



Guidance on Development of Health Risk Assessment as Part of the Annual Wellness Visit for Medicare Beneficiaries—(Section 4103 of the Patient Protection and Affordable Care Act)

General Proceedings from a Public Forum, Expert Input, and the Research Literature for the Design of Patient-Centered Health Assessments

Final Report

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Table of Contents

BACKGROUND4
PURPOSE5
REQUIREMENTS FOR COVERAGE OF AN ANNUAL WELLNESS VISIT6
WHAT CONSTITUTES AN HRA-BASED WELLNESS VISIT?
WHAT IS AN HRA?
CONTENT AND DESIGN
Background
GUIDANCE
MODE OF ADMINISTRATION
GUIDANCE
PRIMARY CARE OFFICE CAPACITY
Background
Guidance
Iraining and Technical Assistance Needed to Support the HRA Plus Process
CONSUMER/PATIENT PERSPECTIVE
GUIDANCE
Methods of Feedback
Feedback for Provider Practices 23
Incentives
DATA24
Background
GUIDANCE
CERTIFICATION
Background
GUIDANCE
EVALUATION AND QUALITY ASSURANCE
Background
GUIDANCE
CONCLUSIONS
REFERENCES
APPENDICES
APPENDIX A. PROPOSED EXAMPLES OF STANDARD QUESTIONS FOR INCLUSION IN A HEALTH RISK
ASSESSMENT (HRA) AS PART OF THE ANNUAL WELLNESS VISIT
BEHAVIORAL RISK FACTORS



PHYSICAL INACTIVITY/LACK OF EXERCISE	35
SMOKING/TOBACCO USE	36
ALCOHOL USE	37
NUTRITION	37
MOTOR VEHICLE SAFETY	37
SUN EXPOSURE	38
BIOMETRIC MEASURES – SELF-REPORTED	38
BLOOD PRESSURE	38
CHOLESTEROL	38
BLOOD GLUCOSE	39
OVERWEIGHT/OBESITY	39
PSYCHOSOCIAL RISK FACTORS	40
PSYCHOSOCIAL RISK FACTORS	 40 40
PSYCHOSOCIAL RISK FACTORS	 40 40 41
PSYCHOSOCIAL RISK FACTORS DEPRESSION HIGH STRESS GENERAL WELL-BEING	 40 40 41 41
PSYCHOSOCIAL RISK FACTORS DEPRESSION HIGH STRESS GENERAL WELL-BEING SOCIAL/EMOTIONAL SUPPORT	 40 40 41 41 41
PSYCHOSOCIAL RISK FACTORS DEPRESSION HIGH STRESS GENERAL WELL-BEING SOCIAL/EMOTIONAL SUPPORT GENERAL LIFE SATISFACTION	40 40 41 41 41 42
PSYCHOSOCIAL RISK FACTORS DEPRESSION HIGH STRESS GENERAL WELL-BEING SOCIAL/EMOTIONAL SUPPORT GENERAL LIFE SATISFACTION SLEEP	40 40 41 41 41 41 41 42 42 42
PSYCHOSOCIAL RISK FACTORS DEPRESSION HIGH STRESS GENERAL WELL-BEING SOCIAL/EMOTIONAL SUPPORT GENERAL LIFE SATISFACTION SLEEP CHEMOPROPHYLAXIS	40 41 41 41 42 42 42
PSYCHOSOCIAL RISK FACTORS DEPRESSION HIGH STRESS GENERAL WELL-BEING SOCIAL/EMOTIONAL SUPPORT GENERAL LIFE SATISFACTION SLEEP DAILY ASPIRIN USE	40 41 41 41 41 42 42 42 42 42 42 42



BACKGROUND

In March 23, 2010, President Obama signed into law the Patient Protection and Affordable Care Act of 2010 (ACA), which included several provisions intended to improve the health of Americans and prevent the onset of preventable chronic disease conditions (1). Section 4103 of the ACA, entitled Medicare Coverage of Annual Wellness Visit Providing a Personalized Prevention Plan, mandates that starting in January 1, 2011, Medicare will cover, without cost to beneficiaries, an annual wellness visit (AWV) that includes a health risk assessment (HRA) followed by provision of a customized wellness or personal prevention plan (2).

Section 4103 also states that an HRA is to be completed prior to, or as part of, a visit with a health professional who may be a physician, medical practitioner, medical professional (e.g., health educator, registered dietician, nutrition professional) or a team of medical professionals. The law specifies that the HRA 1) must identify chronic diseases, injury risks, modifiable risk factors, and urgent health needs of an individual; 2) may be furnished through an interactive telephonic or web-based program; 3) may be offered during the encounter with a health care professional or through community-based prevention programs, or 4) may be provided through any other means appropriate to maximize accessibility and ease of use by beneficiaries, while ensuring the privacy of beneficiaries.

Other provisions of Section 4103 include 1) establishing standards for interactive or Web-based programs used to furnish HRAs, and 2) determining ways of using the HRA in the formulation of a personalized prevention plan for beneficiaries who are administered the HRA. The law also calls for making available to the public an HRA "model" (unspecified) 18 months after the passage of ACA, ensuring that HRAs are made available and easily accessible to beneficiaries, providing support to those wishing to complete HRAs, and publicizing the requirement that beneficiaries complete an HRA prior to, or concurrent with, receiving personalized prevention plan services. The statute recognizes the critical nature of follow-up services by encouraging integration of HRAs with health information technology (HIT), including electronic medical record (EMRs) and personal health records (PHRs), and the leveraging of these technologies in the development of self-management skills and management of, and adherence to, provider recommendations as a means of improving the health of beneficiaries. Further, as part of the law, the Secretary of Health and Human Services is authorized to establish publicly available guidelines for an HRA, to be formulated in consultation with relevant groups and entities.

With this as background, the U.S. Centers for Disease Control and Prevention (CDC) contracted with Partnership for Prevention and its subcontractor Thomson Reuters to develop this guidance document to be used by the Centers for Medicare and Medicaid Services (CMS) to direct health care providers, health promotion vendors, and other professionals wishing to implement Section 4103 of the ACA. The guidance document presented here is informed by interviews with subject matter experts, input received in response to a Federal Register Notice, insights provided by attendees at a public forum hosted by the CDC on February 1–2, 2011, and knowledge by the authors derived from



an understanding of the literature focused on this topic (see Appendix B). The guidance document addresses the use of HRAs and follow-up counseling, coaching and behavior change interventions in clinical settings aimed at improving the health and well-being of Medicare beneficiaries.

PURPOSE

The AWV aims to keep Medicare beneficiaries healthy by promoting positive health habits and a healthy lifestyle. Unlike much of medical care, which is primarily directed at treating acute and chronic illnesses, the AWV intends to prevent the onset of disease and disability, or slow the progression and exacerbation of illnesses. The role of the provider in the delivery of the AWV is to highlight behaviors and lifestyle choices that beneficiaries can adopt to keep them from getting sick, or sicker. The ultimate aim is to improve beneficiaries' quality of life and day-to-day functioning. As such, the AWV is contrasted with mainstream medicine, which is largely focused on treating diseases that are often a consequence of poor lifestyle habits.

The AWV is also not meant to replace the standard "physical examination" or Initial Preventive Physical Examination (IPPE or "Welcome to Medicare Visit"), both of which include a series of screening tests and diagnostic procedures. Further, the intent of the AWV is not to administer assessment instruments that would help the provider predict a future hospitalization or admission to a nursing home. Instead, the main purpose of the AWV is to encourage individuals to take an active role in managing their health to improve their actual and self-assessment of well-being. This would be accomplished by first evaluating beneficiaries' current health and wellness, and then advising and counseling them on ways to remain healthy for as long as possible. The tools used to accomplish this aim include administering an easy-to-use HRA with feedback, along with credible information, advice, tools, resources, and support that will raise patients' awareness of their own health issues, promote self-reliance and self-care, prompt active decision-making, and increase confidence to manage one's health. This is achieved by collecting information relevant to effective patient engagement and providing feedback to the patient that is welcome by the patient and actionable.

To address various facets of the AWV, this guidance document is organized by key topic areas relevant to the successful adoption of Section 4103: 1) content and design of the HRA and follow-up services, 2) mode of administration, 3) primary care office capacity, 4) consumer/patient perspective, 5) data, 6) certification, and 7) evaluation and quality assurance. Under each of these broad categories are listed specific questions posed in the Federal Register Notice (FRN) announcement, dated November 16, 2010 (*3*).

This guidance document is not meant to be prescriptive *per se*. It recognizes that the AWV will undergo ongoing updating and refinement as it is adopted more broadly among practitioners. Rather, this guidance should provide medical professionals and health promotion practitioners with direction on how to implement best practices in a "real world" setting. Further, it is meant to inform the administration of HRAs and follow-up services for other populations not enrolled in Medicare, such as privately



insured individuals and those covered by employer-sponsored health plans.

REQUIREMENTS FOR COVERAGE OF AN ANNUAL WELLNESS VISIT

The law specifies that Medicare will cover, without cost to beneficiaries, an AWV that includes a HRA. Further, the AWV may include the following elements:

- Establishment of a beneficiary's medical/family history,
- Establishment of a list of current providers and suppliers who are regularly involved in providing medical care to the beneficiary,
- Measurement of an individual's height, weight, BMI (or waist circumference, if appropriate), blood pressure, and other routine measurements as appropriate, based on the beneficiary's medical/family history,
- Detection of any cognitive impairment that the individual may have,
- Review of the individual's potential (risk factors) for depression, including current or past experiences with depression or other mood disorders, based on the use of an appropriate screening instrument for persons without a current diagnosis of depression, which the health professional may select from various available standardized screening tests designed for this purpose and recognized by national medical professional organizations,
- Review of the individual's functional ability and level of safety based on direct observation, or the use of appropriate screening questions or a screening questionnaire, which the health professional may select from various available screening questions or standardized questionnaires designed for this purpose and recognized by national professional medical organizations,
- Establishment of a written screening schedule for the individual, such as a checklist for the next 5 to 10 years, as appropriate, based on recommendations of the United States Preventive Services Task Force (USPSTF) and the Advisory Committee on Immunization Practices (ACIP), as well as the individual's health status, screening history, and age-appropriate preventive services covered by Medicare,
- Establishment of a list of risk factors and conditions for which primary, secondary, or tertiary interventions are recommended or are underway for the individual, including any mental health conditions or any such risk factors or conditions that have been identified through an Initial Preventive Physical Examination (IPPE), and a list of treatment options and their associated risks and benefits,
- Furnishing of personalized health advice to the individual and a referral, as appropriate, to health education or preventive counseling services or programs aimed at reducing identified risk factors and improving self management, or community-based lifestyle interventions to reduce health risks and promote self management and wellness, including weight loss, physical activity, smoking cessation, fall prevention,



and nutrition.

The preceding list of required procedures and screening activities to be performed as part of the AWV, while appropriate and certainly comprehensive, is not likely to be easily implemented within the context of a time-limited office visit appointment. Further, there is considerable overlap between what is listed above as part of the AWV and other types of visits to a physician's office for specific screening and treatment services. A key concern voiced by practitioners familiar with the requirements listed above is that they may be so onerous and burdensome that widespread adoption will be limited simply because practitioners may view the requirements for such a visit as adding significant layers of work, and a large time commitment, with tight rules and requirements that are difficult to execute.

Thus, the guidance presented here is written in a way that allows for flexibility in the conduct of an AWV, including incorporation of the current required elements into the HRA, at least in the early phases of ACA implementation, with the intent of learning how the Visit and its component parts work most efficiently so that they may be fined-tuned to achieve the aim of health improvement and risk reduction among Medicare beneficiaries. Consequently, the guidance is written to support a balance between rigorous adoption of best practices and an appreciation of what is reasonable to accomplish in everyday clinical practice.

WHAT CONSTITUTES AN HRA-BASED WELLNESS VISIT?

The CDC's *Guide to Community Preventive Services* (Community Guide), in its recent review of worksite health promotion programs that use HRAs, distinguished between two types of HRA applications: 1) an assessment of health risks with feedback, when used alone, ("HRA Alone"), and 2) an assessment of health risks with feedback as a gateway to more intensive and prolonged health promotion and risk reductions interventions ("HRA Plus") (4). The phrase "HRA Plus" is used throughout this guidance document to highlight the importance of providing additional services in follow-up to the administration of the HRA along with feedback. At a minimum, the HRA Plus process would involve the administration of the HRA and production of a feedback report that would form the foundation of a personal prevention plan. However, for the HRA Plus to be most effective it needs to include the following components that complement the provision of an HRA with a feedback report:

- Multiple or serial administrations of HRAs, with longitudinal feedback provided to participants on their health risk status,
- Ongoing health education programs, provided through pamphlets, books, videos, or interactive computer programs,
- Motivational interviewing, counseling, and coaching provided face-to-face or telephonically to support behavior change and risk reduction,
- Referral to community resources such as fitness facilities, self-help support groups, or neighborhood volunteer programs,



• Referral to local or national health promotion vendors and services such as smoking quit lines and wellness coaches.

The Community Guide systematic reviews of HRA Plus programs, led by Dr. Robin Soler and supported Community Guide staff, evaluated carefully screened studies of health promotion programs and policies introduced by employers over the course of the past thirty years.⁴ The reviews assessed behavioral, biometric, and business-relevant outcomes reported in 51 studies that met inclusion criteria established by the task force. The overall conclusion of the reviews was that HRA Plus programs, judged to be comprehensive, well resourced, and theory-based, *do* exert a positive influence on certain health behaviors, biometric measures, and financial outcomes important to employers. In contrast, HRA Alone programs were ineffectual, largely because they were episodic and lacked the necessary follow-up required for long-lasting behavior change.

Specific findings from the HRA Plus program reviews noted that there was *strong* or *sufficient* evidence that these programs can reduce rates of tobacco use, dietary fat consumption, seat belt nonuse, high blood pressure, total serum cholesterol levels, high risk drinking, and worker absenteeism. The reviews also found improvements in participants' physical activity, overall health and well-being scores, and healthcare use, especially in terms of reduced hospital admissions and hospital days of care. There were also some inconclusive findings. For example, there was insufficient evidence (i.e., not enough studies) to determine whether or not the HRA Plus intervention was effective in increasing fruit and vegetable consumption, body composition (i.e., weight and BMI), and overall physical fitness of participants. Although the above reviews focused on active employees and not Medicare beneficiaries, there is reason to believe that these results may also be generally applicable to the Medicare demonstration entitled Senior Risk Reduction Demonstration, which is being administered by the Office of Research, Development, and Information (ORDI) at CMS (5).

Applying the above findings to the task at hand, i.e., determining what constitutes an effective HRA Plus program within the context of the AWV, it is important to differentiate the HRA Plus's component parts—administration of an HRA and preparation of a personal prevention plan—from the other follow-up elements designed to bring about long-lasting behavior change and risk reduction, i.e., the "Plus" components. These are discussed below.

WHAT IS AN HRA?

Throughout this guidance document, we will refer to the collection and analysis of health-related data used to evaluate the health status or health risk of an individual as an HRA (6). It should be noted, however, that experts in the field, and developers of these instruments, often prefer such terms as health profile, health assessment, or wellness assessment in order to move away from the negative connotation associated with "risk" assessment to one that is more positive, highlighting wellness and attainment of improved health. Nonetheless, for the sake of uniformity, we refer to the tool, questionnaire,



technique, or process referenced in this guidance document as an HRA, which contains the following elements:

- Assessment of personal health habits and risk factors generally supplemented with biometric measurements of physiologic health,
- Quantitative estimation or qualitative assessment of future risk of death or adverse health outcomes,
- A mechanism for providing feedback in the form of educational messages or counseling on ways to change behaviors and health habits to potentially alter one's risk of disease or premature death.⁴

HRAs can play an important role in raising awareness of health issues and motivating behavior change by creating a "teachable moment" that inspires health improvement. In addition to encouraging behavior change, an HRA can serve as a vehicle for triaging individuals into risk-appropriate interventions and tracking changes in the risk profile of individuals and groups over time. This, in turn, allows medical and health promotion practitioners to measure individual progress and overall program impacts. HRAs are often accompanied by biomedical screenings that include measurements of height and weight, blood pressure, cholesterol, blood glucose, and triglycerides.

The HRA was originally developed as a hand-tallied instrument to collect health risk data from individuals to produce a personalized epidemiological-based profile predicting future mortality. The HRA has since evolved into an interactive electronic tool which may provide a personal health assessment score such as a "health age," tailored educational messages on how to reduce risks, on-line modeling of the effects of making lifestyle changes, goal setting guidance, and other messages designed to motivate behavior change and risk reduction.⁷

There are limitations and methodological concerns with the use of HRAs worth noting. For example, inaccurate information may be provided by individuals due to recall bias or a lack of understanding of health risk questions. In addition, HRAs may not be tailored to specific literacy, cultural or age groups, and they can have poor validity and reliability, thereby generating inconsistent results (7).

Experts agree that HRAs alone are rarely effective in inducing long-term behavior change (4, 8, 9). While HRAs inform individuals about health issues, and raise their awareness about what constitutes healthy or unhealthy behaviors, further support is required to help recipients of that information gain the necessary skills to try out new health habits and make them an integral part of their day-to-day routine. Consequently, HRAs should be thought about as a first step in a comprehensive framework of behavior change and risk reduction.

In recent years, HRAs have evolved so that they do more than predict the likelihood of dying from a certain illness within a given timeframe. Contemporaneous HRAs carefully assess one's risk of negative health outcomes, readiness to change certain behaviors, confidence in doing so, and the relative pros and cons for initiating behavior change. This information is then used to motivate and maintain a health promoting lifestyle.



Underlying these tools are constructs derived from behavior change theories described by Bandura; Prochaska and DiClemente; Strecher and Kreuter; Rosenstock, Strecher, and Becker; and Lorig (*10-15*).

As a first step, HRAs need to "provide feedback designed to correct users' inaccurate perceptions of their own risk" (13). This means providing information to users allowing them to accurately estimate the likelihood of future health problems, which for most individuals is underestimated (16-18). Second, HRAs need to provide feedback on behavior change priorities. These priorities may be established across the following five dimensions: 1) epidemiologic risk, 2) readiness to make behavioral changes, 3) self-efficacy, 4) quality-adjusted life years (QALYs), and 5) gateways to behavioral change.

Epidemiological risk is defined as one's morbidity and mortality risk given certain biometric measures, behaviors, demographic information, and family history. Readiness to change assesses the individual's willingness to commit to certain actions aimed at improving health within a given time horizon. Self-efficacy refers to the extent to which one feels confident that he or she can successfully modify a behavior or habit. Qualityadjusted life years take into account one's experience of living, given the addition of years to life. Finally, a gateway to behavior change refers to the likelihood that committing to a certain behavior change will "open the gate" to trying out other behaviors that improve health. Underlying these ideas is the need to tailor the information to the particular characteristics of the HRA participant, considering such factors as motivation and ability to change behaviors, as well as the barriers to change, and ways of overcoming those barriers.

Thus, although the HRA is a useful tool for inspiring behavior change, it requires followup interventions necessary for skill building, development of new health habits, and maintenance of behavior change (8). This involves offering a feedback report that is engaging and easy to understand, followed by interventions listed above. As Woolf et al. have pointed out, by asking, educating, and counseling, health professionals are more likely to assist individuals in modifying health behavior and preventing future disease than by administering tests or physical examinations (7).

It is envisioned that the AMV and HRA Plus process will eventually evolve through the five phases described by Krist and Woolf (19). In phase I, patient information is collected in a uniform and standard fashion through an HRA, which is administered prior to physician visit, preferably at home. In phase II, patient information is integrated with office EMR/PHR records or claims data, or both. In phase III, the clinical and HRA information is translated into language the patient can understand using user-friendly interfaces alongside counseling and coaching. In Phase IV, the patient receives individualized clinical and risk reduction recommendations, including screening reminders, based on the patient's risk profile and evidence-based guidelines. Finally, in Phase V, which is akin to the HRA Plus process, patients are provided vetted health information resources that allow them to make informed decisions about their health and well-being, and the necessary support and guidance services to help them make life altering changes in health habits and lifestyle.



Unfortunately skepticism about the effectiveness of counseling, inadequate reimbursement, and lack of time on the part of clinicians, in addition to the traditional medical focus on testing and procedures, create barriers for effective patient education and counseling. Health practitioners are also often reluctant to focus on the future consequences of current health risk behaviors and feel that testing in general is more effective than talking to the patient (7).

With the previously stated principles as background, below we address each of the areas of emphasis referenced in the Federal Register Notice (FRN) announcement released on November 16, 2010.

CONTENT AND DESIGN

The questions addressed in this section of the guidance document are as follows:

- What are the key HRA domains—what are generic elements of any HRA and what elements must be tailored to specific populations, particularly those stratified by age?
- *How should literacy and other cultural appropriateness factors be factored into the design?*
- *How should the HRA instrument support shared decision-making by providers and patients?*

Background

As noted previously, the lack of time, the overabundance of possible risk factors that could be addressed in an AWV, limited reimbursement, and a lack of confidence on part of providers that long-term health habits are amenable to change, all stand in the way of effective administration of an HRA Plus intervention. Thus, the core questions contained in an HRA should be limited in scope and prioritized, with a capability to tailor and drill down with additional questions depending upon patients' responses and health status, using branch chain logic. A general rule of thumb is that it should take no more than 10–20 minutes to complete the HRA in order to achieve high compliance. Limiting the instrument to high priority items will ensure that the most pertinent and impactful questions are asked and that patient participation is maximized.

Woolf et al. recommends considering the following criteria for the selection of health risk factors to address:

- How serious is the risk factor in terms of predicting poor health outcomes?
- How common is the risk factor, in the general population, and for certain age, gender, and ethnic groups engaged as part of the AWV?
- How accurately can the risk factor be detected—are there survey or interview questions that have been shown to be valid and reliable in identifying people at high risk?



- What is the evidence that potential interventions improve health outcomes? Not all risk factors are equally amenable to intervention; take, for example, obesity and smoking in contrast to seat belt use or installation of a smoke detector in the home.
- How does providing a specific piece of information compare with other health priorities the patient may have? For example, counseling a patient to change eating habits when he or she is frail, suffering from dementia, and close to death is not a good use of time.⁷

Woolf et al. offer a set of primary screening questions linked to specific risk factors, that can be answered in a yes/no format (7). Categories include tobacco use, physical activity, diet, sexual practices, alcohol/drug use, injury prevention (seat belt, drink/drive), sunlight exposure, dental hygiene, mental health/functional status, past medical history, family history, occupational/environmental exposures, travel history, screening status, immunization status, and chemoprophylaxis. Examples of questions recommended include the following:

- Do you smoke cigarettes or use other types of tobacco?
- Do you always fasten your seat belt when you are in the car? Do you ever drive after drinking, or ride with a driver who has been drinking?
- Do you protect yourself from the sun when you are outdoors?
- Are you taking daily aspirin?

Guidance

Balancing Comprehensiveness with Respondent Burden

A key consideration for how an HRA should be structured, and the likelihood that it will be completed, is the burden placed on the patient, in terms of time and complexity. HRAs are most useful in unearthing health and medical information that only the patient can provide, for example exercise habits, diet, depression, and an overall assessment of one's health status. As such, the HRA should supplement and complement data collected through other means including physical examination and laboratory tests and screenings. Ideally, information related to patient demographics, biometric values, medical history, and preventive service use should be prepopulated in an HRA record. Under ideal circumstances, this is accomplished by electronically linking the HRA with EMR or PHR data when these instruments are embedded into a physician's office practice. Today, only a minority of medical practices have instituted electronic data transfer that allows for seamless movement of data across data repositories (*20*). Consequently, HRAs used in many clinical practices today remain independent of other data systems. In the future, integration of routinely collected and HRA data will lessen the burden of completing many parts of an HRA where information is already available from other sources.



The Value of Standardization

Feedback from key stakeholders, including clinicians, academics, advocacy organizations, and health promotion vendors who were involved in the guidance process, was nearly unanimous on the issue of standardization of HRA items. These stakeholders strongly advocated for standardization, noting that it would greatly benefit patients, providers, and vendors if a set of mutually agreed-upon HRA questions could be developed that would form the basis of any HRA instrument. These standard items could be supplemented by other questions and deeper probes into the risk factors examined. The value to standardizing HRA items would be that it would provide common nomenclature and operational definitions for health behaviors and risk factors; allow data to be easily integrated into EMR and PHR records; and support development of community, state, and national HRA data repositories, essential for surveillance and evaluation purposes.

Standardization efforts do face certain challenges. Consensus is needed on what constitutes core vs. optional questions, and the response choices for those questions. Vendors and physicians wish to maintain flexibility in the adoption and use of standard questions based upon the populations they serve. Although the questions may be standardized, feedback reports would not be since these are unique and proprietary depending on the HRA developer and vendor. Finally, HRA developers may have difficulty incorporating standard items into their tools because the algorithms producing feedback reports often depend on a question or set of questions being formulated in a very specific manner.

With these caveats in mind, the guidance provided in this document supports the use of standard items to be included in HRAs administered as part of the AWV. The following list includes the elements thought to be "essential" for an HRA instrument. Examples of "standard" questions that might form the foundation of an HRA instrument are listed as an appendix (see Appendix A) to this document. Those questions are anchored in the interview protocol for Behavioral Risk Factor Surveillance System (BRFSS) fielded annually by the CDC and in previously used and widely available HRA instruments, including the one originally developed by the CDC (*21*). The BRFSS questions have been adapted from interview to written format because most HRA instruments will likely be administered as text, electronically, or as paper and pencil questionnaires.

It is recommended that a "standard" HRA address similar issues as those currently included as the focus of the CMS Senior Risk Reduction Demonstration (SRRD):

- Demographics, family and personal health history.
- Self assessment of health status, frailty, and physical/mental functioning.
- Questions related to biometric measures when these data are not readily transportable from laboratory results or medical records, for example:
 - Overweight and obesity (height/weight; body mass index (BMI); waist circumference),



- Hypertension (systolic/diastolic blood pressure),
- Blood lipids (HDL/LDL and total cholesterol, triglycerides),
- Blood glucose (blood sugar and hemoglobin A1C levels).
- Questions related to psychosocial risks, for example:
 - Depression/life satisfaction.
 - Stress/anger.
 - Loneliness/social isolation.
 - Pain/fatigue.
- Questions related to behavioral risks, for example:
 - Tobacco use.
 - Inadequate physical activity.
 - Poor nutrition or diet.
 - Excessive alcohol consumption.
 - Motor vehicle safety—use of seat belts, drinking and driving.
- Questions related to compliance with screenings, behavioral counseling, and chemoprophylaxis receiving an 'A' or 'B' recommendation from the U.S. Preventive Services Task Force (USPSTF).

For example, a question addressing one's self-assessment of health status might ask: Would you say that, in general, your health is excellent, very good, good, fair, or poor? As for smoking, the question might be phrased: Do you currently smoke cigarettes or use other tobacco products? This could be followed by a more general tobacco use question: Do you currently use chewing tobacco, snuff, or snus? Psychosocial questions may be more complicated. For example, to assess emotional support and life satisfaction, the question might read: How often do you get the social and emotional support you need: always, usually, sometimes, rarely, or never. For general life satisfaction, the question would be worded: In general, how satisfied are you with your life: very satisfied, satisfied, dissatisfied, or very dissatisfied.

Other questions to consider as part of a standardized question set would address the following risk factors:

- Physical inactivity— not engaging in moderate physical activity (e.g., walking) for at least 30 minutes a day, three or more days a week.
- Poor diet— consuming fewer than five servings of fruits and vegetables a day.



• Excessive alcohol consumption—heavy (binge) drinking defined for men as more than two drinks a day and for women more than one drink a day.

For a list of proposed standard questions, see Appendix A of this report.

Literacy and Cultural Appropriateness of HRA Instruments

Patients' race, ethnicity, and general/health literacy play an important role in the adoption of health promoting messages and behavior change recommendations. However, these factors are multidimensional. One's race, ethnicity, education, and cultural heritage alone may not determine the type of HRA instrument that is appropriate, the feedback report most likely to prompt action, or the manner in which follow-up care is provided. Thus, although the above variables need to be factored into the AWV, they are not simply prescriptive, and they need to be considered along with other relevant factors such as an individual's ability and willingness to absorb and act on information provided during the visit.

As a rule of thumb, HRAs should be written at a 5th or 6th grade literacy level, and the questions should be structured so that they are answered efficiently. The language used must be very explanatory. This implies short items that are not double or triple-barreled allowing for concise and straightforward responses. Text size, the use of white space, and image contrast are important in the design of survey instruments. Where appropriate, pictures, diagrams and illustrations should be used to help the patient understand what is being asked, and the feedback being provided.

If feasible, an interactive voice response (IVR) modality that uses the telephone or computer should be offered to individuals unable to read or who are sight-impaired. Also, as is often the case, having available an intermediary who can act as an interpreter, e.g., a child, grandchild, or other relative, to explain questions and follow-up materials is helpful. In terms of language choices, a Spanish version of the HRA should be available and, where needed, other culturally appropriate foreign language versions of the instrument and feedback reports should be provided.

The tendency by academic researchers, psychometricians, and instrument developers to include multiple items related to a given trait or health issue for the purpose of ensuring validity and reliability of a question set should be tempered. Although the validity and reliability of HRA questions are important, insisting on the inclusion of multiple items for a given assessment category may come across as redundant to the respondent and may introduce added response burden related to instrument length and complexity that in the long-run discourages rather than encourages adoption of the HRA Plus process. Instead, practitioners should choose instruments that have been tested and fine-tuned in real world settings containing a minimum item set deemed valid and reliable but not regarded as onerous to the user.

Feedback to the Patient

The HRA Plus process should include the provision of useful, comprehensible, and actionable feedback to the patient, preferably immediately after completion of the



instrument. Once the questionnaire is submitted, a summary feedback report should be generated with information relevant to the patient along with a separate report specifically focused on the needs of the clinician. For the patient, the feedback report should be immediately available on-line following the completion of the instrument if the HRA is administered through the Internet. Alternatively, it can be mailed, faxed, or emailed to the patient and physician.

A quality feedback report should include easy-to-understand recommendations for health improvement listed in priority order. The feedback should support and reinforce behaviors that the patient is taking that positively affect health. Additionally, it should point to areas requiring attention. The report should also direct the patient to resources where additional information, educational materials, and follow up programs are available to support behavior change actions. This can be provided using a URL link on the Internet, supplementary printed materials, nationwide referral telephone numbers, and specific names and contacts for community-based programs and other resources.

Shared Decision-Making

The HRA and feedback report should support shared decision-making between patient and practitioner by first gathering relevant information from the patient and then using that information to prompt productive communication leading to action. Shared decisionmaking should address mutually agreed upon ways the patient can improve health, driven by the patient's health risks, willingness to adopt specific health improvement behaviors, confidence in the patient's ability to affect change, and the availability of tools and resources to support such change. "Nagging" is seldom useful. Rather focusing on "what matters" to the patient is more likely to elicit behavior change. A shared decision-making process helps the patient work through ambivalence about changing life-long habits and involves the patient in making a commitment to action by vocalizing reasons to or not to change.

Operationally, shared decision-making is achieved through a process called motivational interviewing (22). In motivational interviewing, information communicated to the patient is personalized and delivered in a collaborative manner. The information is then repeated by the patient to ensure comprehension. Priority setting is done next with a clear timetable for follow through. Other elements of shared decision making include self-formulated and realistic goal setting, self-monitoring, establishment of support systems, and ongoing feedback discussions with the provider. Patient-provider discussions may uncover barriers to change that include physical pain, emotional difficulties, and lack of confidence in one's ability to change. These and other barriers are then addressed through a conversation between the patient and provider so that a realistic personal prevention plan is formulated with specific and achievable outcomes recorded.



MODE OF ADMINISTRATION

The questions addressed in this section are as follows:

- How will individuals access the HRA (e.g., via kiosk or some other means in the physician's office, Internet, mail-in paper form, other nontraditional healthcare locations, such as, kiosk in a pharmacy)?
- What are the cultural appropriateness factors in patient HRA access?

Background

HRAs were first introduced in a paper and pencil format. However, the evolution of technology has prompted new modes of administration that include: Internet, kiosks located in physicians' offices or pharmacies, telephone IVR, automated touch-tone telephone assessments, personal digital assistants (PDAs), and other self-administered electronic tools accessed online.

Computerized online HRAs are particularly attractive because they involve low-cost data collection, processing and reporting, and, in most cases, rapid, if not instantaneous, feedback of results (*23*). Another advantage of online HRAs is that respondents complete the surveys at their own pace and at a time convenient to them. Moreover, online or Internet-based HRAs allow for automatic skip patterns in the questions, so that users only receive questions relevant to their circumstances based on their responses to previous items. If implemented correctly, online HRAs also enable patients to access their previous results or health history, or both, and track their progress over time. Electronic HRA data can eventually be linked to PHRs and EMRs containing clinical and administrative information. Finally, HRA respondents who fill out the questionnaire online can be directed to a wide range of health resources available over the Internet or in the community.

Depending on where and when the HRA is administered, the process may facilitate efficient physician-patient interactions that are focused and time-efficient. For instance, computer-assisted HRAs that a patient completes prior to a physician's visit enables the physician to review the patient's health risk profile in advance or in conjunction with the patient during the medical consultation, thus saving time for both patient and provider.

Ease of administration and lower costs should not, however, trump accessibility to the HRA. Although the Internet has emerged as an important tool in diffusion of information, there are patients from certain socioeconomic or sociodemographic groups who lack reliable access to the Internet, either because they do not have an Internet connection or are unfamiliar with computers and information technology. Additionally, socioeconomic groups with lower incomes, and where literacy is a problem, often prefer paper and pencil modes of administration, whereas socioeconomic groups with higher levels of education and income may prefer computerized or online versions. Access to an HRA is also constrained by other cultural factors such as language barriers. If the HRA is only administered in English, it poses a problem for nonnative English speakers who may be discouraged from participating in the process.



Guidance

The preferred modality for HRA administration is the Internet, because it is least expensive and easiest to update. Ideally, an HRA would be administered through a "wellness portal" using a secure website tied directly to the physician's office and that office's PHR/EHR IT system. Internet access is available in most homes and in public areas such as libraries and community centers. In contrast, mail-based HRAs are costly and not conducive to branching of questions. However, many seniors still prefer to complete paper-based survey instruments because of their unfamiliarity with computers and concerns about privacy on the Internet.

The timing and location of HRA administration are also important. If given access to computer-assisted HRAs, patients can complete them prior to their physician visit, which enables the practitioner to review the patients' health risk profile in advance of the office visit as well as during that visit along with the patient. This focuses patient visit and supports time-efficient physician-patient interactions.

Touch screen devices and use of kiosks are potential data collection and feedback tools but they have certain limitations. Such devices have been used on a wide scale by large physician practices, integrated healthcare delivery systems, and other care delivery structures where workflow issues are well managed. However, they are expensive to implement and take up space. When offered in public places like pharmacies, they raise concerns related to privacy and confidentiality as well as the efficient flow of data to the physician's office. Additionally, they may become infected by malware and viruses and individuals may not know to clear the cache of confidential information before the next user has access to the device.

Use of phone interviews and IVR devices are also potential methods for gathering data but they too are costly and difficult to administer, especially when a live interviewer is needed. When an interview process is used, HRA topics need to be structured more simply than would be the case in a paper or computer screen format because of the difficulty of remembering questions and response options.

For respondents whose access to technology is limited, having other modes of HRA administration available, such as a traditional paper and pencil, is critical. This is facilitated by ensuring that instruments and personal prevention plans are written clearly at a reading level that conforms to those with basic literacy skills and that the materials are made available in English, Spanish, or other languages where appropriate.

PRIMARY CARE OFFICE CAPACITY

Questions asked in this section are as follows:

• What primary care office capacity is required to utilize HRA data effectively in support of personalized prevention planning?



- Are training and technical assistance necessary for effective practice utilization of an HRA? What entity should provide this technical assistance?
- What are potential or demonstrated community care transition linkages—follow-up outside the office by other providers—that help patients and providers manage priority risks identified by the HRA?
- What is the current practice of HRA in medical practices of various sizes, particularly those with five or fewer physicians?

Background

Few small practices, those with five or fewer physicians, currently engage in HRA Plus programs. Most physicians' offices do not have excess capital to purchase new information technology equipment or software nor do they have trained staff to provide the follow through on patients' personal prevention plans (24). A minority of physicians now employ HRAs and feedback in their practices. Some practices ask a small subset of "HRA-type" questions during regular office visits, such as patients' smoking status, and record this information in the patient record. However, most physicians in small practices are not now prepared to embrace the HRA Plus model on a wide scale, and they will need to be convinced that adoption of that model it will lessen their workload, improve patient health, and not interfere with normal office work flow (24).

For personal prevention plans to be effective, they need to be "built into" the HRA Plus process so that the information collected from patients naturally links to the patients' records and forms the foundation for follow-up counseling and coaching by the provider. Capacity for HRA Plus care, including follow-up counseling/coaching, will increase dramatically over the next few years as large medical groups adopt these principles and individual physicians join integrated medical delivery systems (*24*).

The HRA Plus process will also support the adoption of community health teams whose job is to provide follow-up health and disease management services locally. Today, the average clinician is not sufficiently trained, nor does he or she have the time, to do behavioral counseling and follow-up prevention planning for patients (24). Consequently, the physician's role may be best described as an essential "linchpin" to the HRA Plus process, where much of the follow-up care is delivered using other resources such as community health teams or "physician office extenders." Under this configuration, important follow-up actions are performed by other personnel in the physician's office or in the community. The "extenders" might include trained wellness coaches, dieticians, nurses, mental health, social workers, psychologists, clinical pharmacists, medical assistants, or community health workers. These providers may be located in other parts of the country and deliver services by mail, telephone, or computer. They may be part of a larger organization that provides centrally administered HRAs and feedback reports, counseling and coaching services, behavior change educational seminars, on-line health improvement seminars, and community resource and referral services. In this type of arrangement, where external resources are brought into the HRA Plus process, the physician acts as the trusted referral source to patients, which, in turn, increases the likelihood that the resources are accessed and used by patients. An effective HRA Plus



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model would build on the 5 As of patient care summarized as 1) assess, 2) advise, 3) agree, 4) assist, and 5) arrange for follow-up (25). Other methods for broadening the physician's reach beyond a one-on-one patient encounter include the use of emails, group visits, and telephone.

Guidance

The HRA Plus process should help streamline physicians' practices and lead to more effective care rather than overwhelm or distract office staff. Disease management, health promotion counseling, and other patient care initiatives, including those provided by health plans or other vendors that are linked to the practice, need to be coordinated with the HRA Plus process to avoid duplication of effort and confusion on part of patients receiving multiple interventions.

General principles for successful adoption of the HRA Plus program by physician practices include the following:

- Paper or online access to a credible HRA instrument.
- Delivery of printed personal prevention plan reports and follow-up materials.
- A trained practitioner, preferably a wellness "coach," to provide follow up counseling on an ongoing basis.
- Take home materials geared to the highest priority health promotion and prevention issues that are relevant and most likely to be addressed by the patient.

Training and Technical Assistance Needed to Support the HRA Plus Process

Utilization of the HRA Plus process will involve time and training to effectively integrate its use into the normal workflow of primary care practice. To achieve this, medical practices will need assistance from HRA developers, in partnership with professional groups and federal agencies, such as CDC and CMS, to train office staff on technical issues (data input/transfer/integration with EMR/PHR data) and health education elements of HRA Plus. Importantly, physicians and staff will need help in understanding the content of HRA questionnaires, how to interpret HRA feedback reports, how to use the information for risk stratification, and how to coordinate efforts with community and external resources. Training will also be needed to navigate through the electronic data transfer process and on how to best use reports as part of a typical patient encounter. To facilitate the adoption of HRA Plus practices, practitioners should be offered continuing medical education (CME) credits as an incentive for participating in specific AWV and HRA Plus training.

It is also crucial that the HRA Plus process is incorporated into other federal initiatives aimed at improving care delivery, including the Patient Centered Medical Home (PCMH), Accountable Care Organizations (ACO), and Community Health Teams (CHT).¹ Training should be provided to primary care physicians, nurse practitioners, and physician assistants in medical home practices on ways to leverage the HRA Plus



materials into their environments and how to support patients in self-management and behavior change efforts. In addition, the newly formed CMS Center for Medicare and Medicaid Innovation (CMMI), charged with testing innovative payment and service delivery models in Medicare and Medicaid, should provide technical assistance to primary care practices team members, ACOs, and medical home pilot programs wishing to integrate HRA Plus techniques into their practices (*26*).

Community Care Transition Linkage

Not all risk factors are best managed in the physician's office. For example, smoking cessation and weight management programs offered in the community or through nationwide specialized providers are generally more effective than physician counseling alone, although combining physician counseling with external resources is most effective. Additionally, medical or pharmacy management services may be best provided by nurse care managers and specialist pharmacists.

Physician practices wishing to adopt the HRA Plus model should consider partnering with a health promotion service available through a commercial vendor, health plan, local community health team, or local public health department as natural extensions of the physician relationship. This linkage to external expert resources would take full advantage of the referential power of the physician who lacks the time to conduct long-term behavioral counseling. The "outsourced" service is more likely to be accessed if it is endorsed by the physician.

Physicians are also encouraged to develop electronic "file drawers" of services available in the community and elsewhere that address the risk factors that are the focus of HRA Plus. Where established, local Area Agencies on Aging (AAA) and Aging Disability Resource Centers (ADRC) should be contacted and connected to physicians' practices (*26, 27*). Other community support functions may include home delivered meals, transportation for shopping, program eligibility and benefit counseling, translation services, respite care, and fitness programs.

CONSUMER/PATIENT PERSPECTIVE

Questions addressed in this section are as follows:

- *How can HRA data be shared with the patients for their feedback and follow up in primary care practice?*
- What role, if any, do incentives play in motivating patients to take the HRA or participate in follow-up interventions, or both?

Background

Today, few physicians ask their patients to complete an in-depth HRA instrument (28, 29). Patients may be given feedback about various aspects of their care, such as laboratory results, but they are seldom counseled about how to initiate meaningful



lifestyle changes that are long lasting. Consequently, there is often insufficient information sharing between the physician and patient regarding health risks and ways to modify those risks. Anecdotally, physicians have reported that they are reluctant to offer advice on lowering or eliminating a risk, such as smoking, because they think the patient already knows that he or she must quit but is unwilling to do so. Patients at risk, for example smokers, report that they have not attempted to quit because the physician has not brought up the topic, and so they inferred that it may not be important enough to address (*30*).

In employed populations, when HRAs are administered by an outside vendor, the data are often stored at the vendor site in a proprietary database rather than sent to the physician or electronically connected to the patient's PHR or EMR. This may be because individuals completing the HRA do not have a primary care physician who is identified to the vendor to whom the report would be sent, patients may lack contact information for the physician's practice, or patients may be reluctant to share the information without being assured that their data will remain protected and confidential. This lack of communication between HRA vendors and clinicians' offices creates a critical knowledge gap; leaving out important patient information that can inform physician management of the patient's health and wellness.

Guidance

Methods of Feedback

Physicians and other providers should provide patients with tailored feedback reports, including reference information for health and disease management resources, counseling and other community information. The report should prioritize and highlight the patient's health risks, and the physician should help the patient understand why certain risks may be of greater concern than others. The physician should also provide the patient with information about how to change behaviors to reduce these risks and engage the patient in the decision-making process, along with devising a patient-centered wellness plan. In addition to providing a written report, information sharing should occur during a face-to-face meeting or by telephone, allowing the patient to ask the doctor any follow-up questions.

The written feedback report can be delivered in hard copy or on a computer screen. Complementary feedback mechanisms include face-to-face meetings, over the telephone conversations, and follow-up electronic communications using secure email or PDA devices such as a Smartphone, Tablet, or Blackberry. Feedback reports need to be tailored based on the demographic, psychosocial, and risk profiles of patients. They need to highlight and encourage positive health behaviors, note areas that call for change or improvement, the relative priority of change efforts based on risk and patient readiness to change, and an overall "wellness score" that can be tracked over time. These feedback reports, and follow-up coaching and counseling, should consider patient attributes such as age, ethnicity, gender, perceived health status, readiness to change, confidence in one's ability to change, as well as personal and cultural factors. It is important to provide patients with longitudinal data charting their progress in terms of health improvements and risk reduction. Recommendations should be action-oriented, with specific advice on



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what patients should do with the results, contact information for physicians and health improvement coaches, information about relevant community resources, and directions on how to enroll in health and disease management programs, when appropriate.

After the patient is given the opportunity to review the feedback report, he or she should be allowed time to ask questions and schedule follow-up consultations. The report format should be easy to read, possibly color-coded for risks (green/yellow/red), and action-oriented.

Physicians may experience great efficiencies in care delivery by bringing physician extenders into the process (e.g., health educators, social workers, community health workers, nutritionists, personal trainers, mental health workers) and these health promotion professionals can review feedback reports with patients and provide follow-up coaching and counseling. If physician extenders or outside vendors are used, a clear communication channel needs to be formed between the physician's office and the outside service providing HRA Plus services. This is more easily accomplished when the physician initiates the contact and establishes the link between the two entities.

Feedback for Provider Practices

Physicians also need information that is actionable and can be applied to care management of their patients. For physicians, highlighting priority interventions based on patients' health risks and preferences is essential. Further, HRA data, in aggregate, can be leveraged to provide feedback to provider practices on their performance. For example, after completing an HRA, patients may be asked to identify their personal physician or physician practice from a scroll-down menu to which the HRA data are tied. Summary reports can then be produced that inform individual physicians, or groups of physicians, about the health risk profile of their patients and improvements in that profile over time. Additional data related to satisfaction with and access to care can also be collected and reported in aggregate. This process gives the patient a greater sense of control and empowerment over the HRA process.

Incentives

Although numerous studies have shown that incentives increase participation in workplace-based HRA Plus programs, these incentives are generally tied to benefit plan design, reduced insurance premiums, adjustment to coinsurance or copayments, and cash or gift rewards (*31*). These types of arrangements are not feasible for a Medicare population. However, providing incentives to clinicians for providing good care under an umbrella "pay for performance" model may induce more physicians to provide HRA Plus services, but only if the service is viewed as enhancing patient care, is "easy" to deliver, not overly expensive, and where the provider feels in control of the process. Research has shown that physician incentives can be a useful tool to increase patient completion rates for the HRA and participation in health promotion programs (*32, 33*).

As part of the AWV, it is unreasonable to expect that physician practices will incent patients to participate in the program. On the other hand, to achieve high compliance, the physician should personally ask the patient to complete the form and then review the



results along with a next-steps action plan. Doing so will eliminate the need for offering a financial inducement for participation.

Thus, instead of providing incentives to patients for completion of HRAs, incentives should be offered, in the form of reimbursement and additional pay for performance bonuses, to physicians who comply with guidance recommendations. Providing practices with a billing code for the AWV and HRA Plus process will legitimize the additional time they spend with patients on these activities.

DATA

Issues addressed in this section are as follows:

- With respect to information technology (IT), how could HRA data entered in any form populate electronic health records, and what special challenges and solutions occur if the data are entered in a nonelectronic form?
- Are there standardized and certified tools available to support this data migration from multiple data entry sources?

Background

To achieve the aims of improving patients' health and well-being, HRA data need to be incorporated into the patient files, preferably in an electronic format. This is challenging since many different types of HRAs are available and PHR and EMR data and systems are not yet standardized and linkable. The advantages of integrating HRA and patient record data are numerous including: increasing involvement of patients in the decision-making process; streamlining care processes and reducing overhead costs; providing clinicians with relevant information from the patient's perspective; and improving population health surveillance reporting. Although the majority of physicians are today situated in small practices where digital records are primitive or nonexistent, this is likely to change over the next decade as more practices adopt HIT into their businesses and interoperability standards are developed. Today, however, HRA data are most likely not linked to clinical records because of differences in database design, formatting, or other technical reasons.

There are additional challenges associated with the transfer of HRA data into medical records. They include proprietary applications for both HRA and EMR/PHR systems; complexities in searching, indexing or disaggregating data at the individual level; individual providers and health care delivery systems not wishing to invest in costly hardware and software; concerns about privacy and confidentiality; and lack of interest in aggregating data for surveillance or research purposes.

In 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act allocated federal dollars to encourage Medicare and Medicaid physicians to invest in computer systems and information technology to improve the health of patients and deliver high quality healthcare (*34*). The act also has provisions to facilitate



the standardization and certification processes to ensure that the IT system complies with the Office of the National Coordinator for Health Information Technology (ONCHIT) (35). In order to receive an incentive payment from the government, providers must adopt an IT system certified by ONCHIT and use that system in a manner that improves patient care, described as "meaningful use." Also included in the Act are additional privacy provisions related to electronic patient records. These include rules about where and to whom data can be sent with and without patient permission, notifications to patients in the event of a security breach, 'audit trails' to providers so patients can see where their information is sent, and penalties imposed on providers who fail to uphold these standards (35).

Guidance

HRA data should be incorporated into patient records and electronic format is preferred for both HRA and EMR/PHR records. If HRA data are collected using a paper and pencil methods, key data elements should then be entered into the patient chart electronically. It is recommended that clinical integration of HRA data into the patient file be specified as part of stage two "meaningful use" requirements (*36*). To link HRA and patient data, a common variable such as the patient Social Security number (SSN) or Medicare Health Insurance Claim (HIC) number can be used.

The preferred format for HRA data storage is Extensible Markup Language (XML) (37). XML is preferred because it is portable, nonproprietary, and can store information across any platform. It can also store hierarchical information and can encapsulate information to help systems with different formats communicate with one another. XML also allows for structured documents to be sent via the Web (37). In addition, there are numerous interoperability standards that support data migration from multiple data entry sources, including ASTM Continuity Care Record (CCR) integration, HL7 Clinical Document Architecture (CDA) integration, HL7/ASTM Continuity of Care Document (CCD) integration, and Integrating the Healthcare Enterprise (IHE) integration (38-41).

Providers need to be informed about the process necessary for transitioning between paper and electronic records. Providers should ensure their HIT system is compliant with the standards and certifications set forth by the ONCHIT and recognize that there are penalties for noncompliance. Additionally, providers should be made aware of revised HIPAA rules that include the appropriate use of electronic records, including when it is necessary to obtain patient permission to share data with other entities.

CERTIFICATION

The question asked here is

• What certification tools and processes should complement the HRA Guidance and how should they be made available to support primary care office selection of an HRA instrument?



Background

Currently there are no widely sanctioned or accepted standards for HRA Plus administration through physician practices and for Medicare beneficiaries (42). HRA standards largely directed at the vendor community, driven by employer interests, have been developed by National Committee for Quality Assurance (NCQA) and the Utilization Review Accreditation Committee (URAC) for wellness vendors providing health promotion services (43, 44). The introduction of the AWV offers an opportunity for federal agencies and their advisory groups to develop industrywide standards for the HRA Plus process, which, in turn, may drive more organizations to secure accreditation and certification from national accreditation organizations.

HRA Plus certification would ensure valid and reliable instruments and follow-up materials administered in a patient-appropriate manner are employed as part of the AMV. Certification of tools and processes by independent third parties, such as NCQA and URAC, would increase the likelihood that only evidence-based practices are applied. The federally qualified certifying organizations would review and recognize HRA tools and methods on a regular basis and update standards as new materials and processes are introduced through innovation. Results of accreditation assessments would need to be made public so providers can make choices related to potential partnerships with health promotion vendors.

Caveats related to certification include the following: it is costly and time consuming; requirements for certification may hinder continued development, innovation, and customization of HRA tools and processes; providers may view certification as further external intrusion into their practice of medicine by imposing another "unfunded mandate" by CMS. On the other hand, if the responsibility for certifying tools and processes is placed on instrument developers and health promotion vendors, then the burden is transferred over to a third party rather than to the practitioner.

Guidance

A CDC/CMS appointed advisory group should be formed to support HRA Plus evolution. This advisory group should provide preliminary certification of the HRA Plus process, within the broad guidelines set forth in this document, and then fine-tune standards for HRA Plus processes over time as experience accrues. After this initial phase of 1–2 years, a more formal certification process should be created to recognize HRA Plus tools and materials that are valid, evidence-based, and contain a standard set of core measures, but allow flexibility to tailor these to specific populations and evolving technologies. Throughout this process, a list of the certification guidelines should be made publicly available along with a transparent methodology for scoring the comparative effectiveness and customer satisfaction for certified HRA Plus tools and processes.

The following guidance principles are proposed for certification of HRA Plus materials and processes:



- Provision of an HRA and feedback report to patients through multimodal delivery methods such as web, paper, mobile, IVR.
- Inclusion of a set of "standard" questions, as recommended in this guidance document.
- Capability to share output and data with EMR, PHR, and other types of electronic patient records.
- Provision of an individualized, tailored personal prevention plan specifically addressing the unique needs of the Medicare beneficiary.
- Provision to practitioners of a tailored summary of individual wellness risk factors and recommendations for reducing those risks along with references and resources,
- Tailored immunization and preventive screening recommendations to match national • guidelines and individual variables such as age, gender, ethnicity, and personal health history.
- Ability to add additional items and configure custom questions developed specifically for the needs of Medicare beneficiaries for data gathering, and identified research purposes.
- Ability to track and report longitudinal data, providing individuals with an annual • comparison or benchmark data from previous HRA administrations.
- Ability to refer beneficiaries to local or national resources by offering recipients additional programs and services to assist with lifestyle behavior change, behavioral health, and medical condition self-management.
- Documentation of the validity and reliability of the HRA and the evidence-base for follow-up materials.
- Compliance with 508 rules related to providing materials for visually impaired individuals.
- Compliance with data security and participant informed consent and disclosure provisions.
- Ability to verify completion of the HRA Plus process for reimbursement.
- Capacity to revise HRA program information, recommendations, and guidelines as new evidence emerges.

It is advised that the certification process first seek to endorse HRAs that are in the public domain, similar to the approach used in certifying Consumer Assessment of Healthcare Providers and Systems (CAHPS) patient surveys (45). This will ensure that cost is not a barrier to HRA adoption or a burden to physicians and health plans. The implementation and certification process should be straightforward and easily navigable. Certification information should be made readily available on the CMS website and "scored" by awarding one, two, or three stars based upon a set of criteria. Certification tools and processes should allow for innovation. For a physician to submit a reimbursement claim



to Medicare, the HRA Plus process should be certified by one of several approved independent certification entities, to be determined by CMS.

EVALUATION AND QUALITY ASSURANCE

The question addressed here is:

• *How should the HRA Guidance be evaluated and updated with respect to individual and population-level (practice-based panel management) health outcomes?*

Background

There are two parts relevant to this issue: 1) the need to update guidance principles on an ongoing basis so that they align with emerging science related to health promotion and disease prevention, and 2) the need to evaluate the AMV and HRA Plus programs at key milestones to determine whether they are working effectively or need to be fine-tuned.

In terms of updating the guidance document and the principles contained therein, it is important that such updates be focused on the entire health improvement process (HRA Plus) and not just its individual parts (i.e., the HRA itself). Because HRAs and follow-up materials on the market are currently nonstandard and generally proprietary, it is necessary that their elements and the evaluation criteria used to examine their efficacy be reviewed an updated frequently (every 1–2 years). Specifically, the validity and reliability of HRA instruments needs to be assessed regularly and current information on their psychometric properties needs to be available to physicians wishing to use these tools, with comparisons made to other widely used and valid measures such as the Medicare Health Outcome Survey (*46*).

Guidance

CDC and CMS should form an advisory group made up of representatives from their respective agencies, academia, medical practitioner, consumer, and other stakeholder groups that would be responsible for ongoing review of the HRA Plus process. This group, modeled after the USPSTF and the Task Force on Community Preventive Services, would update standards and guidelines drawing from resources resident in governmental agencies and professional associations, including, but not limited to, the following: U.S. Preventive Services Task Force; The Community Guide to Preventive Services; Office of the U.S. Surgeon General; National Heart, Lung, and Blood Institute; National Institute of Mental Health; Healthy People 2020, Institute of Medicine (IOM), and relevant professional associations including the American Medical Association and American College of Preventive Medicine.

In addition, the WMV and HRA Plus process should be evaluated periodically on key structure, process, and outcome measures. Structure and process measures would focus on the ease of adoption of alternative program design elements, health- and cost-effectiveness of these delivery models, HRA Plus participation and engagement rates,



patient and provider satisfaction, sustainability for use in primary care, and adherence to current and emerging best practices of health promotion implementation practices in clinical settings. Outcome measures should primarily focus on reduction of risk factors and behavior change across patient populations, improving the quality and value of primary care services, and the impact these have on health care utilization and cost.

The evaluation process should be delegated to an objective third-party organization. Questions addressed by these evaluations should include 1) Are physicians and patients become engaged in the process on a large scale? 2) Has the process improved health and reduced health risks? 3) Has utilization of preventive services increased? 4) Have beneficiaries' self-assessments of health improved? 5) Have patients changed their health habits for the better? and 6) Have patients' quality of life and overall functioning improved? Data gathered from these evaluations will guide development, refinement, and targeting of additional intervention aimed at individuals and populations.

Clinician and patient progress should be tracked annually. It is important to provide feedback to clinicians on the extent to which they are providing a worthwhile service (participation statistics), whether their patients are improving (behavior change and risk reduction outcomes), the overall value of interventions, and the impact of their efforts on utilization and costs. Ideally, data on these measures would be aggregated so that physician peer-to-peer comparisons can be made and communitywide progress on key health metrics can be tracked.

There is also "real world" research needed on the operational aspects of the HRA Plus process that explores, for example, how to achieve high participation and engagement rates; the features and characteristics on the most effective feedback reports; how to best use of color, font size, on feedback reports; the extent to which web links are accessed; whether written, person-to-person, telephonic or Internet communication is most effective; optimal ways to access follow-up resources; and whether using physician extenders through community health teams, or external vendors, positively influence patients' health cost-effectively.

In these evaluations, it is important to garner data from valid and reliable HRA tools that use standard data elements so that comparable data can be analyzed over time and across populations. This information can also be repackaged to provide feedback to healthcare providers on key participation and performance outcomes.

It is likely that HRA Plus programs are more relevant to certain subpopulations than others. For example, individuals more prone to having chronic diseases (given, for example, demographic factors), but who have no documented history of chronic illness, may be priority candidates for health improvement programs. CMS may therefore consider a triage process that focuses the deployment of HRA Plus programs on these sub-populations who may benefit the most from the program.

As local and third-party evaluations and quality improvement results become available, smaller practices should be encouraged, through CME or certification, to adopt lessons learned from these studies and introduce relevant changes in their HRA Plus processes.



CONCLUSIONS

Medicare's adoption of an AWV as part of the ACA is a positive development and will likely increase delivery of health promotion and disease prevention services in a primary care setting. The AWV should be based on sound principles that form the foundation of the HRA Plus process. CMS requirements for the AWV can and should be incorporated into the administration of the HRA and provision of a feedback report and personal prevention plan. Further, clinical and behavioral interventions promoting good health can flow naturally from this annual patient-physician encounter. It is important to keep this process straightforward, easily implementable and meaningful to practitioners and patients and not overly complicated or burdensome

It is important to note that just administering an HRA to patients, and providing them with a feedback report, will likely have little beneficial effect on key outcomes. As has been shown in workplace settings, follow-up support is necessary to achieve long-term behavior change and adoption of new health habits. Thus, the AMV needs to be viewed as the starting point for a health improvement program that is reinforced by other health care interventions made available through physician practices, community resources, and specialized vendors.

Factors that will drive wide adoption of the HRA Plus process include its integration with the AWV, its directness of purpose to providers and patients, simplicity of use, its cost, and its ability to be minimally disruptive of normal patient flow. HRA Plus components need to be phased in over time, with increased reimbursement and payment incentives coupled with a more comprehensive and impactful delivery system. For example, an aspiration for the program would be to seamlessly link laboratory, PHR/EMR, and HRA data so that a complete medical record is available to the physician and other health professional staff treating a patient. This type of sophisticated data linkage in the early stages of this program is not yet achievable for most practices, and patient self-report of biometric measures may be "good enough," at least as a starting point. To make the program workable in its early stages, a variety of HRA Plus resources need to be applied, and the testing of alternative models needs to occur. Having said that, certain minimum acceptable levels of quality need to be established to avoid providing useless or harmful materials as part of the AMV and HRA Plus process.

Finally, for the AMV to be successful, it is important that it, along with the HRA Plus process, not be viewed as a "waste of time." It should be demonstrably different from a typical patient-physician encounter where only clinical data are discussed. Further, the process should not be focused on patients hearing about their "bad habits" but rather on "what matters" to them and what they can do about it. This is not a trivial task. To convince patients to alter their lifestyles, behavior change theory needs to be applied by trained wellness professionals. Additionally, the health and financial implications of this legislation to the physician, patient, and healthcare system need to be at the forefront of this initiative. An important question yet to be addressed is how will improvements in the health of beneficiaries lead to improved quality of care and efficient use of scarce healthcare dollars. Hopefully, the implementation of the AWV with the HRA Plus



component will help answer this question by demonstrating better care at a better value.

With the passage of the Affordable Care Act, we are now at a transformative time for health and healthcare in our country. Emphasizing health promotion and disease prevention in the Medicare population is important for this transformation to succeed. The new AWV, incorporating principles of HRA Plus, and appropriately implemented, holds great promise for improving the health and well-being of the Medicare population.



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APPENDICES

APPENDIX A. PROPOSED EXAMPLES OF STANDARD QUESTIONS FOR INCLUSION IN A HEALTH RISK ASSESSMENT (HRA) AS PART OF THE ANNUAL WELLNESS VISIT

(Note: The validity and reliability, and the age and cultural appropriateness of the following items need to be determined before they are adopted widely.)

BEHAVIORAL RISK FACTORS

PHYSICAL INACTIVITY/LACK OF EXERCISE

How many days a week do you usually exercise?

_____ days per week

On days when you exercise, for how long do you usually exercise (in minutes):

_____ minutes per day

• Does not apply

How intense is your typical exercise?

- Light (like stretching or slow walking)
- Moderate (like brisk walking)
- Heavy (like jogging or swimming)
- Very heavy (like fast running or stair climbing)
- I am currently not exercising



SMOKING/TOBACCO USE

Do you currently smoke cigarettes or use other types of tobacco?

- Yes
- No

Are you a former smoker?

- Yes, and I quit
- No, I've never smoked
- Does not apply

If you quit smoking, how long ago did you quit smoking cigarettes?

- Less than 6 months ago
- 6–11 months ago
- 1–5 years ago
- 6–10 years ago
- More than 10 years ago
- Does not apply

Indicate below if you currently use any of these other tobacco products:

- Cigars
- Pipes
- Chewing tobacco/snuff
- I use no other tobacco products



ALCOHOL USE

In a typical week, how many days do you drink alcohol?

_____ days per week

On days when you drink alcohol, how many alcoholic drinks do you consume?

drinks per day

In a typical week, how often do you have 5 or more alcoholic drinks on one occasion?

- Never
- Once a week
- 2–3 times per week
- More than 3 times per week

NUTRITION

On a typical day, how many servings of fruits and/or vegetables do you eat? (1 serving = 1 cup of fresh vegetables, $\frac{1}{2}$ cup of cooked vegetables, or 1 medium piece of fruit. 1 cup = size of a baseball.)

_____ servings per day

On a typical day, how many servings of high fiber or whole grain foods do you eat? (1 serving = 1 slice of 100% whole wheat bread, 1 cup of whole-grain or high-fiber ready-to-eat cereal, $\frac{1}{2}$ cup of cooked cereal such as oatmeal, or $\frac{1}{2}$ cup of cooked brown rice or whole wheat pasta.)

_____ servings per day

On a typical day, how many servings of fried or high-fat foods do you eat? (Examples include fried chicken, fried fish, bacon, French fries, potato chips, corn chips, doughnuts, creamy salad dressings, and foods made with whole milk, cream, cheese, or mayonnaise.)

_ servings per day

MOTOR VEHICLE SAFETY

Do you always fasten your seat belt when you are in the car?

- Yes
- No

Do you ever drive after drinking, or ride with a driver who has been drinking?

- Yes
- No



SUN EXPOSURE

Do you protect yourself from the sun when you are outdoors?

- Yes
- No

BIOMETRIC MEASURES—SELF-REPORTED

(To be completed by the patient only when the HRA is not prepopulated using laboratory, EMR/PHR, or other medical practice source data.)

BLOOD PRESSURE

If your blood pressure was checked within the past year, what was it when it was last checked?

- Low or normal (at or below 120/80)
- Borderline high (120/80 to 139/89)
- High (140/90 or higher)
- Don't know/not sure
- Does not apply

CHOLESTEROL

If your cholesterol was checked within the past year, what was your total cholesterol when it was last checked?

- Desirable (Below 200)
- Borderline high (200-239)
- High (240 or higher)
- Don't know/not sure
- Does not apply



BLOOD GLUCOSE

If your glucose was checked within the past year, what was your fasting blood glucose (blood sugar) level the last time it was checked?

- Desirable (Below 100)
- Borderline high (100–125)
- High (126 or higher)
- Don't know/not sure
- Does not apply

Have you ever been told by a doctor or a health professional that you have diabetes or high blood sugar?

- Yes
- No (skip to next section)

If you have had your hemoglobin A-1C level checked within the past year, what was it the last time you had it checked?

- Desirable (6 or lower)
- Borderline high (7)
- High (8 or higher)
- Don't know/not sure
- Does not apply

OVERWEIGHT/OBESITY

What is your height? (for example, 5 Feet 06 Inches = 5'6'')

Feet _____ Inches _____

What is your weight?

Weight in pounds _____



PSYCHOSOCIAL RISK FACTORS

DEPRESSION

Over the past 2 weeks, how often have you felt down, depressed, or hopeless?

- Almost all of the time
- Most of the time
- Some of the time
- Almost never

Over the past 2 weeks, how often have you felt little interest or pleasure in doing things?

- Almost all of the time
- Most of the time
- Some of the time
- Almost never

Have your feelings caused you distress or interfered with your ability to interact socially with friends?

- Yes
- No

During the past 6 months, how often have you felt sad or depressed?

- Almost all of the time
- Most of the time
- Some of the time
- Almost never

In general, how satisfied are you with your life?

- Very satisfied
- Satisfied
- Dissatisfied



• Very dissatisfied

HIGH STRESS

How often is stress a problem for you?

- Never/rarely
- Sometimes
- Often
- Always

How well do you handle the stress in your life?

- I'm usually able to cope effectively
- At times I have problems coping
- I often have problems coping

GENERAL WELL-BEING

In general, would you say your health is

- Excellent
- Very good
- Good
- Fair
- Poor

SOCIAL/EMOTIONAL SUPPORT

How often do you get the social and emotional support you need:

- Always
- Usually
- Sometimes
- Rarely
- Never



GENERAL LIFE SATISFACTION

In general, how satisfied are you with your life:

- Very satisfied
- Satisfied
- Dissatisfied
- Very dissatisfied

SLEEP

_____ How many hours of sleep do you usually get each night?

CHEMOPROPHYLAXIS

DAILY ASPIRIN USE

Have you discussed taking a daily aspirin with your doctor?

- Yes
- No



APPENDIX B. LIST OF EXPERT WORK GROUP MEMBERS AND PUBLIC FORUM PANELISTS

(Note: Persons listed in *italics* are expert work group members; persons listed in **bold** are public forum panelists)

David Anderson, PhD, LP, Senior Vice President and Chief Health Officer, StayWell Health Management

Larry S. Chapman, MPH, President and CEO, Chapman Institute

Basit Chaudhry, MD, PhD, Senior Researcher, Clinical Transformation, Healthcare Analytics, IBM Research

Amy Compton-Phillips MD, Associate Executive Director, Quality, The Permanente Federation (Kaiser Permanente)

Dee Edington, PhD, Professor of Movement Science, School of Kinesiology, University of Michigan

Seth Foldy, MD, MPH, Director, Public Health Informatics and Technology Program Office, Centers for Disease Control and Prevention

James Fries, MD, Professor Emeritus, Medicine - Immunology & Rheumatology, Stanford University School of Medicine

David C. Grossman, MD, MPH, Group Health Pediatrician and Medical Director of Preventive Care, Group Health Cooperative

Don Hall, DrPH, CHES, Founder and Chief Development Architect, Wellsource, Inc.

David C. Kibbe, MD, MBA, Principal, The Kibbe Group LLC and Senior Advisor, Center for Health Information Technology, American Academy of Family Physicians

Alex Krist, MD, MPH, Fairfax Family Medicine Residency Faculty, Department of Family Medicine, Virginia Commonwealth University

Ron Loeppke, MD, MPH, Vice-Chairman, U.S. Preventive Medicine

Ronald J. Ozminkowski, PhD, Vice President, Healthcare Information and Innovation, Ingenix (UnitedHealth)

Nico Pronk, PhD, FACSM, Senior Investigator, HealthPartners Research Foundation and Vice President for Health Management and Health Science Officer for JourneyWell



Page **43** of **44**

Cary Sennett, MD, PhD, Fellow, Economic Studies and Managing Director for Health Care Finance Reform, Engelberg Center for Health Care Reform, Brookings Institution (participated in former position as Chief Medical Officer, MedAssurant Inc.)

Brenna Haviland Shebel, CHES, Assistant Director, Institute on Health Care Costs and Solutions, National Business Group on Health

Alan P. Spielman, MBA, President and CEO, URAC

Victor J. Strecher, PhD, Professor, Health Behavior & Health Education; Director, Health Media Research Laboratory; Director, Cancer Prevention and Control, University of Michigan School of Public Health; and Chairman & Founder of HealthMedia, Inc.

Jennifer K. Taylor, PhD, Director, Team Leader, Clinical Operations & Evaluation, Corporate & Government Customers, Pfizer Inc

Sarah Thomas, MS, Vice President, Public Policy and Communications, National Committee for Quality Assurance

John H. Wasson, MD, Professor of Community and Family Medicine and Herman O. West Professor of Geriatrics, Department of Community and Family Medicine, Dartmouth Medical School

Dennis White MS, MBA, Senior Vice President of Value-Based Purchasing, National Business Coalition on Health

Eric Zimmerman, MPH, MBA, Chief Marketing Officer, Redbrick Health

