9) | 729 (36.5) | |
| Obese | 404 (23.8) | 545 (27.3) | |
| Smoking status | | | |
| Current | 56 (3.3) | 90 (4.5) | **<0.0001** |
| Former | 356 (21.0) | 557 (27.8) | |
| Never | 1,287 (75.8) | 1,357 (67.7) | |
| Prior personal history of | | | |
| Diabetes | 145 (8.5) | 173 (8.6) | 0.9153 |
| Coronary heart disease | 129 (7.6) | 189 (9.4) | **0.0466** |
| Colorectal cancer | 21 (1.2) | 25 (1.3) | 0.9749 |
| Breast cancer (women only) | 107 (8.0) | 118 (8.3) | 0.7432 |
| Charlson score | | | |
| 0 | 1,514 (89.1) | 1,828 (91.2) | **0.0285** |
| 1 | 118 (7.0) | 98 (4.9) | |
| 2+ | 67 (3.9) | 78 (3.9) | |
| High risk for developing | | | |
| Diabetes | 232 (13.7) | 357 (17.8) | **0.0022** |
| Coronary heart disease | 117 (6.9) | 167 (8.3) | **0.0258** |
| Colorectal cancer | 225 (13.2) | 332 (16.6) | **0.0179** |
| Breast cancer (women only) | 251 (18.8) | 246 (17.4) | 0.6322 |
| Pre-visit self-perceived risk inaccurate | | | |
| Coronary heart disease | 804 (51.2) | 777 (42.8) | **<0.0001** |
| Diabetes | 1,017 (65.4) | 1,112 (60.7) | **0.0047** |

| Characteristics | Intervention N (%) | Control N (%) | *p*-value |
|---|---|---|---|
| Colorectal cancer | 865 (51.3) | 928 (46.9) | **0.005** |
| Breast cancer (women only) | 675 (54.8) | 648 (50.0) | **0.0142** |

*Note:* Boldface indicates statistical significance (*p*<0.05).

**Table 3**

Patient-Provider Discussion, Improvement in Accuracy of Self-perceived Risk, and Plans for Breast Cancer Screening

| | Intervention N (%) | Control N (%) | AOR | 99% CI | Adjusted p-value |
|---|---|---|---|---|---|
| **During your last doctor visit did you talk with you PCP about:** | | | | | |
| Your risk of developing diseases in the future, such as cancer, heart disease or diabetes? [a] N Intervention 1,673 N Control 1,847 | 905 (54.1) | 841 (45.5) | 1.34 | (0.97–1.85) | 0.02 |
| Changes you can make to make to improve your health? [a] N Intervention 1,672 N Control 1,852 | 1,313 (78.5) | 1,372 (74.1) | 1.67 | (1.07–2.61) | **0.003** |
| Speaking to a genetic counselor to consider getting genetic test (among those at high risk for at least one of the four conditions with at least one family member) [b] N Intervention 346 N Control 422 | 27 (7.8) | 32 (7.6) | 1.09 | 0.71–1.67 | 0.61 |
| **Accurate self-perceived risk following primary care visit (among those who did not have the condition and who were inaccurate prior to the visit):** | | | | | |
| Coronary heart disease [b] N Intervention 804 N Control 777 | 186 (23.1) | 142 (18.3) | 1.29 | 0.95–1.75 | 0.03 |
| Diabetes [b] N Intervention 1,017 N Control 1,112 | 163 (16.0) | 140 (12.6) | 1.31 | 1.02–1.69 | **0.006** |
| Colorectal cancer [b] N Intervention 865 N Control 928 | 241 (14.4) | 160 (8.1) | 1.94 | 1.43–2.63 | **<0.0001** |
| Breast cancer (women only) [c] N Intervention 675 N Control 648 | 142 (21.0) | 103 (15.9) | 1.39 | .097–2.00 | 0.02 |
| **Patient-reported discussion and plans for mammography (Women aged 40–75, without breast cancer):** | | | | | |
| During your last doctor visit did you talk with your PCP about whether you should get a mammogram this year (Women aged 40–75)? | 825 (85.7) | 905 (88.7) | 0.77 | (0.57–1.03) | 0.02 |

|  | Intervention | Control | AOR | 99% CI | Adjusted p-value |
|---|---|---|---|---|---|
|  | N (%) | N (%) |  |  |  |
| N Intervention 963 N Control 1,020 |  |  |  |  |  |
| Do you plan to get mammogram in the next 1 year? |  |  |  |  |  |
| Women aged 40–75 years[d] N Intervention 950 N Control 1,008 | 883 (93.0) | 954 (94.6) | 0.78 | (0.51–1.18) | 0.1228 |
| Women aged 40–49 years[d] N Intervention 228 N Control 244 | 205 (89.9) | 227 (93.0) | 0.65 | (0.31–1.41) | 0.1535 |
| Women aged 50–75 years[d] N Intervention 722 N Control 764 | 678 (93.9) | 727 (95.2) | 0.80 | (0.47–1.38) | 0.2906 |

*Note:* Boldface indicates statistical significance (*p*<0.01).

[a] Adjusted for age, sex, marital status, BMI, smoking status, comorbidity score, being at high risk for developing colon cancer, breast cancer, diabetes or coronary heart disease, pre-visit survey modality. Clustered by site.

[b] Adjusted for age, sex, marital status, BMI, smoking status, comorbidity score, pre-visit survey modality. Clustered by site.

[c] Adjusted for age, marital status, BMI, smoking status, comorbid score, pre-visit survey modality. Clustered by site.

[d] Adjusted for age, marital status, BMI, smoking status, comorbidity score, breast cancer risk, pre-visit survey modality. Clustered by site

PCP, primary care provider