

Ethics Guidelines for the Development and Use of Health Assessments

The Society of Prospective Medicine Board of Directors

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Introduction

Dedicated to advancing the development, utilization, and evaluation of prospective medicine strategies, the Society of Prospective Medicine (SPM) advocates the following ethics guidelines to assist developers and administrators of a wide variety of health assessments (HAs) in making appropriate decisions in the construction and use of HA instruments. Health assessments include instruments known as health risk appraisals or health risk assessments (HRAs), health status assessments (HSAs), various lifestyle-specific (e.g., nutrition, stress, and physical activity) assessment instruments, wellness, and behavioral/habit inventories. In the last 40 years, health assessment technology has proliferated and diversified. Today, health assessment tools are an essential component in the planning and delivery of health care and promotion programs in health care, business, industrial, and educational settings.

Although the purpose of health assessment instruments may differ, the ethical considerations for their use are remarkably similar. The Society of Prospective Medicine establishes these *General Ethics Guidelines* to both minimize the potential harm from misuse and to enhance the potential benefits of health assessments:

- maintenance or improvement of personal health and quality of life, and
- ability to establish disease and health risk tracking for improved care.

General Ethics Guidelines

The following seven guidelines defined by SPM help to protect the rights and safety of individual participants and to facilitate the appropriate use of health assessment instruments by both individuals and organizations.

1. Health Assessment Program Planning

Each HA program should have a well defined, written statement detailing the goals, objectives, methodology, and requirements for participation.

2. Health Assessment Instrument Selection

Several factors should be examined when selecting an HA instrument, e.g., appropriateness for the target population, credibility of the scientific basis and/or database(s) underlying its construction, and cultural and ethnic sensitivity. Other key factors include the ease of use, the types of data analyses performed, and the clarity and intelligibility of reports generated.

3. Health Assessment Participant Orientation

Individual participants should receive an orientation, either written or oral, before completing an HA. This orientation describes the purpose of the assessment, the science base of or approach underlying the instrument, the time commitment for completion, who has access to the results, the information to be reported, and the use of the results.

4. Health Assessment Administration

Individual participants should be free to accept or decline any HA without fear of consequences.

5. Health Assessment Data Security

The data and report from HAs are private and should not be shared with others unless expressly permitted by the individual participant. Administrators of HAs are responsible for protecting individual data or results from unauthorized access and must respect the wishes of the individual participant. The information obtained from the HA should not be used to discriminate on the basis of job eligibility or insurability or render harm in any manner.

6. Health Assessment Report Interpretation

If the assessment generates individual reports, as with HRAs, individuals should receive a report that is easily understood. The reporting should be accompanied by an explanation of the implications of the results for the individual's health and well being. If possible, a competent health educator or provider should be available to explain the report and answer questions.

7. Health Promotion Resource Accessibility

When individuals receive personal reports as a result of the assessment process, a list should be made available to them of local and national resources that ameliorate risk factors or other problems identified. When individual reports are not returned to participants, general resource information appropriate

to the characteristics of that group should be made available to the participants.

Guidelines for Developers and Administrators

These specific recommendations to developers of health assessment (HA) instruments or administrators of HA programs are provided to encourage integrity and standards of excellence in the creation and use of HA technologies. Chapters in the SPM Handbook of Health Assessment Tools also include suggestions and recommendations specific to those who develop and administer various HA technologies.

Recommendations for the Ethical Development of HAs

Instrument Development

SPM recommends that developers base the development and revision of their HA instruments on the latest scientific principles of contemporary test and/or survey construction, computer programming, and, if appropriate, electronic communication technology. Careful attention to accuracy, currency, and appropriateness of databases when used, supporting theory, and methodology for quantifying variables, as well as sufficient studies on reliability and validity are recommended. Effective HA instruments frequently include:

- Comprehensible, reasonable, and relevant recommendations for behavior change and risk reduction.
- Listings of health maintenance or behavior change services and resources when behavior change is an expected outcome.
- Summary reports in diverse formats, e.g., graphic, verbal, and quantitative for more effective communication.
- Instructions for computer use written to accommodate the lowest level of participant capability for use of computerized instruments.
- Support materials to assist with administration and interpretation of reports.

Support Materials

It is recommended that developers furnish comprehensive and regularly updated support materials, e.g., a published workbook or manual, to the purchasers of HA technology. Suggested

considerations, topics, and information to be included in these materials are:

Appropriateness of HA instrument for target audience

- Age, gender, race, and ethnicity
- Reading comprehension level and language
- Available options for individuals who are unable to take the HA in the usual way (e.g., visually impaired, unable to read)
- Estimated time to complete HA and to read the report

Scientific basis for the HA instrument

- A description of any databases used and the demographics of the data sources
- A description of methodology/approaches for quantifying risk factors or summary scales
- Descriptions of, or reference to, studies that document reliability, validity, and appropriateness of the instrument
- The timeliness of the research base, e.g., the date, version number, or relevant resources (if appropriate to that type of instrument)

Protection of the confidentiality of individual participants

- Encourage the protection of individual privacy.
- Encourage the storage of reports and data in ways that protect an individual's information from inappropriate exposure that can lead to harm of or discrimination against the individual.
- Encourage users to carefully limit access to participant data.
- Encourage the presentation of group reports in ways that successfully conceal the identity of individual participants.

Conditions for HA instrument administration and interpretation

- Combine HA administration with clinical screenings, e.g., blood pressure, cholesterol, height, and weight whenever possible and appropriate.
- Provide counseling or interpretation that explains the individual report, or which explains the results if an individual participant report is not generated.
- Provide interventions or local and national resource-referral for individuals who wish to follow-up on recommendations in their HA report.
- Avoid claims for intervention program efficacy unless the claims can be documented in a reliable and scientific way. Claims should address age, gender, and race as well as other possibly

significant variables that might affect intervention programs.

- Recommend that the participant seek medical care or consultation with a physician if serious health problems are suspected, based on the participant's results.
- Clearly state the level of competence or health-knowledge needed by individuals who are delivering orientations about an HA or who are providing counseling or interpretation related to the results.

Recommendations for the Ethical Use of HAs

Administrators or purchasers of HAs should consider four steps in their use. The following section describes useful information and ethical considerations within each of these four steps.

- Program Planning
- Instrument Selection
- Health Assessment Administration
- Data Use

Program Planning

Outline the program purpose or objectives, and the desired outcomes. Proposed outcomes vary based upon the type of event. Use proposed outcomes to plan required logistics and referral resources. For example:

- If HA use is designed to raise awareness and educate at a health fair, plan to provide educational materials and a skilled human resource(s) during the screening.
- If a health screening is part of a comprehensive program or health risk management initiative, additional planning and resources for clinical screening to obtain cholesterol, blood pressure, height and body weight data, as well as referral sources, interventions, etc., may be required. Consider the lead-time needed for the scheduling of clinical screening resources.
- If participant behavior change is an objective of the program, plan to arrange for suitable resources to be available at the time the participant receives the HA report. Local resources and/or information including physician referral should be available for participants seeking assistance with health problems or behavior change.
- Create and make available to all potential participants a written statement of program goals, objectives, methodology, and requirements for participation.

- If the HA will be re-administered at regular intervals, prepare a timeline for subsequent measurements.
- Date stamp historical data if being saved as part of ongoing monitoring, research, or evaluation.
- Identify delivery modes (on-site paper and pencil, computerized, etc.), and determine logistics. Order materials and equipment as needed, and schedule time and space for actual administration of instrument.
- Whenever possible, schedule an orientation for potential participants to the HA process, in advance of commitment to actual participation. A formal orientation should address the individual's rights to participate or not participate, risks, benefits, tasks, purpose of testing, as well as restrictions on access to the individual's results and how results may be used. Orientation to an HA at a health fair should also be preceded by a brief description of the test source, objective, type of report, and how data will be used. A written description should be available to the participant.
- Schedule training and development for personnel involved in HA administration and interpretation.
- Make best effort to ensure that HA administrators, who are on hand to orient the user or interpret the results, possess sufficient health education experience, education, and/or training to understand typical participant questions and answer them appropriately. Having at least one administrator present who has a fundamental knowledge in epidemiology, pathophysiology, and/or psychometrics is helpful.
- Understand the administration process of the selected HA. At least one administrator who is present at the assessment should have the ability to provide accurate, objective interpretation of results. Ideally, staff should have the ability to explain relationships between risk factors, health status, and health.
- Understand the specifics of any behavior changes that may be recommended to reduce identified risk factors, and how those changes may be maintained
- Make no claims for intervention program efficacy unless the claims can be documented in a reliable and scientific way. Claims should address age, gender, and race, as well as other possibly significant variables that might affect intervention programs.

- Encourage individuals to take an active role in improving or maintaining their current health status.
- Determine how to identify high-risk participants with potentially serious risk factors, how to make referral to a physician or other health care provider, and how to schedule for counseling and/or other support services. Where the administration site is a clinic or medical office, appropriate provisions for follow-up should still be made.

Health Assessment Instrument Selection

In selecting an HA for use with a population, consider the following factors:

- Evidence of a scientific base for HA instrument including published manual or materials describing scientific foundation of this health assessment methodology. The supporting materials should include a thorough description of any databases used, methodology/approach for quantifying risk factors, and any studies regarding reliability, validity, and appropriateness of the instruments.
- Timeliness of risk algorithms, if included.
- Appropriateness of HA instrument for target population, including age, gender, and reading comprehension level.
- Cultural and ethnic sensitivity in the HA questions and report language.
- Inclusion in HA reports of a directive to seek medical care or consultation with a physician if a serious health problem is detected. If individual reports are not generated, provision for alerting and referring individuals with serious problems to appropriate resources.
- Ease and effectiveness of use including:
 - ▶ Availability of support materials to assist with administration and interpretation of reports
 - ▶ Availability of diverse feedback formats, e.g., graphic, quantitative, and qualitative for more effective communication
 - ▶ Recommendations for conditions under which the particular instrument should be administered and interpreted to avoid possible misuse
 - ▶ “User friendly” input format and understandable report (if computerized)
- Provision of (by program vendors who analyze the data):

- ▶ Assurance of the confidentiality of individual reports and description of who has access to what information under what conditions
- ▶ Description of the process by which information is collected, analyzed, reported, and utilized
- ▶ Description of the normative data upon which results are based
- ▶ Documentation as to the level of competence in the administration, scoring, and interpretation of the data
- ▶ Clear and complete description of the costs of their services

Health Assessment Administration

HA administrators have the following ethical obligations:

- To clearly communicate that the individual participant is free to refuse participation without fear of consequences. An HA cannot be used as a pre-employment or pre-insurance "predictive screening" instrument for the purpose of denial of employment or employment with limiting conditions; nor can it be used as an instrument for screening for continued employment or continued insurance. Such use is in conflict with the *Americans with Disabilities Act*, which prohibits employment discrimination on the basis of disability.
- To respect individual rights and personal dignity of participants regardless of race, ethnic background, gender, age, disability, religion, sexual orientation, etc.
- To clearly communicate that the HA is not a substitute for a medical examination, and is not in itself a diagnostic tool.
- To take extraordinary measures to ensure security of personal information. Information must be stored in ways that protect an individual's data from casual, inappropriate exposure. Methods should guarantee that individual confidentiality is protected and that HA data are not available to those who might bring harm to the individual.
- To combine administration of HAs with clinical screenings whenever appropriate. Make local resources and/or information available for referral of participants seeking assistance with health problems or behavior change.
- If incentives are offered to participants, to ensure that those incentives are only to motivate

participation in the assessment or in a follow-up program or intervention, not for actual medical results.¹

Data Use

Since privacy of medical data is not legally guaranteed at this time, HA administrators need to take steps to ensure, as much as possible, that individual scores on HA instruments are safeguarded. SPM recommends that:

- Data be protected at all times to ensure that it is not available to those who might harm or discriminate against the HA participant.
- Group reports successfully conceal the identity of individual participants. (Carefully consider the appropriateness of creating a group report of less than 25-50 participants unless these results are normed against national statistics and the report clearly states that the small group size makes any comparisons suspect. Additionally, this data should be used carefully since individuals within a small population can be more easily identified.)
- Before participating, the individual should clearly understand the purpose of the health assessment and who will have access to his/her information. This principle is supported when:
 - ▶ the administrator provides the participant with a clearly visible, easy-to-understand disclosure statement; or
 - ▶ the participant signs an easy-to-understand, advised consent form.
- The participant should always know that s/he is free to decline the health assessment.

Quick Tips for the First Time User

- Plan your event or program, including the process.
- Be sure of the details.
- Select the appropriate instrument.
- Use qualified HA administrators.
- Have resources available for those participants determined to be at need.
- Protect the data.

For additional resources, visit the SPM Website at <http://www.spm.org>.

Deciding Between "Do-It-Yourself" and Hiring a Provider

Do you have the experience and the resources to:

- Select an HA?
- Plan the event or program?

- Administer the event or program, obtaining and reporting accurate information with a high response rate at a reasonable cost?
- Handle the logistics, and arrange for the resources?
- Counsel/communicate with the participants?
- Manage the data?

If not, consider using a provider who can offer planning and implementation services.

The Society of Prospective Medicine invites your written comments regarding the usefulness and appropriateness of these General Ethics Guidelines and Recommendations.

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Footnotes:

¹ *This recommendation may seem at odds with the normal and typical procedures of many health promotion professionals of the last 20 years. However, under the Health Insurance Portability and Accountability Act of 1996 (HIPAA), discounts and rebates (as in benefits linkages, incentives, and disincentives) "...can be established in return for adherence to programs of health promotion and disease prevention ("bona fide wellness programs"), but they cannot be conditioned on actual medical results; this would constitute discrimination." So, participants can be rewarded (receive an incentive) for participating in an HA and smoking cessation program but cannot be rewarded for a particular outcome, (i.e., quitting smoking).*