FINAL PROGRESS REPORT

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Title:

Using Health Risk Appraisal to Prioritize Primary Care Interventions

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1. Structured Abstract

Purpose: The study aimed at the development and pilot testing of a novel, patient-centered, and comprehensive Health Risk Appraisal (HRA) tool in primary care practices.

Scope: HRAs have been implemented in a variety of settings; however, few studies have examined the impact of computerized HRAs systematically in primary care. A novel HRA approach may improve longitudinal health and wellness through prevention.

Methods: A team of researchers constructed a novel model for a patient goal-directed HRA approach and incrementally developed and tested a patient-centered HRA technology through a 5-year project in primary care practices (n=4 practices and 200 patients). Outcomes were measured before and 12 months after the intervention by using the HRA, patient surveys, and qualitative feedback. Intervention patients received detailed feedback from the HRA, and they were encouraged to discuss the HRA report at their next wellness visit in order to develop a personalized wellness plan.

Results: Estimated life expectancy and its derivatives, including Real Age and Wellness Score, were significantly impacted by the HRA implementation ($P<0.001$). The overall rate of 10 preventive maneuvers improved by 4.2% in the intervention group vs. control ($P=0.001$). The HRA improved the patient-centeredness of care as measured by the CAHPS PCC-10 survey ($P=0.05$). HRA use was strongly associated with better self-rated overall health (OR = 4.94; 95% CI, 3.85-6.36) and improved up-to-dateness for preventive services (OR = 1.22; 95% CI, 1.12-1.32). A generalized linear model suggested that an increase in the Wellness Score was associated with improvements in patient-centeredness of care, up-to-dateness for preventive services, and being in the intervention group (all $P<0.03$). Patients who were satisfied with their HRA experience found the HRA report relevant and motivating, and they thought that it increased their health awareness. Clinicians emphasized that the HRA tool helped them and their patients converge on high-impact, evidence-based preventive measures.

Key Words: health risk appraisal, health information technology, goal-directed care prioritization, wellness

2. Purpose

This research program, entitled "Using Health Risk Appraisal to Prioritize Primary Care Interventions," had three specific aims:

1) Conduct a systematic review of the existing literature in order to refine a novel implementation model of a clinically integrated Health Risk Appraisal (HRA) implementation that will help clinicians prioritize evidence-based interventions;
2) Refine and pilot test the integrated HRA technology within a primary care practice-based research network to determine the feasibility of implementation and the efficacy of the instrument;
3) Conduct a randomized clinical trial to examine the impact of this integrated HRA approach on important patient outcomes, including estimated life expectancy, patient-centeredness of care, and provider and patient satisfaction in primary care practices.

3. Scope

Current initiatives to improve the quality of medical care focus on developing clinical practice guidelines based upon the findings from clinical trials, and then applying them to the care of patients while taking into account patient preferences and contextual issues. This probably works best for the management of patients with one or only a few health conditions. However, it appears to break down in the face of multiple, coexisting problems. As an example, Boyd and colleagues found that if an elderly patient with five common chronic conditions was to follow the relevant guidelines for each condition, she would, conservatively, have to take 12 different medications at five different times during the day at a cost of over $400 per month.[1] Even assuming that such a complicated regimen could have positive health benefits, the potential for adverse medication effects and interactions and the likelihood of incorrect adherence would be substantial, negating some or all of the benefits and negatively impacting quality of life.

From the clinician's perspective, patients with multiple health conditions can be extremely challenging. Clinical guidelines usually deal with one medical problem at a time, with little guidance about how to integrate them. Large numbers of prompts and reminders can have a deleterious effect on the provider's willingness to respond, often leading to suboptimal care. [2] The time required to identify, evaluate, and manage multiple health conditions can overwhelm a system designed for single, curable problems. It has been estimated, based on current Clinical Practice Guidelines, that implementation of United States Preventive Services Task Force Guidelines alone would take over 7 hours a day per primary care clinician. [3] Similarly, it has been estimated that, based on current practice guidelines, primary care clinicians would need over 10 hours per day to manage their patients with the top 10 chronic diseases, if the diseases were uncontrolled. [4] From the patient's perspective, physicians may appear to care more about their diseases than about them as human beings. The actual impacts of suggested interventions are rarely presented in such a way that patients can intelligently participate in the decision-making process or feel a commitment based upon a clear understanding of the potential benefits for them. [5]

When many interventions are suggested, it is rational to prioritize them. In fact, considering recent advances in the identification, characterization, and clinical detection of risk factors for adverse outcomes (e.g. through DNA mapping), it could be argued that we all have multiple health "conditions," and that prioritization will become increasingly important for all patients. One way to prioritize available interventions is to agree upon goals and objectives prior to the consideration of the available diagnostic and treatment options. [6-9] It can be argued that an important goal for most patients is the prevention of premature death and disability. Using health risk appraisal (HRA) techniques in the context of a clinician-patient relationship, strategies related to this goal could, in theory, be prioritized based upon their effectiveness, impact, and acceptability. Effectiveness would be based upon clinical trials, impact on the size of effect on the desired outcome (e.g. survival), and patient acceptability on the desirability of the potential benefit to the individual patient and the burdens and risks associated with the intervention.

HRAs have been a widely used health education tool for promoting individual behavior change [10, 11]. During the 1980s and 1990s HRA activities took place in many worksite programs, universities, community wellness initiatives, health fairs, and healthcare organizations. HRA feedback was appealing to individual users, employers, and payers because its quantification of personal risk status was new and interesting. Despite the popularity of HRAs, reviews of the literature have found limited evidence that HRA instruments alone change individual behavior. [12, 13] Since then, it has become clear that most early implementations of HRA tools have neglected a crucial element in the process of making HRA a successful tool in improving the health of individual users. First, it is not enough to provide feedback on the individual's health status. Tailored, effective, and simple ways of achieving personal goals must also be determined and properly communicated. Second, primary care providers should be key participants in assisting a person to carry out his or her wellness plan. [14] HRA instruments must be integrated into comprehensive, primary care-driven wellness programs that also provide ongoing personal support and access to community resources. Therefore, there is a considerable potential for a new generation of "enhanced" HRAs that combine successful HRA tools with a novel implementation approach that puts a particular emphasis on continuing involvement of the individual's primary care provider.

The effectiveness of HRA instruments was reviewed recently in a U.S. Department of Human Services Health Care Financing Administration report in 2003. [15] This review concluded that:

1) The HRA questionnaire without follow-up interventions is not an effective health management strategy.
2) HRA instruments combined with health promotion programs are more likely to produce favorable improvements.
3) Effective HRA programs demonstrated a positive impact on behavioral, psychosocial, and general health status variables, but more research is needed to examine the effect of HRA tools on clinical screening.
4) Several RCTs found that HRAs have an initial beneficial effect on some health parameters in older adults, but more evidence is needed.
5) There is limited evidence that a comprehensive health promotion program that incorporates an HRA instrument can be cost-effective, but more research is necessary.

6) At the time of the report, very little data was available to determine the cost-effectiveness of computerized HRA systems.
7) No data were available on racial and ethnic populations, and few studies examined language specific implementations.
8) HRAs have been used and tested primarily in institutional and community health promotion programs. No data are available on the use of HRA instruments in primary care settings, as part of the regular care delivery process.

The report also demonstrated that HRAs focused on primary and secondary prevention, providing relatively little guidance on tertiary prevention (i.e. management of chronic conditions). However, there is no compelling reason for excluding tertiary prevention because chronic health conditions can be viewed as risk factors for undesirable outcomes (e.g. premature death or disability and decreased quality of life). This approach integrates prospective medicine into the workflow of ambulative care and provides a unified platform for addressing current patient needs and overall wellness in the same process.

The National Institutes of Health (NIH) has recently initiated the Roadmap Project "Re-engineering the Clinical Research Enterprise" that aims at developing and testing new approaches to clinical research in order to bridge the gap between knowledge and practice and to accelerate the adoption of new technologies. Successful demonstration projects show that re-engineering primary care practices around evidence-based, patient-centered care is possible. [16, 17] Multifaceted interventions incorporating Health Information Technology (HIT) combined with system-level changes are particularly promising. [18] In addition to various Electronic Health Records, effective HIT implementations include patient tracking tools, registries, and clinical decision support systems.

Advances in the use of electronic health records, chronic disease and preventive care registries, and other electronic decision support systems provide an opportunity to integrate HRA instruments as a way that prioritizes interventions designed to prevent premature death and disability, particularly in patients with multiple health conditions.

4. Methods

To establish a theoretical framework for the innovation, the investigators studied the use of various HRA instruments in clinical settings. They interviewed community clinicians and their staff to receive input regarding how patient-centered HRA might fit into their practices and what features could make it acceptable and useful. Investigators then identified key informants and experts throughout the country who used HRA approaches in their organizations. Based on the information obtained, the research team formulated an implementation model of optimal HRA use in primary care and developed an HRA prototype leveraging user-centered design techniques. Consequently, investigators pilot tested the HRA concept in two primary care practices to determine the feasibility, acceptability, obstacles, and other factors critical to successful implementation and integration of the HRA tool into the practice work-flow. In addition, they addressed technical problems that arose in the course of the implementation. Based upon substantive feedback and personal interaction with patients and clinicians, researchers refined the implementation model and the technology.

Finally, investigators developed a web-based HRA instrument that was integrated into an existing patient portal, and they tested the implementation in four Oklahoma community practices serving patients with multiple health conditions.

Development of the Integrated HRA Tool

In the context of a 5-year, AHRQ-sponsored K-Award, our team has designed, implemented, and pilot tested a novel, web-based HRA tool. The tool was embedded within a previously developed, comprehensive personal health record (PHR), the "My Wellness Portal" (https://mpsrs.us/WPortal). [19] The development of the HRA tool followed a rigorous, user-centered design process, which included an extensive literature search, the study of a dozen existing tools, interviews with seven national HRA developers and vendors, and input from key informants. This was followed by multiple development and testing cycles that were led by a patient advisory panel and by in-depth, semi-structured interviews (cognitive testing and "think-out-loud" sessions) with a convenience sample of HRA users who represented a diverse patient panel. Finally, to refine the tool, the HRA was beta tested with 30 patients in two community primary care practices.

Architecture of the HRA Risk Engine

We incorporated existing risk prediction methods into an innovative approach that has not been implemented in primary care practices before. The HRA risk engine takes its baseline information from National Center for Health Statistics (NCHS) population life tables for the 15 leading causes of death and all others as a 16^{th} cause, for all ages (0-110 years), both genders, and several races/ethnicities (Caucasian, African American, Hispanic/Latino, Native American, and Asian/Pacific Islander). Age-, gender-, and race-specific probability of death (q_d) values are used in a standard life-table calculation procedure to provide a *baseline* estimated life expectancy (ELE). The baseline estimate is the life expectancy of an "average" person in the particular age, gender, and ethnicity group (national peer group).

To calculate an *individualized* ELE, baseline probabilities of death (q_d values) are converted into cumulative hazard (λ) values assuming an exponential survival distribution for each year ($\Sigma\lambda = -\ln(1-Pdeath[t])$. Lambda values are then distributed among the 15 leading causes of death (and all other causes as a sixteenth cause) according to the naturally occurring distribution ratios of deaths as indicated by NCHS life tables. As part of this project, a list of over 200 significant modifiable and unmodifiable risk factors encompassing 13 health domains that are connected to the main causes of death has been carefully identified by an expert physician panel in our academic center via evidence review and consensus. The HRA tool asks specifically about these risk factors (**Table I**). Consequently, using relative risk (RR) values available from meta-analyses and large, representative epidemiological studies, the 16 lambda values are adjusted according to individual risk factors and personal preferences gleaned from the HRA based on the Cox Proportional Hazards Model. [20] Finally, adjusted lambda values are summed for each year, and corresponding probability of death values for each year of life are calculated. These personalized probabilities of death are then used in a second life table calculation to arrive at a life expectancy estimate that is highly tailored to each person.

Table I. Health and wellness domains incorporated into the comprehensive Health Risk Appraisal (HRA) tool. The web-based risk engine dynamically constructs a personalized questionnaire at run time with branching logic based on personal characteristics, past and current entries, and available evidence on risk factors. The user can define the granularity and, in some cases, the specificity of data entry.

HRA Domains	HRA Sub-Domains	No. of Items
Demographics	Age; Gender; Race/Ethnicity; Residence; Education; Marital Status; Employment; Income Level; Insurance	10
Vitals/Labs	Weight; Height; (Body-Mass Index); Waist Circumference; Lipid Panel; Blood Pressure; Glycosilated Hemoglobin (HbA1c)	11
Behavioral Health	Dietary Habits; Physical Activity; Tobacco Use; Alcohol Use; Drug Use	22
Environmental Health	Stress/Anxiety; Hazardous Materials; Outdoors Risks; Crime Rate; Violence/Abuse; Unemployment	14
Self Health History	35 Leading Chronic Conditions and Their Varieties	47
Family Health History	16 Leading Hereditary Risk Factors (1^{st} and 2^{nd} Degrees)	16
Healthcare Utilization	Outpatient Visits; Hospitalizations/Nursing Home Admissions; Emergency Department Visits; Major Surgeries	4
Allergies & Misc. Risks or Risk Modifiers	Immune Compromise; Vitamin Deficiency; Egg Allergy; G-globulin; Varicella; Guillain-Barre; Organ Removal	10
Personal Safety	Sun Protection; Car-Related Risks; Risky Sports; Fire/Smoke Alarm; Pool Safety; Motor Cycle; Firearms	15
Sexual Health	Menses; Sexual Activity; Pregnancy; Menopause; Birth Control; Hormon Replacement Therapy; Fertility; Sexually Trans. Disease	16
Mental Health	Depression/Anxiety; Mental/Cognitive Activity; Suicide; Trauma; (PHQ-9 test triggered by a positive PHQ-2 test)	16
Preventive Services	Preventive Services History Related To 15 Preventable Or Modifiable Health Conditions	23
Health-Related Quality of Life & Personal Goals	Self-Rated Overall Health; Self-Rated Quality of Life; Refusal Of or Concern With Care; Meaningful Life Activities	11

An individualized list of preventive care recommendations is created for a particular person by a separate recommendation algorithm based on age, gender, and personal preferences, utilizing set theory and United States Preventive Services Task Force (USPSTF) guidelines. [21, 22] This list of recommendations is then prioritized based on the estimated impact on length of life. To predict the estimated impact of individual preventive interventions on life expectancy, a difference is calculated between the LE associated with the patient's current risk profile and the LE of a risk profile modified by the preventive maneuver.

Repeating this procedure for each recommendation results in a list of estimated impacts on life expectancy for each personalized intervention. Items are then ranked according to their efficacy, but in the future they could also be ranked according to their cost, acceptability, or "effort effectiveness," a measure that could be defined as an analogue of cost-effectiveness. In addition to LE estimates that are provided for clinicians, the HRA tool also delivers "patient-friendly" derivatives, including a Real Age and a Wellness Score [23], that are transformed from LE estimates. In our HRA tool, Real Age was a risk-matched virtual age estimate (risk of death from 16 causes), and the Wellness Score was an age-standardized outcome calculated from life years gained or lost compared to peers. The score ranged between 0 and 135, including the range around 100 that indicated "average" health. These parameters were represented both numerically and on a color-coded visual-analog scale (VAS) in the web-based HRA report, which was presented to the patient for discussion with his/her primary care clinician.

Validation of the HRA

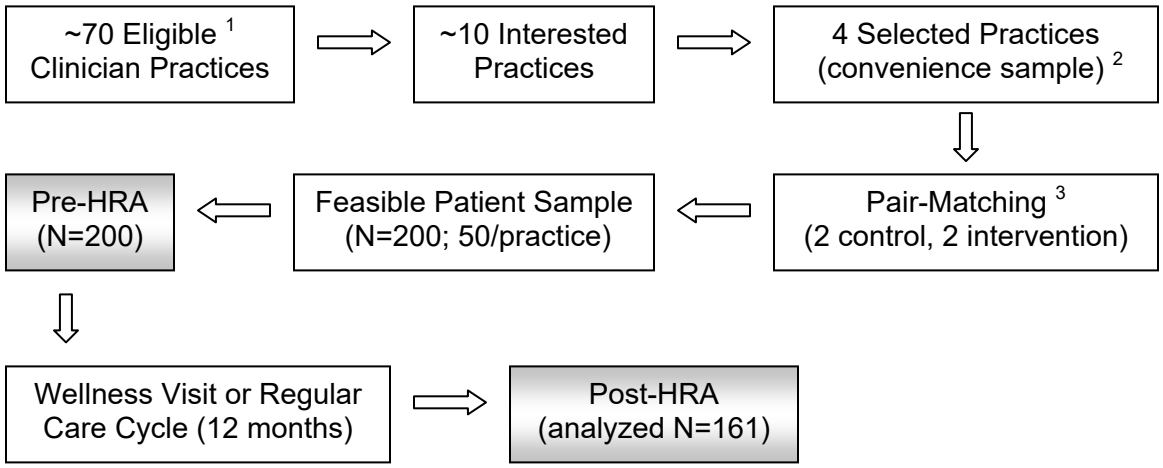
Predictions and discriminative performance of the HRA tool have been validated against observations from longitudinal studies and other risk prediction methods in three separate modeling experiments, indicating a performance that was not inferior to the performance of 118 existing tools for predicting mortality (AUC-ROC=0.70). [24]

Study Protocol

In order to conduct a pilot study, a convenience sample of four Oklahoma Physicians Resource/Research Network (OKPRN) primary care practices were carefully pair matched and assigned to control and intervention groups in a quasi-experimental design (see **Figure 1)**, yielding 200 patients (50 per practice). We considered practice size (small, midsize, or large), location (urban, suburban or rural) and type (private, academic, or public), in addition to patient mix and number of patients seen per week. We selected a pair of rural, private, small family practices and another pair of suburban, midsize, clinician group practices. Primarily middle-aged and older adults with multiple health conditions were invited to participate. The research assistant (RA) scheduled a dedicated, 45- to 60-minute visit with patients in these practices to obtain written informed consent and complete a baseline HRA and other study surveys. This was necessary to ensure that the impact of the HRA can be adequately measured. Upon need, the RA made a study packet available that contained instructions on participating remotely via the internet. All patients (including control and intervention groups) completed the same web-based HRA and a corresponding survey. Patient outcomes were measured before and 12 months after the implementation through the HRA questionnaire, patient surveys, and qualitative feedback received via open-ended questions. Control patients completed the HRA questionnaire and a self-administered survey but did not receive an HRA report. Intervention patients received detailed feedback from the HRA at the time of completing the questionnaire, including estimates of overall health, description of health strengths and challenges, and a prioritized list of tailored recommendations for preventive care with individual impact estimates. They were also encouraged to discuss the HRA report at their next annual wellness visit and follow their personalized wellness plan.

Figure 1. Participant Flow Diagram of the Health Risk Appraisal Pilot Study

(1) The inclusion criteria for practices were: practice is stable, no concurrent implementation of another major intervention, willingness and capacity to adopt the HRA tool, and clinician sees at least 30 middle-aged and older adults per week.
(2) A convenience sample was chosen to maximize the chance of successful implementation and testing based on practice characteristics and available study resources.
(3) A quasi-experimental, controlled design was followed, including pair-matching of control and intervention sites based on practice and patient care characteristics



Patient-Centeredness of Care

We measured patient-centeredness of care, as we described it in a previous study [19], using an adapted version of the Consumer Assessment of Health Care Providers and Systems (CAHPS) survey separately from the HRA. [25] We calculated a composite score from selected CAHPS survey questions, summing scores 1 to 8, 10, and 11. [19] The 10 questions describe patient-clinician interactions as they relate to preventive care. Pre- and post-intervention differences in patient-centeredness scores were calculated for each patient and the differences were compared between control and intervention groups.

Provision of Preventive Services

Self-reported HRA feedback was reviewed to determine the number and type of selected preventive services received and patient behavioral health patterns before and during the 12-month study period. We used preventive services reports to populate the HRA risk engine, which generated personalized recommendations based on USPSTF, [22] Advisory Committee on Immunization Practices (ACIP), [26] and American Academy of Family Physicians (AAFP) [27] guidelines.

Quantitative Analyses

We analyzed quantitative data with the help of SAS 9.1.3 software (SAS Institute, Cary, NC). We conducted difference-in-differences analyses [28] to determine the impact of the HRA on the patient-centeredness of care. These analyses compared the magnitude of the change in patient-centeredless scores between groups and time points.

Logistic regression and generalized linear models were constructed using the backward stepwise approach to examine the relationships between various outcome variables and covariates gleaned from the HRA instrument. Covariates included age, gender, number of comorbidities and office visits, up-to-dateness on preventive services, self-rated health and quality of life, body mass index, smoking status, and level of physical activity.

Qualitative Analyses

Open-ended patient feedback was collected via free text entries at the end of the patient survey. Responses were analyzed using standard content analytic techniques. Briefly, two reviewers studied a collection of patient responses and generated propositions for emerging themes. These were then compared between reviewers and argued to consensus in order to arrive at the essence of participant opinion for each question relating to the utility, usability, perceived impact, and future potential of the HRA tool.

5. Results

Strategic pair-matching of four OKPRN practices (two control and two intervention) yielded a reasonably homogeneous patient population (N=200) across study groups. **Table II** describes the patient characteristics in both arms of the study. Apart from a moderately elevated frequency of office visits in the intervention group, patient characteristics in the two study arms did not differ significantly. About 77% of intervention patients reported that they considered the HRA report in the course of preventive care planning.

Table II. Patient characteristics at baseline by study arm (pair-matched control and intervention practices; N=4)

Patient Characteristics	Control (N=98)	Intervention (N=102)	Significance (P)
Mean age (years)	59.9±10 [a]	60.4±11 [a]	0.36 (t Stat)
Ratio of female patients	65%	72%	0.07 (Chi^2)
Ratio of non-Caucasian minorities	8%	5%	0.07 (Chi^2)
Ratio of married patients	73%	67%	0.20 (Chi^2)
Ratio of patients with at least high school education	94%	95%	0.52 (Chi^2)
Household income less than $40K per year	9%	12%	0.22 (Chi^2)
Average number of chronic conditions per patient	2.7	3.2	0.06 (Chi^2)
Ratio of active smokers	11%	15%	0.20 (Chi^2)
Mean Body Mass Index (kg/m^2)	30.1±7 [a]	30.8±6 [a]	0.23 (t Stat)
Self-rated overall health (0 to 4 scale)	2.76±0.8 [a]	2.61±0.8 [a]	0.12 (t Stat)
Self-rated satisfaction with life (1-10 scale)	7.57±2.1 [a]	7.48±1.9 [a]	0.32 (t Stat)
Average number of office visits per patient per year	3.4	4.95	<0.001 (Chi^2)

([a]) Given as Mean ± S.D.

Bivariate analyses suggested that estimated life expectancy (ELE), measured by the HRA and its derivatives and including Real Age and Wellness Score, were significantly impacted by the HRA intervention. The mean increase in ELE across the intervention population was 8 months higher than expected, simply by aging over a year (13 vs. 5 months; $P<0.001$), and also significantly higher compared to the ELE measured in the control group (13 vs. 7 months; $P<0.001$). Correspondingly, while the mean increase in Real Age was 7 months in the control group ($P=0.03$), it did not change significantly in the intervention group during the study period ($P=0.20$), suggesting a decreasing estimated risk of death from multiple causes. Wellness Score, a third health indicator, showed a modest but significant mean increase, from 67.6 to 69.9 in the intervention group ($P=0.03$) compared to the control group, for which there was no significant change (74.34 and 74.65 respectively; $P=0.29$).

Patient-reported recommended preventive maneuvers included receiving smoking counseling, mammography, Papanicolaou test, prostate-specific antigen test, colon cancer screening, aspirin chemoprophylaxis in cardiovascular disease, HbA1c measurement for diabetics, healthy diet, physical activity, and seatbelt use. The overall rate of preventive services improved from 59.1% to 63.3% in the intervention group ($P=0.001$) compared to the control group (55.1% and 54.0% respectively; $P=0.40$).

A difference-in-differences analysis that accounted for time trends suggested that the HRA, measured by the CAHPS PCC-10 ambulatory survey on a 10-point scale, modestly improved the patient-centeredness of care. There was no significant difference between the two groups' scores at baseline (7.54 and 7.63 respectively; $P=0.49$), but the pre-post score difference between the intervention and control groups was 0.81 points (+0.28 and -0.53 respectively; $P=0.05$).

Logistic regression models indicated that HRA use was strongly associated with better self-rated overall health (OR = 4.94; 95% CI, 3.85-6.36) and improved up-to-dateness for preventive services (OR = 1.22; 95% CI, 1.12-1.32). Modeling the relationship of treatment to patient-centeredness of care revealed that an increase in the CAHPS PCC-10 score was more likely in the intervention group (OR = 1.21; 95% CI, 1.12-1.30).

We applied an exploratory generalized linear model to examine the relationship of Wellness Score to covariates in the intervention group. An increase in patient Wellness Score showed significant association with improvements in patient-centeredness of care, up-to-dateness for preventive services, and being in the intervention group, but it suggested an inverse relationship to the number of patient visits, comorbidities, BMI, and smoking (all $P<0.03$).

Open-ended feedback indicated that patients were satisfied with their HRA experience and found the HRA report relevant and motivating. Patients expressed that the HRA helped them "*focus on maintaining healthy choices*" and provided a "*roadmap to getting well.*" They emphasized that the HRA report improved their awareness of medical issues they had as well as future issues that may arise (e.g., "[the HRA] *makes me look at what I am doing to my body*"). Both patients and clinicians underscored that the HRA helped them focus and converge on high-impact, evidence-based preventive measures (e.g., "[the HRA] *reminds me to go to the doctor more often and stick to what he tells me to do*" and "*it shows me what areas to focus on improving or minimizing to make my life healthier"*).

When asked about ways to improve the HRA tool, patients responded that more granular data entry options and an open-ended feedback capability would help them perceive that their personal record was accurate. Patients also suggested that reminding them to prepare for the completion of the HRA by collecting their records (e.g., blood pressure readings, labs, etc.) in advance could facilitate the assessment process.

6. List of Publications and Products:

1) A publication on the HRA Study is available from *Applied Clinical Informatics*: http://aci.schattauer.de/en/home/issue/special/manuscript/19362/show.html
Reference: Nagykaldi Z, Voncken-Brewster V, Aspy CB, Mold JW. Novel Computerized Health Risk Appraisal May Improve Longitudinal Health and Wellness in Primary Care: A Pilot Study. *Applied Clinical Informatics*, 2013; 4: 75–87

2) A publication on the "My Wellness Portal" trial is available via Medline: http://www.ncbi.nlm.nih.gov/pubmed/22403196
Reference: Nagykaldi Z, Aspy CB, Chou AF, Mold JW. Impact of a Wellness Portal on the Delivery of Patient-Centered Preventive Care. *J Am Board Fam Med*, 2012 Mar-Apr;25(2):158-167.

3) The Wellness Portal–integrated HRA tool is available to primary care practices and wellness organizations in Oklahoma at https://mpsrs.us/WPortal/index.jsp

7. Inclusion of AHRQ Priority Populations

The HRA Study included 270 patient and 10 clinician participants over the 5-year period. Approximately half on these participants reside in rural and underserved areas in Oklahoma. The mean age of participants was around 60 years, indicating an overwhelming majority of older adults and the elderly in the study population. About 10% of participants indicated that their median household income was less than $40,000 per year. Patients in the HRA study had an average of about three chronic health conditions.

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Program Director/Principal Investigator (Last, First, Middle): Nagykaldi, Zsolt Ph.D.

PROGRESS REPORT FOR LAST YEAR AND NO-COST EXTENSION PERIOD	GRANT NUMBER 5K08HS016470	
	PERIOD COVERED BY THIS REPORT	
PROGRAM DIRECTOR / PRINCIPAL INVESTIGATOR Zsolt, Nagykaldi, Ph.D.	FROM 07/01/2012	THROUGH 12/31/2013

APPLICANT ORGANIZATION
University of Oklahoma Health Sciences Center

TITLE OF PROJECT (Repeat title shown in Item 1 on first page)
Using Health Risk Appraisal to Prioritize Primary Care Interventions

A. Human Subjects (Complete Item 6 on the Face Page)		
Involvement of Human Subjects	☒ No Change Since Previous Submission	☐ Change
B. Vertebrate Animals (Complete Item 7 on the Face Page)		
Use of Vertebrate Animals	☒ No Change Since Previous Submission	☐ Change
C. Select Agent Research	☒ No Change Since Previous Submission	☐ Change
D. Multiple PD/PI Leadership Plan	☒ No Change Since Previous Submission	☐ Change

Objectives of the K08 Award for the last year of funding and the no-cost extension period (7/1-12/31/2013):

In the final year of the project, Dr. Nagykaldi will apply for separate funding to conduct a randomized, controlled clinical trial of the Health Risk Appraisal (HRA) implementation in eight clinician practices (four control and four intervention clinicians). The study will estimate the impact of the integrated HRA implementation on patient outcomes, including patient stages of change for recommended actions, estimated life expectancy, patient-centeredness of care, and patient / provider satisfaction with the HRA instrument. We will also measure adoption, implementation, and maintenance of implementation in the intervention practices and will estimate the cost to the practice for both implementation and maintenance of the HRA instrument.

Specific Aims:

1) Test the rates of adoption, implementation, and maintenance of the HRA tool in intervention practices.

2) Estimate the impact of the integrated HRA tool on patient outcomes including: patient stages of change for recommended actions, changes in estimated life expectancy, patient-centeredness of care, and patient/provider satisfaction with the HRA tool.

3) Estimate the per clinician cost of implementation and maintenance of the HRA tool in intervention practices from the perspective of the practice.

4) Disseminate the HRA tool in Oklahoma in primary care practices and other health organizations.

OUTCOMES

According to K08 requirements and in order to receive separate, dedicated funding for the RCT, Dr. Nagykaldi collaborated extensively with his colleagues and consecutively submitted an AHRQ R01 (1 R01 HS020641-01), an NIH/NINR R01 (1 R01 NR013923-01A1), an R21 (1 R21 HS020320-01), a P01 Prevention Center Grant study (1 P01 HS021127-01), and a PCORI application (R-APD-1306-02032) between the end of 2010 and 2013. Given the extraordinarily competitive environment and drastically decreased levels of federal funding in the past several years, none of these proposals have resulted in actual funding yet, although reviewers valued the submissions highly. For example, the R21 submission achieved a 32 score (20^{th} percentile) in an AHRQ study section while the last R01 submission received a 38 score in a National Institute of Nursing Research study section in early 2013.

Despite these challenges, Dr. Nagykaldi is continually pursuing funding for a randomized, controlled trial to measure the impact of the HRA approach on patient and practice outcomes. Several potential partners and centers of excellence have been approached nationally (UNC Sheps Center for Health Services Research, NYU Division of Comparative Effectiveness and Decision Sciences) to augment Dr. Nagykaldi's research team with additional expertise in patient-centered outcomes research and behavioral interventions in primary care settings.

In addition to pursuing grant funding, Dr. Nagykaldi moved ahead with publication and dissemination of the HRA tool regionally through the Oklahoma Physicians Resource/Research Network (OKPRN). In February of 2013, Dr. Nagykaldi published a milestone paper in *Applied Clinical Informatics* that described the new HRA method. This paper represents a crucial step toward further investigations in HRA use in primary care because this novel method has not been published in a peer-reviewed journal before.

Another line of (unfunded) work included research and inclusion of Health-Related Quality of Life (HRQoL) measures into the HRA tool. Based on various published methods and emerging evidence from epidemiological surveillance initiatives conducted by the WHO and other international organizations, Dr. Nagykaldi developed and incorporated a preliminary Estimated Health Expectancy (EHE) score into the HRA. This measure is an indicator of disability-free life expectancy and, thus, it can indicate healthy functioning and ability to participate in meaningful life activities, which are major determinants of HRQoL. This is a completely new line of research within the primary care HRA field and it substantively complements Dr. Nagykaldi's previous work in clinical decision support for the purpose of life extension (the second large domain of health and wellness). This work has been initiated in 2012 in collaboration with Dr. Carrie Ciro, who is the Director of the Occupational Performance Laboratory at the OUHSC School of Allied Health, Department of Rehabilitation Sciences. The collaboration also aims at bridging a historic gap between the approach of clinicians and that of OT/PT specialists for the preservation and improvement of human functioning. During the summer of 2013, Dr. Nagykaldi conducted another (unfunded) pilot study; with the help of a medical student, it investigated the acceptability, utility, and feasibility of the novel HRQoL module using user-centered design techniques and qualitative research methods. Patients and clinicians have been interviewed in detail about their experience using the module and their feedback helped improve the module's design. During the summer of 2014, the development of the HRQoL module will be completed, and a second (unfunded) small study will be conducted, with the help of a medical student, to optimize the patient report component of the module. Further studies and a publication of results are planned.

In summary, Dr. Nagykaldi has completed his K08 curriculum, accomplishing all major milestones that were proposed in the original application except for the ability to secure funding for a final, large, randomized, controlled trial, which was due to obstacles beyond his control. In addition, he initiated and continually pursues new lines of research stemming from his K08 work, which are to extend the functionality of the HRA to include quality-of-life measures and to continue the dissemination of the HRA approach locally and nationally.

With regards to dissemination, among several initiatives, Dr. Nagykaldi has secured and initiated a service contract with HealthChoice, the main insurer of state employees in Oklahoma, to incorporate the HRA into a statewide wellness program for about 12,000 members of the Oklahoma State. This initiative is currently underway and accruing participants. Plans are being developed to analyze and compare this dataset to data collected in clinical settings in the course of the K08 Award; this will assess the impact of the environment on HRA outcomes and the differences in the HRA audience, including clinical, employee, and payer settings.

Other stakeholders are also increasingly interested in using the HRA. For example, the University of Oklahoma College of Nursing is working with 20 inner-city African American churches in minority and underserved neighborhoods in N.E. Oklahoma City; the church members have a high prevalence of morbidity and mortality that are appropriate for a systematic health risk assessment approach. Dr. Nagykaldi is currently working with these communities to disseminate the HRA tool, and he is assisting community health professionals in its use. With the help of an interdisciplinary team, Dr. Nagykaldi submitted an intramural pilot proposal to the Oklahoma Shared Clinical and Translational Research Institute (OSCTRI) to build and test an HRA-based health intervention, which would include a systematic health assessment, triage, health coaching, and continuing community-level follow-up. Leveraging preventive services for tobacco use, colon cancer, and breast cancer in the HRA process, another pilot proposal was submitted to the Stephenson Cancer Center for matching OSCTRI funding.

Summary of K08 Study Outcomes:

Novel Computerized Health Risk Appraisal May Improve Longitudinal Health and Wellness in Primary Care

Objectives: Health Risk Appraisals (HRAs) have been implemented in a variety of settings, however few studies have examined the impact of computerized HRAs systematically in primary care. The study aimed at the development and pilot testing of a novel, comprehensive HRA tool in primary care practices.

Methods: We designed, implemented, and pilot tested a novel, web-based HRA tool in four pair-matched intervention and control primary care practices (N=200). Outcomes were measured before and 12 months after the intervention by using the HRA, patient surveys, and qualitative feedback. Intervention patients received detailed feedback from the HRA ,and they were encouraged to discuss the HRA report at their next wellness visit in order to develop a personalized wellness plan.

Results: Estimated life expectancy and its derivatives, including Real Age and Wellness Score, were significantly impacted by the HRA implementation ($P<0.001$). The overall rate of 10 preventive maneuvers improved by 4.2% in the intervention group vs. control ($P=0.001$). The HRA improved the patient-centeredness of care as measured by the CAHPS PCC-10 survey ($P=0.05$). HRA use was strongly associated with better self-rated overall health (OR = 4.94; 95% CI, 3.85–6.36) and improved up-to-dateness for preventive services (OR = 1.22; 95% CI, 1.12–1.32). A generalized linear model suggested that the increase in the Wellness Score was associated with improvements in patient-centeredness of care, up-to-dateness for preventive services, and being in the intervention group (all $P<0.03$). Patients were satisfied with their HRA experience, found the HRA report relevant and motivating, and thought that it increased their health awareness. Clinicians emphasized that the HRA tool helped them and their patients converge on high-impact, evidence-based, preventive measures.

Conclusions: Despite study limitations, results suggest that a comprehensive, web-based, and goal-directed HRA tool can improve the receipt of preventive services, patient-centeredness of care, behavioral health outcomes, and various wellness indicators in primary care settings.

C. Significance

In the past year of the K08 study, Dr. Nagykaldi completed the HRA pilot that is pivotal to the success of future investigations of goal-directed HRA design and implementation. As preliminary results above indicate, the HRA has a significant potential for improving the patient-centeredness of care, patient activation, and collaboration between patients and clinicians that can facilitate the improvement of biomedical, behavioral, and psychosocial determinants of health. Based on these findings, Dr. Nagykaldi submitted several grant proposals (two R01s, two R21s, a Center Grant, an NSF application, and a PCORI proposal) in order to conduct a more definitive study on the HRA. Some of these proposals received competitive scores, but none have been funded. Dr. Nagykaldi conducted a number of conference presentations and published the results of the pilot HRA study.

D. Plans - Beyond the K08 Timeline

Dr. Nagykaldi continues the development of the HRA tool and dissemination of the novel approach according to strategies discussed above.

E. Publications and Presentations Related to the K08 Research

2012

Publication: Nagykaldi Z, Aspy CB, Chou AF, Mold JW. Impact of a Wellness Portal on the Delivery of Patient-Centered Preventive Care. *J Am Board Fam Med*, 2012 Mar-Apr;25(2):158-167.

Presentations:

1) The Impact of Health Risk Appraisal in Primary Care. Annual OKPRN-OAFP Scientific Assembly (June 16th, Tulsa, OK)
2) Novel Comprehensive Health Risk Appraisal May Improve Longitudinal Health and Wellness in Primary Care: A Pilot Study. Annual AHRQ PBRN Meeting (June 21st, Bethesda, MD)
3) A Computer-Tailored Program to Improve the Self-Management of COPD Patients In Primary Care. Annual AHRQ PBRN Meeting (June 21st, Bethesda, MD)
4) Spreading Innovations in Primary Care Systems Redesign: Moving From Theory to Practical Methods. 40th Annual NAPCRG Meeting (December 4th, New Orleans, LA)
5) Novel Web-based Comprehensive Health Risk Appraisal May Improve Longitudinal Health and Wellness in Primary Care: A Pilot Study. 40th Annual NAPCRG Meeting (December 5th, New Orleans, LA)

2013

Publication: Nagykaldi Z, Voncken-Brewster V, Aspy CB, Mold JW. Novel Computerized Health Risk Appraisal May Improve Longitudinal Health and Wellness in Primary Care: A Pilot Study. *Applied Clinical Informatics*, 2013; 4: 75–87.

Presentations:

2013

1) Novel Web-Based Comprehensive Health Risk Appraisal May Improve Cancer Prevention In Primary Care Settings. 2013 Stephenson Cancer Center Research Symposium. (March 29th, Oklahoma City).
2) Shifting the Focus From Disease To Health: A Paradigm Change To Achieve Patient-Centered Care. Keynote Lecture at the 7th Annual Health Research Forum (April 16th, Waco, TX).
3) Personalized Health Risk Assessment - The Best Approach To Medicare Annual Wellness Visits. Annual OKPRN-OAFP Scientific Assembly (June 14th, Norman OK).
4) The Relationship Between Pets and Multiple Child Health Indicators (the Child Health Screener Study). 150th Annual Convention of the American Veterinary Medical Association. (July 19th , Chicago, IL).
5) Integration of Health-Related Quality of Life Into Systematic Health Risk Assessment And Personalized Care Planning. 41st Annual NAPCRG Meeting (November 12th, Ottawa, Ontario).

2014

1) Outcomes of the Future: Composite quality metrics that indicate health benefit (panel presentation on the HRA approach to comprehensive care quality measurement). 2014 AMIA iHealth Conference (February 1st, Orlando, FL).

F. Project-Generated Resources

The HRA tool and the hosting Wellness Portal website were substantially improved as a result of continued testing and extensive feedback. The HRA gained more traction regionally and statewide during the past year. About 400 OUHSC employees have used the Wellness Portal HRA as part of the OU Fit wellness program, run by the university. Other entities, including small local companies, are also interested in using the HRA for employee health initiatives. Another AHRQ funded project (Task Order #5) has made substantial gains in Oklahoma using the state's health information exchange (HIE) network: SMRTNet. This initiative is very interested in leveraging the Wellness Portal and the new HRA tool developed by Dr. Nagykaldi to extend its functionality to patients and practices throughout the state. The HRA is now also available to about 12,000 state employees as part of a comprehensive, payer-based wellness program.

G. Research Development

Mentored research development in the final year included frequent meetings with the mentor (Dr. Mold) and other advisors (Drs. Aspy, Scheid, Hamm) pertaining to the K08 study and other ongoing studies with high relevance to the K08 curriculum. In addition, Dr. Nagykaldi became a standing (permanent) member of the AHRQ Health Care Effectiveness and Outcomes Research (HEOR) study section in 2013, which has been instrumental to his improvement as an independent investigator with critical scientific appraisal skills, enhanced grantsmanship, and broader knowledge in his field. Similarly, based on his work, Dr. Nagykaldi was promoted to the rank of Associate Professor by the University of Oklahoma Health Sciences Center in 2012. Other academic opportunities related to the K08 curriculum included mentoring of students and new investigators in the area of health information technology implementation research, primary authorship in several new grant submissions, publications, and frequent conference presentations. In July of 2013, Dr. Nagykaldi was appointed as Assistant Director of Research in his department's Research Division.

As a particularly notable accomplishment, a recent AHRQ proposal, led by Dr. Nagykaldi as the PI, that aims to test a preventive services delivery system in three rural Oklahoma counties received a perfect score (10) from the review panel in February 2014 and, thus, is expected to be funded starting in July 2014. The award provides $1.6M for 4 years (Nagykaldi PI, 40% FTE) and incorporates the HRA tool as one of the options for patients to use to engage in preventive healthcare. The investigator team is excited about this opportunity that will help them further the dissemination of their last decade's developments.

H. Other Activities

Curriculum Development:

Continuing refinement and adoption of the department's Practice Facilitator curriculum, the Practice Enhancement Assistant Training Manual and the nationally accredited Practice Facilitator Training curriculum are administered by the Millard Fillmore College (University at Buffalo).

Society Memberships and Peer Review Activity in 2012-13:

2005 - present	Society of Teachers of Family Medicine (USA)
2005 - present	Reviewer for the Journal of Public Health Management and Practice (JPHMP)
2006 - present	Reviewer for the Journal of the American Board of Family Medicine (JABFM)
2006 - present	Reviewer for the Annals of Family Medicine

2007 - present	Member of the Continuity of Care Record Development & Acceleration Task Force (AAFP)
2009 - present	Reviewer for the North American Primary Care Research Group (NAPCRG)
2009 - present	Member of the OUHSC Faculty Senate Information Technology Advisory Committee (ITAC)
2009 - present	Member of the Health Alliance for the Uninsured (HAU) HIT/Data Committee
2009 - present	Member of the Board of the Oklahoma Pharmacy Resource/Research Network (OKPhRN)
2010 - present	Reviewer for Health Affairs
2010 - present	Member of the Oklahoma State Medical Association Health IT Committee (OSMA-HIT)
2011 - present	Member of the Oklahoma State Medical Association Health IT Governance Committee (HITGC)
2011 - present	Peer Reviewer for Implementation Science (BiomedCentral)
2011 - present	Peer Reviewer for the American Journal of Managed Care (AJMC)
2012 - present	Peer Reviewer for the International Journal of Healthcare Technology and Management (IJHTM)
2013 - present	Standing Member of the AHRQ Health Care Effectiveness and Outcomes Research (HEOR) Study Section
2013 - present	Member of the international North American Primary Care Research Group (NAPCRG)
2013 - present	Member of the Journal of American Board of Family Medicine Editorial Board
2013 - present	Member of the Society of Participatory Medicine (SPM)
2013 - present	Peer Reviewer for the American Journal of Public Health (AJPH)

I. Research Development and Other Activities Planned

Dr. Nagykaldi will continue to maintain and expand his varied academic activities, including grant writing/ review and publication writing/review. He will also continue mentoring a Dutch PhD student in his Department, as a collaborative effort with the Maastricht University Department of Public Health and Primary Care in the Netherlands, and medical students and residents from the University of Oklahoma.

J. Mentor's Report

Dr. Nagykaldi and I meet regularly to discuss progress on his K08 project. He continues to meet, and often exceed, expectations and most milestones. Not for lack of trying, he has had difficulty getting funding for the randomized ,controlled trial required to prove that the HRA is an effective intervention when used in primary care settings. However, a pilot project strongly supports that conclusion. The work he is doing represents a major new approach to clinical care, providing a tool that both engages and activates patients and provides clinicians with information needed for prioritization. This K08 work is related to other projects being carried out in our Division/Department. Dr. Nagykaldi continues to publish on a regular basis and participate in high-level academic activities. Several of his recent publications have received national recognition. He continues to mentor medical students as well as a PhD candidate from the Netherlands. He has recently been promoted to Associate Professor and Assistant Director of the Research Division, and he was elected to serve on the Board of Directors of our practice-based research network.