Abstract: The focus of the PhenX (Phenotypes and eXposures) Toolkit is to provide researchers whose expertise lies outside a particular area with key measures identified by experts for uniform use in large-scale genetic studies and other extensive epidemiologic efforts going forward. The current paper specifically addresses the PhenX Toolkit research domain of physical activity and physical fitness (PA/PF), which are often associated with health outcomes. A Working Group (WG) of content experts completed a 6-month consensus process in which they identified a set of 14 high-priority, low-burden, and scientifically supported measures. During this process, the WG considered self-reported and objective measures that included the latest technology (e.g., accelerometers, pedometers, and heart-rate monitors). They also sought the input of measurement experts and other members of the research community during their deliberations. A majority of the measures include protocols for children (or adolescents), adults, and older adults or are applicable to all ages.

Measures from the PA/PF domain and 20 other domains are publicly available and found at the PhenX Toolkit website, www.phenxtoolkit.org. The use of common measures and protocols across large studies enhances the capacity to combine or compare data across studies, benefiting both PA/PF experts and non-experts. Use of these common measures by the research community should increase statistical power and enhance the ability to answer scientific questions that previously might have gone unanswered.

Introduction

During the past 60 years, data have continued to accumulate, demonstrating numerous health benefits of a physically active lifestyle throughout the life span and the health advantages of being physically fit.1–3 Further, PA/PF increasingly are being recognized as important exposure variables when evaluating gene–environment interactions to determine risk for major chronic diseases. However, there is general agreement that most studies investigating the combined role of genetics and PA/PF on health and performance outcomes have been severely limited because of inadequate sample size.4–6 The ability of researchers to combine data across studies could increase the statistical power to associate phenotypic, environmental, and genetic data with disease outcomes, enhancing the opportunity to identify meaningful results that previously might have gone undetected. Also, standardized measurement methodologies facilitate replication of study findings and the comparison of data collected during studies of various population subsets.

A portfolio analysis of grants funded by the National Cancer Institute highlighted the need for guidance and resources for physical activity assessment. Grants funded between September 2004 and January 2009 that measured physical activity as an exposure, outcome, or covariate were reviewed for details about assessment method. The 87 grants identified were sorted by study design and use of physical activity measure (exposure, outcome, or covariate). These grants used 33 different self-report measures and at least six different accelerometer-based devices and pedometers.

In several cases, instruments that were not suited to the needs of the study design were used (Heather Bowles, PhD, National Cancer Institute, personal communication, 2010). For example, a surveillance instrument in-
tended to characterize the activity level of a population might be used inappropriately to assess change in activity in a clinical trial with physical activity as a primary outcome. This diversity of methods presents a serious challenge for contrasting or combining study data in a uniform manner. This paper describes the development and content of the PA/PF domain within the Phenotypes and eXposures (PhenX) Toolkit. PhenX is a source for standardized measures across a variety of content areas and is described in general before focusing on the details of the PA/PF domain.

Methods
The PhenX Toolkit

The PhenX Toolkit was developed as a source of high-priority, low-burden, and evidence-based measures for use by a wide variety of researchers. Although investigators are likely to be knowledgeable in selecting and implementing measures in their own content area, they quickly may become overwhelmed by the myriad of measures available in other fields. Further, once a measure is identified, the appropriate implementation of that measure also must be understood.

The PhenX Toolkit provides investigators with measures, background information, and use guidance that allow the inclusion of measures that could enhance their studies. The Toolkit provides standard measures related to complex diseases, traits, and environmental exposures. Use of PhenX measures not only may facilitate combining results from different studies but also could enable secondary analyses to expand studies beyond their primary research focus. The Toolkit can be accessed by a researcher who is planning a new study or looking to add measures to an ongoing study, with particular emphasis on those researchers seeking to add measures outside of their primary research focus.

The PhenX Steering Committee identified 21 research domains—alcohol, tobacco and other substances; anthropometrics; cancer; cardiovascular; demographics; diabetes; environmental exposures; gastrointestinal; infectious disease and immunity; neurology; nutrition and dietary supplements; ocular; oral health; physical activity and physical fitness; psychiatric; psychosocial; reproductive health; respiratory; skin, bone, muscle, and joint; social environments; speech and hearing—and provided guidance to a Working Group (WG) of content experts in each domain during the measure selection process.

In the Toolkit, researchers can browse by domains or measures or search using keywords. The selected PhenX measures are saved in a cart from which the researcher can generate a report with information about the measures and protocols of interest. In addition, data collection worksheets can be generated for each measure to facilitate data collection. Data Element Dictionaries are available and Toolkit users also can use the Collections search strategy. Collections have been developed to facilitate identification of measures related to a specific topic. For example, under the heading of Risk Factors, Behavior and Attitudes, a Collection will contain a grouping for Health Promotion measures, including the exercise measures selected by the PA/PF WG. The Health Status Collection also includes measures of PA/PF in combination with measures from several other domains.

Available in the Toolkit are a glossary of terms, frequently asked questions, a basic guide document, links to supplemental information about the other measures considered by the WGs, and additional resources. Toolkit users can provide direct feedback to the Toolkit project team through a link on the website.

The Physical Activity and Physical Fitness PhenX Domain

As is true in any research endeavor, instruments are designed to assess particular measures in a specific context. It is important to note that for complex domains such as PA/PF, it is especially important to match the assessment tool to the study objectives and population. A questionnaire designed to assess population levels of physical activity is not likely to do well at measuring change in activity level for an individual. The PhenX PA/PF WG provided measures and protocols for clearly delineated content areas and subpopulations.

The PhenX PA/PF Domain was designed to meet the needs of researchers interested in measures of PA/PF as outcomes, predictors, or covariates. The Federal Advisory Committee for the 2008 Physical Activity Guidelines noted that its attempts to synthesize the evidence relating physical activity to health outcomes were hampered by the variety of questionnaires used to assess physical activity and different approaches to data analysis and presentation.

Working Group Process

The PA/PF WG followed a predefined 6- to 8-month consensus process to come to agreement on a set of high-priority, low-burden, and evidence-based measures, with a measure defined broadly as a standardized way of capturing data on certain characteristics of a study subject. Measures include exposures, clinical assessments, and quantitative or qualitative traits. PA/PF WG members were selected on the basis of their experience in the development, evaluation, and use of PA/PF measures in studies investigating the health benefits and risks of physical activity, sedentary behavior, and physical fitness in youth (aged 5–17 years); adults (aged 18–65 years); and older adults (aged >65 years) across various races and ethnicities. The WG consisted of two co-chairs, four content experts, a steering committee liaison, and a WG manager. PhenX also has liaisons appointed from many of the NIH institutes and centers who are invited to participate in any of the relevant WGs’ deliberations and meetings. In addition, the WG members consulted with numerous domain experts regarding the availability and selection of specific protocols.

With initial guidance from the PhenX steering committee regarding potential areas of inclusion to be considered, WG members completed their review and recommendations of measures and protocols for the Toolkit between September 2009 and February 2010. The initial list of possible measures underwent substantial discussion and revision over a period of approximately 4 months. These discussions took place during several conference calls and one in-person meeting involving WG members, steering committee members, NIH liaisons, National Human Genome Research Institute (NHGRI) staff, and PhenX staff. Further discussions took place via e-mail and on a web portal, providing a secure space for WG member interaction.
After defining the general scope of the PA/PF domains, a listing of possible measures was developed and discussed. From this broad list of measures, a target of no more than 25 measures with associated protocols was set for review by the PhenX steering committee and eventually submitted to the scientific community for their review and comment. The PA/PF WG was limited to selecting no more than 15 measures.

**Desired Measure and Protocol Characteristics**

It was a requirement of the PhenX steering committee that a majority of protocols needed to have low subject and investigator burden and implementation costs consistent with data collection in large population studies. No more than two measures were to be considered high burden. The goal was to select high-quality and well-established protocols recommended by domain experts. Also, the protocols needed to have utility for investigators who are not PA/PF domain experts and to be relevant for at least the next few years.

During the initial WG deliberations, extended discussions were held regarding which PA/PF measures should be included in the Toolkit. Priority was given to measures demonstrated to be related to major health outcomes and for which well-established protocols could be identified. Protocols needed to be in the public domain or available at a low cost from the source and include implementation instructions published in sufficient detail so that replication was possible. Several measures were considered as desirable for the Toolkit, but existing protocols did not meet selection criteria, especially the need for broad validation, demonstrable utility, or reproducibility in the target population. As a result, the WG carefully examined the strengths and limitations of the protocols proposed for each measure, with particular emphasis on protocols such as lifetime physical activity for adults and older adults, and any PA/PF measure for young children (aged <6 years).

It was decided that both PA objective measurement protocols and self-report protocols be included. The WG agreed to refer to measures using devices such as accelerometers or heart rate monitors as “objective” because of the common use of this term in the PA/PF literature. The WG also agreed that "objective" does not automatically mean better than "subjective" self-report measures: the information obtained is simply different. Also, for some PA/PF measures, separate protocols would be included for youth, adults, and older adults.

Physical fitness measures selected by the WG included cardiopulmonary fitness (three protocols—laboratory, field, and nontest estimate); integrated fitness; muscle strength; and physical functioning (objective and subjective protocols). For physical activity measures, the WG selected total physical activity (three protocols—screener, comprehensive, objective); walking/ambulation (objective); and sitting/sedentary (self-report). Protocols also were included for measures of physical activity self-efficacy; neighborhood environments (as a determinant of physical activity behavior); and physical activity readiness (safety screening questionnaire). Measures and protocols were selected by the WG based on a consensus process.

Although the recommendations for PA/PF measures and protocols were made by the WG, from early in the process, outreach to and consensus gathering from numerous experts in the field took place. Individual WG members made contact primarily through e-mail with scientists who had substantial experience developing or implementing various protocols for evaluating a specific measure. In some cases, these scientists directed WG members to useful documents, especially regarding the nature of protocol reliability and specifics of protocol implementation.

Near the end of the process, PhenX staff posted 14 measures on the Internet via the PhenX Toolkit for review and comment by the scientific community. Each PhenX domain used this outreach process to obtain feedback from domain experts. In addition to general notices being sent to the scientific community, e-mails were sent to individuals and groups identified by the WG members who would provide the most useful feedback on the measures.

Researchers had 2 weeks to respond with their thoughts on the value of the measures and if they should be included in a core set of genomewide association measures that could be used by researchers in genetic and epidemiologic research fields. WG members also contacted their colleagues from other institutions and organizations for suggestions and received helpful feedback from a total of 34 researchers. The WG members reviewed and carefully considered this feedback as they chose the final set of measures and protocols.

**Results**

The WG identified 14 measures (Table 1) that can be classified as metrics of PA/PF, mediators or moderators of activity, and a precursor to fitness assessment. Under metrics of physical activity, measures selected were a short physical activity screener, a comprehensive reported measure, and a comprehensive objective measure, as well as an objective measure of walking and a reported measure of sitting. Metrics of fitness included performance-based measures of integrated fitness (endurance, strength, and flexibility); cardiorespiratory fitness; muscle strength; and physical functioning ability; as well as a non-exercise test of cardiorespiratory fitness. Selected mediator and moderator measures were physical activity self-efficacy, physical activity neighborhood environment, and a subjective measure of functional limitations. The WG also selected a measure of physical activity readiness that is recommended for use prior to physical fitness assessments in adults and older adults.

Table 1 contains a listing of 14 different measures with a total of 21 protocols in order to meet the measurement needs of youth, adults, and older adults. A brief description is provided for each measurement protocol, and references are included that provide some development and evaluation information regarding the measurement protocol. Additional references to published articles and manuals of procedures for the protocols are provided under “Sources” for each measure in the online toolkit.

**Discussion**

In the process of selecting measures and protocols for the PA/PF domain in the PhenX Toolkit, a number of issues needed to be addressed. It quickly became apparent that...
for a number of well-established measurement tools used to assess PA/PF in published studies with a health orientation, data documenting validity, reliability, and sensitivity to change were limited or lacking. This was especially true when the goal was to evaluate the physical activity of individuals instead of groups.

Even for some of the measures included in the Toolkit, the protocols were validated in a limited number of population groups, with much of the data collected on non-Hispanic white subjects. Until additional protocol validation and reliability studies are conducted and published, investigators should always consider evaluating the reliability of a protocol when planning a study. Additionally, the nature of the populations, resources available to implement the protocol with particular emphasis on the resources necessary for protocol administration, data management, and statistical analysis and availability in the public domain or available at low cost should be considered.

Within the past decade, the development of objective measurements of body movement, especially the use of accelerometer-based sensors, has provided a

### Table 1. Physical activity and physical fitness measures for PhenX Toolkit

<table>
<thead>
<tr>
<th>Measure</th>
<th>Description of measurement protocol</th>
</tr>
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<tbody>
<tr>
<td>1. Cardiorespiratory Fitness—Submaximal Exercise Test Estimate</td>
<td>A submaximal exercise test used to estimate maximal oxygen uptake ($V_{O2\text{max}}$). The heart rate is measured during the test and is one of the variables required to complete the equation to estimate $V_{O2\text{max}}$.</td>
</tr>
<tr>
<td>(a) 1-Mile Walk</td>
<td>The participant is asked to complete a 1-mile walk test as quickly as possible on a track. Walk time and heart rate are used to estimate $V_{O2\text{max}}$.</td>
</tr>
<tr>
<td>(b) Treadmill Test</td>
<td>The participant is asked to walk on a treadmill at a 5% grade for 4 minutes. Heart rate is used to estimate $V_{O2\text{max}}$.</td>
</tr>
<tr>
<td>2. Cardiorespiratory Fitness—Non-Exercise Test Estimate</td>
<td>Cardiorespiratory fitness is estimated from a non-exercise test model that includes gender, age, BMI, resting heart rate, and self-reported physical activity.</td>
</tr>
<tr>
<td>3. Integrated Fitness</td>
<td>Multiple tests used to assess a person's general fitness.</td>
</tr>
<tr>
<td>(a) Child</td>
<td>Children’s fitness test includes the Progressive Aerobic Cardiovascular Endurance Run (PACER) test (similar to a shuttle run); curl-up; trunk lift; push-up (or modified push-up); and back-saver sit and reach.</td>
</tr>
<tr>
<td>(b) Adult</td>
<td>Adult fitness test includes half sit-ups (abdominal muscle strength); standard or modified push-ups (upper-body muscle strength); and sit and reach (flexibility).</td>
</tr>
<tr>
<td>(c) Older Adult</td>
<td>A battery of tests for older adults is completed with the assistance of an examiner.</td>
</tr>
<tr>
<td>4. Muscle Strength</td>
<td>Hand-grip strength is measured with a device called a dynamometer. The dynamometer is squeezed as forcefully as possible.</td>
</tr>
<tr>
<td>5. Physical Activity—Neighborhood Environment</td>
<td>Self-administered questions about the characteristics of the participant’s neighborhood that may influence opportunities to exercise (e.g., walk, run, bicycle).</td>
</tr>
<tr>
<td>6. Physical Activity Readiness</td>
<td>Self-administered physical and medical questions used to determine whether the person needs to visit a doctor or fitness expert prior to an increase in physical activity.</td>
</tr>
<tr>
<td>7. Physical Activity Self-Efficacy</td>
<td>Scales that include self-administered questions used to assess the person’s perceived ability to exercise on a regular basis.</td>
</tr>
<tr>
<td>(a) Adolescent</td>
<td>A scale that includes questions about situations in which respondents have free time and whether they perceive they could be physically active during those times.</td>
</tr>
<tr>
<td>(b) Adult</td>
<td>A scale that includes questions about the person’s perceived ability to overcome barriers that may impede participation in physical activity on a regular basis.</td>
</tr>
<tr>
<td>8. Physical Functioning—Objective</td>
<td>Brief performance tests used to evaluate a person’s balance, gait, strength, and endurance.</td>
</tr>
<tr>
<td>9. Physical Functioning—Subjective</td>
<td>The interviewer asks the participant (or proxy) a series of questions about the level of difficulty he or she has performing everyday activities.</td>
</tr>
</tbody>
</table>
whole new approach to physical activity assessment. The technology for data acquisition by these sensors continues to rapidly evolve, as do new analytic procedures for extending use of the data. The results of these advancements will substantially enhance current objective measures and protocols in the near future. For example, multicomponent machine-learning analysis of raw signals from multiple triaxial accelerometers will provide accurate determination of the type, intensity, and bout duration of the activity performed. Other advancements include the simultaneous monitoring of multiple wireless sensors, each providing information on different parameters, such as accelerometers (motion); inclinometers (position); altimeters (elevation); and GPSs (location).

Another recent development is the increasing number of scientists attempting to better understand the independent role that sedentary behavior, especially sitting, plays in chronic disease risk.30 Much of the data supporting a positive association between sedentary time and health risk initially came from questions directed at specific behaviors such as TV viewing. More recently, data have been acquired from questionnaires asking about amount of time sitting and accelerometer-based protocols used to detect low-intensity activities (lying, sitting, and standing). For the measure of sitting, the WG selected recently developed questionnaires for use in youth and adults.

It is very likely that tools for measuring sedentary behavior with greater validity and reliability will become available in the near future. New technologies also should facilitate the development of self-report (activity logging using mobile devices) and objective measurement (small, unobtrusive wireless sensors providing an array of physiologic or movement data) for the entire spectrum of physical activity including sedentary time. As new measures evolve, the best approach to assessing physical activity and sedentary behavior may be a combination of self-report and existing device-based objective measures, such as accelerometers or pedometers.

Other Physical Activity Measurement Resources for Use by Investigators

In addition to the PhenX Toolkit, several other resources for assisting investigators with their measurement of physical activity recently have been made available. In July 2009 an NIH-sponsored workshop titled “Assessment of Physical

Table 1. Physical activity and physical fitness measures for PhenX Toolkit (continued)

<table>
<thead>
<tr>
<th>Measure</th>
<th>Description of measurement protocol</th>
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<tbody>
<tr>
<td>10. Sitting/Sedentary Behavior</td>
<td>A self-report estimate of how many hours and minutes the person spends sitting or doing sedentary activities.</td>
</tr>
<tr>
<td>(a) Adolescent</td>
<td>The self-administered questions provide an estimate of how many hours and minutes an adolescent spends doing sedentary activities each day before and after school during a typical school week (including the weekend).22</td>
</tr>
<tr>
<td>(b) Adult</td>
<td>A self-reported estimate of how many hours and minutes a person spends sitting watching TV or traveling in a vehicle on a typical weekday or weekend day.23</td>
</tr>
<tr>
<td>11. Total Physical Activity —Comprehensive</td>
<td>These recall questionnaires are used to capture physical activities from the last several days to estimate general physical activity levels.</td>
</tr>
<tr>
<td>(a) Adolescent</td>
<td>The adolescent is asked to recall all of the physical activities he or she engaged in during the previous 3 days by completing an activity log.24</td>
</tr>
<tr>
<td>(b) Adult</td>
<td>The 7-Day Physical Activity Recall (7-Day PAR) is an interviewer-administered instrument used to recall and record all of the physical activities the participant engaged in during the previous 7 days.25</td>
</tr>
<tr>
<td>(c) Older Adult</td>
<td>A self-administered questionnaire is used to capture physical activities the respondent engaged in during the past 4 weeks.26</td>
</tr>
<tr>
<td>12. Total Physical Activity —Objective Measure</td>
<td>An accelerometer is used to continuously measure the frequency, duration, and intensity of movements; a minimum of 4 days is recommended.27</td>
</tr>
<tr>
<td>13. Total Physical Activity —Screener</td>
<td>Self-administered questions about the usual level of physical activity associated with the person’s job and leisure-time activities in the past year.28</td>
</tr>
<tr>
<td>14. Walking–Ambulation Objective Measure</td>
<td>An accelerometer-based pedometer is used to measure the number of steps the respondent takes during a measurement period (e.g., 3 days).29</td>
</tr>
</tbody>
</table>

Note: References for each measure are key publications describing the development or validation of the measure. Additional references for each measure are in the toolkit on the PhenX Toolkit website (www.phenx.org).
Activity Using Wearable Monitors: Best Practices for Monitor Calibration and Use” was held, with the proceedings published as a supplement to Medicine and Science in Sports and Exercise. This report provides a comprehensive discussion of many of the measurement issues related to the objective assessment of physical activity.

In July 2010, another NIH-sponsored workshop was held titled “Measurement of Active & Sedentary Behaviors: Closing the Gap in Self Report Methods.” A very informative webinar series preceded the workshop, and is available online at www.nccor.org/upcoming_events_webinars_2010.html. Proceedings from this workshop will be published as a supplement to the Journal of Physical Activity and Health in 2012. Finally, a second update of the Compendium of Physical Activities was published in 2011, and the updated compendium is available online at sites.google.com/site/compendiumofphysicalactivities. This website provides a number of useful features to investigators, including bibliographic references for all activities in the compendium with measured values.

**Conclusion**

Although the inclusion of PA/PF measures and protocols in the PhenX Toolkit will aid investigators in combining data across genomewide association studies, these measures have the potential for a broader application by researchers in multiple disciplines. Investigators planning genetic, clinical trial, or epidemiologic studies in disciplines ranging from cancer to diabetes to cardiovascular health, or even obesity, can benefit from the inclusion of PhenX PA/PF measures. As healthcare practitioners worldwide move toward an integrated healthcare approach, leaving behind the outdated single cause/single disease model, they will need data that take into account multiple risk factors.

Chronic diseases often attributed to more than one risk factor require an integrated health research methodology in which inter-related health issues are addressed. The preponderance of data espousing the benefits of a physically active lifestyle make the inclusion of PA/PF measures in most chronic disease studies vital to a successful integrated healthcare approach. The ability to compare these data sets not only across studies, but also across disciplines, will further enhance the scientific understanding sought by researchers in multiple fields.

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The PA/PF WG members included William Haskell, PhD (Co-Chair) from Stanford University; Rick Troiano, PhD (Co-Chair), from the National Cancer Institute; Barbara Ainsworth, PhD, from Arizona State University; Kong Chen, PhD, from the National Institute of Diabetes and Digestive and Kidney Diseases; Patty Freedson, PhD, from the University of Massachusetts at Amherst; Struan Grant, PhD from the Children’s Hospital of Philadelphia; David Marquez, PhD, from the University of Illinois at Chicago; Jose Ordovas, PhD (SC Liaison), from Tufts University; Michael Phillips (Working Group Manager) from RTI International; and Jane Hammond, PhD (Working Group Supervisor), from RTI International.

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