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Introduction

Health is influenced by many factors, genetic, behavioral, and environmental, that are present prior to conception and continue throughout an individual's life span. Since childhood health predicts adult morbidity and mortality, it is beneficial to attain, sustain, and monitor health from childhood to adulthood. The United States and other countries have designed programs to measure or improve the health of the population in many different domains, including physical fitness, and at all ages. Key to setting national health agendas and priorities, as well as goals for individuals, is having goals for public health, metrics with which to determine health reliably and accurately in various areas, and an understanding of how close the population or individuals are to the established goals.

Examples of surveillance programs designed to measure health in various dimensions in the United States are the National Health Interview Survey (NHIS), the National Immunization Survey (NIS), the Behavioral Risk Factor Surveillance System (BRFSS), the National Health and Nutrition Examination Survey (NHANES), and the National Youth Physical Activity and Nutrition Study, to name a few. In addition to such national surveys, states may conduct their own surveys to track health status. Health programs can be established in the school environment or be part of the school curriculum (e.g., physical education classes), with the purpose of improving or evaluating health status among youth. While surveys of physical activity among youth have been carried out in recent years, however, national fitness surveys have not been conducted since the 1980s (see Chapter 2), although the NHANES includes components pertinent to physical fitness, and a 2012 NHANES Youth Fitness Survey is currently under way.

As discussed in Chapter 2, there have been many efforts to identify fitness tests and standardize a battery of such tests for youth. To this day, however, an array of tests continues to be used, selected based on various historical circumstances and understandings of the science. This report represents an effort to provide an evidence-based approach to selecting field-based fitness measures for youth for inclusion in a national fitness survey. Recommendations for tests to be used in schools and other educational settings are provided as well.

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BACKGROUND

To better understand the content of this report, it is important to distinguish between physical fitness and physical activity. *Physical fitness* has been defined as "a set of attributes that people have or achieve that relates to the ability to perform physical activity" (HHS, 1996, p. 21). The focus of this report is on the potential health-related components of physical fitness: body composition, cardiorespiratory endurance, musculoskeletal fitness, and flexibility. *Physical activity*, on the other hand, is defined as "any body movement produced by muscle action that increases energy expenditure" (Castillo-Garzon et al., 2006, p. 213). There are many types of physical activities, such as exercise (physical activity with the purpose of improving fitness), sports, dance, and recreational activities. Box 1-1 and Appendix B provide the committee's operational definitions of physical fitness and other terms used throughout the report.

BOX 1-1
Terms Used in This Report

Body composition: the components that make up body weight, including fat, muscle, and bone content.

Cardiorespiratory endurance: the ability to perform large-muscle, whole-body exercise at moderate to high intensities for extended periods of time (also referred to as aerobic fitness or aerobic capacity) (Saltin, 1973).

Criterion-referenced standards (criterion measures): evaluation standards used to interpret physical fitness test scores and provide information about a participant's health status.

Cut-point (cutoff score): a test score that represents the minimum level of performance that must be achieved for a participant to be said to be at reduced risk or fit/healthy.

Flexibility: "the intrinsic property of body tissues that determines the range of motion achievable without injury at a joint or group of joints" (Holt et al., 1996, p. 172).

Musculoskeletal fitness: a theoretical construct reflecting the integrated function of an individual's muscle strength, endurance, and power to enable the performance of work against one's own body weight or an external resistance.

Physical activity: "any body movement produced by muscle action that increases energy expenditure" (Castillo-Garzon et al., 2006, p. 213).

Physical fitness: "a set of attributes that people have or achieve that relates to the ability to perform physical activity" (HHS, 1996, p. 21).

Reliability: the dependability of test scores, their freedom from error, and their reproducibility in repeated trials on the same individual.

Validity: the extent to which a test measures what it is designed to measure; the degree to which evidence supports the interpretation of test scores (Eignor, 2001).

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Fitness tests are conducted for several purposes for both individuals (e.g., goal setting, planning for improvement, preparing for specific tasks) and society at large (e.g., assessing current fitness status, tracking changes, research). The ultimate purpose, however, is to improve the health and physical performance of individuals, as well as the population as a whole. As noted above and described in detail later in this report, fitness surveys have been conducted in the United States at both the national and state levels. Similarly, other countries have developed fitness test batteries and conducted national surveys (see Chapter 2).

Early national fitness tests included items commonly described as skill-related fitness, as well as items focused on health-related fitness. Since the first national fitness test was developed in 1958, appropriate items for inclusion in fitness test batteries have been the subject of debate. The first national health-related physical fitness test was developed in 1980 (AAHPERD, 1980), and since then there has been increased emphasis on defining the relationship of fitness items to health. While measures of performance-related fitness are designed to evaluate a person's capability to carry out certain physical tasks or activities, the focus of health-related fitness testing is on concurrent or future health status. The measurement of health-related fitness in youth is the focus of this report. As more sophisticated research and statistical methods, computer technologies, and data management systems have emerged, the link between fitness tests and health has been more firmly established. Nevertheless, there is more to be done. This report is based on a systematic review of the literature designed to answer key questions concerning fitness and health in youth.

STATEMENT OF TASK

This study was undertaken to identify measures of fitness for which there is evidence of an association with health outcomes and to provide guidance for interpreting fitness test scores (e.g., setting health-related cut-points for specific tests). The committee was asked to be attentive to the practicality of the recommended tests and to discuss considerations and pros and cons for these tests. The specific questions posed in the committee's statement of task are shown in Box 1-2.

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BOX 1-2
Statement of Task

An ad hoc committee will recommend physical fitness test items for assessment of youth fitness components that are associated with health outcomes. The recommended items will be suitable for inclusion in a national survey of fitness in children and youth. The committee will make use of a systematic review of the literature conducted by the Centers for Disease Control and Prevention. In examining the review, the committee will evaluate the relationships between the fitness components and health outcomes (e.g., cardiovascular disease risk factors, musculoskeletal health, diabetes, obesity and others). Further, for selected fitness components the committee will examine the relationships between performance on specific test items and health outcomes.

In addition to the primary task above, the committee will answer the following questions:

1. For recommended test items for which there is evidence of an association with health, how should performance for the test items be interpreted? Should the interpretation be based on a cut-point approach? Are there alternative approaches to interpret performance?
2. If the association between a particular test and health outcomes reveals no obvious relationship to health, what strategy is most appropriate for identifying a criterion-referenced standard? In such a case, the committee may consider the use of norm-referenced standards.
3. How do demographic characteristics and overweight and obesity affect the tests scores and subsequent evaluations?
4. What additional research is needed to augment the evidence (or lack thereof) about the associations between fitness measures and health outcomes?

The committee will also study to what extent is change in performance on a fitness test item (e.g., handgrip strength or 1.5-mile walk/run) associated with change in health outcomes in youth who are apparently “healthy” but include both obese and nonobese. In addition, the committee will identify the strengths and weaknesses of fitness test items in regards to their practicality and as indicators of health outcomes in a school setting and, based on practicality, will provide recommendations for the most appropriate measures for each fitness component.

METHODS

An 11-member committee was convened to answer the questions posed in the statement of task shown above. The committee members had extensive expertise in fitness and physical activity and were selected specifically for their knowledge of youth health issues, body composition and maturation, and motor coordination; methodologies for developing fitness measures related to health; physical education, physical activity, and fitness in schools; and national fitness surveys. Many committee members also are familiar with the various fitness test batteries that have been used throughout history and in different countries and that have responded to specific situations and purposes. Committee members are knowledgeable as well about the many factors (e.g., demographic characteristics) that interact with youth performance on tests for the various fitness components. Because the statement of task also requested that the

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committee be mindful of practical considerations when selecting fitness tests for use in the field, many of the committee members have practical experience with implementing fitness test batteries.

In addition to its members' extensive knowledge of fitness and health, the committee drew on other sources to inform its decisions about the selection of fitness test items. A major resource for inferring relevant associations between specific fitness test items and health markers in youth was a systematic review of the peer-reviewed scientific literature, designed and conducted by the Centers for Disease Control and Prevention (CDC) and encompassing the period 2000-2010. Further detail on the conduct of this review is presented in Chapter 3. For two fitness components—cardiorespiratory endurance and musculoskeletal fitness—the committee received the results of the review in the form of abstracted tables along with the full articles, and then selected the articles to review in depth based on its assessment of the quality of the research. Although articles on flexibility were not coded separately in the literature review, the committee reviewed several studies focused on the other fitness components that included a flexibility measure. A systematic review of the literature with respect to body composition also was not conducted because, even though this component is frequently included in fitness test batteries, its relationship to health is well known. Although the committee did not participate in the design of the literature review, members had ample opportunities to interact with the CDC in order to understand the nature of the review. The CDC literature review also did not include integrity and feasibility studies. The committee conducted further literature searches and reviews in other areas, for example, to assess the integrity of specific fitness tests or to complement the CDC's systematic review.

In addition, the committee drew on the work and experience of other organizations and countries to the extent that this information is available to the public. The committee also benefited from expert presentations during an open session on November 15-16, 2011; the agenda for this open session is in Appendix A. Presenters had extensive experience in the development of fitness test batteries and in the associations of fitness with metabolic risk factors and body composition. Other presenters had experience in implementing and interpreting results of a battery of fitness tests in the field, providing the committee with insight into feasibility considerations and challenges encountered at the time of test implementation.

The main purpose of this report is to identify fitness measures that are associated with health markers in youth and that are also practical in a field setting. To accomplish this purpose, the committee agreed on various concepts and on a general conceptual framework that guided its decisions. Before reviewing the literature, the committee decided on a stepwise process for identifying the best test items for each fitness component. As will be obvious from the description in Chapter 3, the literature review was designed to provide information about potential associations of fitness tests with health markers (or risk factors) and outcomes in youth as opposed to those that might be seen later in life. For that reason, the majority of health issues explored during the review were health markers (or risk factors) for a disease and not health outcomes per se, as most health conditions or diseases do not manifest until adulthood. As is clear from the discussion throughout the report, studies that follow youth into adulthood are infrequent. Since the 1980s, moreover, organizations and relevant government agencies have focused their efforts on the health benefits of physical activity among youth rather than on fitness, which was the focus prior to the 1980s. The lack of a recent focus on fitness has resulted in a less than ideal scientific literature base addressing questions of fitness and health. Nevertheless, the knowledge base has increased sufficiently to support the conduct of a national

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Fitness Measures and Health Outcomes in Youth

fitness survey. The focus on health in youth is a unique feature of this report and one that presented many challenges given the inadequate amount and nature of the relevant literature. However, this focus is in tune with current thinking that factors related to health in adults cannot necessarily be extrapolated to youth, and therefore, health markers in youth need to be defined and reviewed.

While the committee provides guidance for developing cut-points (cutoff scores) for and interpreting performance on fitness tests, it did not develop specific cut-points for the recommended test items. Rather, the committee suggests an ideal approach to establishing cut-points. Recognizing that all the data necessary to establish cut-points do not exist for all the recommended tests, the committee also provides alternative approaches for establishing interim cut-points when such data are unavailable. In addition, there are aspects of fitness testing that the committee did not address in depth, such as protocols for the recommended tests, specific training for test administrators, or the appropriateness of fitness components that were not included in the committee's statement of task. Finally, the studies reviewed were designed to collect evidence on the relationship between fitness tests and health in healthy youth. Studies on overweight and obese youth were included in the review; however, studies in special populations, such as athletes or people with disabilities[1] or congenital diseases, were not reviewed. Therefore, the committee's findings, conclusions, and recommendations do not target those special populations.

ORGANIZATION OF THE REPORT

This report is organized into chapters dedicated to background on measuring fitness in youth; the committee's methodology; and its findings, conclusions, and recommendations. Chapter 2 provides a historical perspective on the origins of youth fitness testing and the changes that have occurred over the years both in the tests and in their uses. This chapter includes a table describing fitness test batteries currently used around the world. Chapter 3 describes in detail the methodology used by the committee to identify test items, including the CDC's systematic review, which was the primary basis for the committee's conclusions and recommendations. Chapters 4, 5, 6, and 7 present the committee's rationale for recommending test items for the four fitness components, respectively—body composition, cardiorespiratory endurance, musculoskeletal fitness, and flexibility—highlighting the findings of the scientific literature. As noted earlier in this chapter, the primary purpose of this report was to make recommendations for a national survey. A secondary purpose was to make recommendations for the use of fitness tests in schools and other educational settings.[2] Because tests vary based on their potential uses, separate chapters were prepared for each of these two uses of fitness test items. Chapter 8 presents the committee's recommendations for national surveys of youth fitness. Chapter 9 describes the importance of fitness in the context of education, details factors to consider when implementing fitness tests in schools and other educational settings, and presents the committee's recommendations for specific fitness tests for educational settings. Finally, Chapter 10 includes the committee's recommendations for future research.

[1]A disability is defined as any restriction or lack of ability to perform an activity in the manner or within the range considered normal for a human being. For the purposes of this report, this term should be construed in the broadest sense, covering impairments (i.e., a problem in body function or structure), activity limitations (i.e., a difficulty encountered by an individual in executing a task or action), and participation restrictions (i.e., a problem experienced by an individual in involvement in life situations).

[2]Other educational settings include, for example, gymnasiums and fitness centers.

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REFERENCES

AAHPERD (American Alliance for Health, Physical Education, Recreation and Dance). 1980. *Health related physical fitness test manual*. Reston, VA: AAHPERD.

Castillo-Garzon, M. J., J. R. Ruiz, F. B. Ortega, and A. Gutierrez. 2006. Anti-aging therapy through fitness enhancement. Clinical Interventions in Aging 1(3):213-220.

Eignor, D. R. 2001. Standards for the development and use of tests: The standards for educational and psychological testing. *European Journal of Psychological Assessment* 17(3):157-163.

HHS (U.S. Department of Health and Human Services). 1996. *Physical activity and health: A report of the Surgeon General*. Atlanta, GA: HHS, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion.

Holt, J., L. E. Holt, and T. W. Pelham. 1996. Flexibility redefined. In *Biomechanics in sports XIII,* edited by T. Bauer. Thunder Bay, Ontario: Lakehead University. Pp. 170-174.

Saltin, B. 1973. Oxygen transport by the circulatory system during exercise in man. In *Limiting factors of physical performance*, edited by J. Keul. Stuttgart, Germany: Thieme Publishers. Pp. 235-252.

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Summary

Physical fitness is a state of being that reflects a person's ability to perform specific exercises or functions, and is related to present and future health outcomes. In the United States, serious efforts to assess the physical fitness of youth with a battery of tests began in the 19th century. These efforts intensified during times of war, focused primarily on improving athletic performance and military preparedness. Over time, the focus of such surveys shifted to assessing health rather than performance, reflecting growing concern about the current and future health of the nation's youth. While measures of performance-related fitness are designed to evaluate a person's capability to carry out certain physical tasks or activities, the focus of health-related fitness testing is on the concurrent or future health status of the subject under assessment.

The first U.S. national survey of youth fitness in 1958 was followed by surveys in 1965 and 1975 and then in 1985-1986. States and schools have continued to assess fitness in youth during the past two decades; after the 1985-1986 survey, however, there was no national-level assessment of youth fitness until 2012, as part of the National Health and Nutrition Examination Survey. Several factors may account for this gap, including the fact that interest and effort have been directed more toward understanding the role of physical activity in youth. This shift and the challenges inherent in associating fitness in youth with health have resulted in few advances in our understanding of the physiology and outcomes of fitness.

Assessment of fitness historically has encompassed such components as body composition, cardiorespiratory endurance, musculoskeletal strength and endurance, and flexibility. Examples of tests used historically in national surveys and schools are the progressive shuttle run and mile run tests for cardiovascular endurance, measurement of body mass index (BMI) for assessment of body composition, the curl-up and push-up tests for muscular endurance, and the sit-and-reach tests for flexibility.

While the components of fitness measured and the specific test items included in protocols have varied considerably across test batteries and over time, youth fitness testing has become a well-established institution in school physical education programs during the past half-century. In a school context, tests are being used as institutional fitness assessment tools, as educational tools to teach youth and their families about the importance of physical fitness, and as communication tools to guide individuals on attainable goals for maintaining fitness and health. These efforts are costly in terms of not only human capacity and financial resources, but also the extensive training and organizational and communication skills required for their

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implementation. Most important, it is essential to use appropriate tests and understand the results in a health context to minimize misclassification and stigmatization of youth. Selection of the best tests is therefore a crucial process, and knowledge gaps in this area were an important motivator of the present study.

This study was undertaken in light of the past challenges encountered in identifying fitness tests related to health in youth, spurred by a renewed interest in fitness as one of the key tenets of health.

STUDY APPROACH

Given the gaps in knowledge noted above, the Institute of Medicine (IOM) convened an 11-member committee with expertise in fitness measures, body composition and maturity, physical activity, physical education, the development of cut-points (cutoff scores), motor development and skill, and modifiers of fitness to conduct this study. The committee was asked to assess the relationships between fitness tests and health outcomes in youth based on a review of the literature designed and conducted by the Centers for Disease Control and Prevention (CDC) (the committee's statement of task is shown in Box S-1). The CDC search criteria included longitudinal, experimental study designs in which fitness and health were measured in healthy[1] children aged 5-18 during 2000-2010. The CDC searches were conducted specifically for the fitness components cardiorespiratory endurance and musculoskeletal strength and endurance. The relationship of body composition measures to health is well established, so a systematic review of their relationship to health was not conducted. Although time and resources did not allow for a systematic review of the flexibility component, the committee evaluated the relationships between flexibility and health outcomes in studies from the CDC review that included a flexibility measure.

[1]The criteria included overweight and obese youth, but excluded youth with various disabilities or congenital diseases. Since the primary task for this study was to identify fitness tests appropriate for a national youth fitness survey of the general youth population, the committee did not review additional literature specific to populations with disabilities, such as those with cognitive or physical impairments, activity limitations, or participation restrictions (as defined in Appendix B).

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BOX S-1
Statement of Task

An ad hoc committee will recommend physical fitness test items for assessment of youth fitness components that are associated with health outcomes. The recommended items will be suitable for inclusion in a national survey of fitness in children and youth. The committee will make use of a systematic review of the literature conducted by the Centers for Disease Control and Prevention. In examining the review, the committee will evaluate the relationships between the fitness components and health outcomes (e.g., cardiovascular disease risk factors, musculoskeletal health, diabetes, obesity and others). Further, for selected fitness components the committee will examine the relationships between performance on specific test items and health outcomes.

In addition to the primary task above, the committee will answer the following questions:

1. For recommended test items for which there is evidence of an association with health, how should performance for the test items be interpreted? Should the interpretation be based on a cut-point approach? Are there alternative approaches to interpret performance?
2. If the association between a particular test and health outcomes reveals no obvious relationship to health, what strategy is most appropriate for identifying a criterion-referenced standard? In such a case, the committee may consider the use of norm-referenced standards.
3. How do demographic characteristics and overweight and obesity affect the tests scores and subsequent evaluations?
4. What additional research is needed to augment the evidence (or lack thereof) about the associations between fitness measures and health outcomes?

The committee will also study to what extent is change in performance on a fitness test item (e.g., handgrip strength or 1.5-mile walk/run) associated with change in health outcomes in youth who are apparently “healthy” but include both obese and nonobese. In addition, the committee will identify the strengths and weaknesses of fitness test items in regards to their practicality and as indicators of health outcomes in a school setting and, based on practicality, will provide recommendations for the most appropriate measures for each fitness component.

To guide its review and deliberations, the committee created a conceptual framework that depicts the potential relationships between physical fitness components and health as they are modified by various factors, such as demographic characteristics, maturity status, motor skills, and genetics. In addition to this conceptual framework, the committee developed the following set of general criteria for selecting tests to be implemented in the field:

- identification of a relationship between a fitness component and health markers;
- evaluation of the quality of the studies and the strength of the evidence for a relationship between fitness test items and health markers in youth, based on the CDC’s systematic review;

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- identification of health-related test items;
- evaluation of the integrity of test items (i.e., validity and reliability); and
- evaluation of the feasibility of implementing test items.

In its statement of task, the committee was asked not only to select test items for a national fitness survey but also to consider the practicality of their implementation. The committee reviewed only the evidence for field-based methods because, even if they are more prone to error than laboratory methods, they require less highly specialized training and are conducted with mobile equipment, adequate for assessing large samples of youth. The committee also recognized that national surveys and schools and other educational settings[2] raise different implementation issues. In addition, the conduct of fitness tests in schools may be driven by goals beyond health, such as educating about the importance of specific fitness components. Because of their role as educational tools, certain test items will be beneficial in a school fitness test battery even if their relationship to health cannot as yet be confirmed in youth. Therefore, the committee developed separate sets of recommendations for these two settings.

Implementing the best health-related fitness items entails important steps that relate to the interpretation and communication of the test results in a health context. Identifying one or more health outcomes that are related to the test items of interest, then, is essential. Equally important is understanding the relationship between the test items and the associated health outcomes in quantitative terms so the results can be interpreted in a health context. For this purpose, a criterion-referenced cut-point—a test performance score below (or above) which a risk to health may exist—can be used. Ideally, criterion-referenced cut-points would be derived from population-based data on the relationship between a fitness test and a health outcome or marker in youth. As noted earlier, however, data on the relationship between fitness and health in youth are limited, mainly because of the difficulty of identifying such associations when health constructs in youth are not well defined. When data in youth populations are not available, alternative approaches can be followed to derive cut-points (interim cut-points). Box S-2 provides the committee's guidance on methods for selecting criterion-referenced cut-points and interim cut-points for health-related fitness testing in youth.

[2]Other educational settings include, for example, gymnasiums and fitness centers.

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BOX S-2
Guidance for Developing Cut-Points

The committee determined that a criterion-referenced method should be employed in developing cut-points. That is, a test taker's performance should be compared against an absolute criterion that is related to health. The following are options, depending on the available evidence:

- When a confirmed concurrent relationship exists between health outcome measures and fitness tests in youth, criterion-referenced cut-points can be determined by using a data mining procedure that establishes the statistical evidence for that relationship.
- When a confirmed concurrent relationship exists only in adults but not in youth, either a relative position or a panel-driven method can be used, whereby interim criterion-referenced cut-points in youth are derived from the percentile values (related to health outcomes) extrapolated from the adult population or by a panel of experts using cut-points for adults and other available information (e.g., growth curves and performance characteristics for different ages and genders).
- When no confirmed relationship exists in either youth or adults, a comparatively relative position method can be employed, whereby interim criterion-referenced cut-points are derived from the percentile values (related to health outcomes) extrapolated from a different test. When the percentile from another test is used, the two tests should be as comparable as possible in their nature (e.g., require movement of the body) and in the dimension they measure (e.g., upper-body strength).

CONCLUSIONS AND RECOMMENDATIONS

The committee developed conclusions and recommendations regarding fitness measures for youth for each of four components of fitness: body composition, cardiorespiratory endurance, musculoskeletal fitness, and flexibility. For each of these components, the committee identified test items, reviewed the evidence on these items, applied the general criteria for selection listed earlier, considered modifying factors, assessed the feasibility of implementation, and applied the guidance in Box S-2 for selecting cut-points. In general, the studies reviewed provided insufficient data with which to assess the influence of several potential modifiers—age, gender, race/ethnicity, body composition, maturation status, motor skill—on performance on tests of cardiorespiratory endurance, musculoskeletal fitness, and flexibility.

As noted earlier, the committee's recommendations are specific to the implementation of fitness measures either in a national youth fitness survey or in schools and other educational settings. The recommended tests for a national youth fitness survey represent valid, reliable, feasible, and safe tests for the assessment of health-related fitness in youth for population-level health-monitoring purposes. National survey fitness tests are intended to be implemented by skilled national administrators of such surveys (i.e., those familiar with the procedures for conducting large surveys and the protocols for fitness tests) in school settings. For schools, recommendations are made for fitness tests that are low in cost and equipment requirements such that they are practical for school-based implementation. Regardless of the setting, test

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administrators and those interpreting and communicating the results should receive appropriate training in conducting and interpreting the tests to minimize measurement and classification errors and prevent adverse events. Finally, the committee offers recommendations for future research that would advance understanding of youth fitness measures and their association with health outcomes.

Conclusions About Components of Fitness

The committee's conclusions relate to the four components of fitness detailed above: body composition, cardiorespiratory endurance, musculoskeletal fitness, and flexibility.

Body Composition

Body composition denotes the sum of the basic components that make up body weight, including fat, muscle, and bone content. The committee defined body composition operationally as a component of fitness, a health marker, and a modifier of fitness. Field-based measures of body composition relate to different dimensions. For example, skinfold is an indicator of subcutaneous fat, whereas waist circumference is an indicator of abdominal adiposity, and BMI measures body weight for height. These measures also vary in that they have been associated with different health markers; for example, skinfold measures are related to risk factors for cardiovascular disease and metabolic syndrome, waist circumference has been associated with cardiovascular disease, and BMI is related to risk of diabetes and hypertension. When implementing and interpreting measures of body composition, it is important to note that many factors, such as physical activity, calorie consumption, age, and maturation, influence body composition measures. The committee selected measures of body composition based on their relationship to health markers, their integrity, and their feasibility.

The committee concluded that the above three measures of body composition—skinfold, waist circumference, and BMI—are important to collect in a national youth fitness survey. Each is a proximal estimation of body fat and has increased standard of error over laboratory measures. Moreover, the measurement of body composition is multidimensional; no single measure is considered representative of all body composition tenets for youth of all morphologies.

In selecting measures of body composition, some feasibility factors must be considered: the availability of administrators with the highly specialized training required and the accessibility of appropriate space in which to conduct the test. The reliability of skinfold and waist circumference measurements depends on the skill of the test administrator; to avoid the introduction of errors in the measurements, specific and intense training is required. Training is also required to minimize concerns related to privacy in the administration of these measures. Also to ensure privacy, the appropriate space should be available for conducting the tests. Given the challenges associated with avoiding measurement errors, maintaining good reliability, and ensuring privacy in the administration of skinfold and waist circumference measurements, only BMI measurement is recommended for administration in schools.

Cardiorespiratory Endurance

Cardiorespiratory endurance is the ability to perform large-muscle, whole-body exercise at moderate to high intensity for an extended period of time. There is a well-established association between cardiorespiratory endurance and health outcomes in adults and health markers or risk factors in children—in particular, body weight, body composition,

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cardiometabolic risk factors, blood pressure, cognitive function, and pulmonary function. Although the fitness tests and protocols used vary substantially, the cardiorespiratory endurance tests associated most frequently and strongly with a positive change in health markers or risk factors are heart rate extrapolation tests (i.e., those that use a treadmill or cycle ergometer and measure cardiorespiratory endurance as maximal oxygen consumption [VO_2max]) and the progressive shuttle run. The health markers most frequently assessed are related to body weight or adiposity and cardiometabolic risk factors. The heart rate extrapolation and progressive shuttle run tests have high validity and reliability. In terms of feasibility, the progressive shuttle run is advantageous when time and financial constraints exist with respect to the necessary training and equipment. Treadmill and cycle ergometer tests are valid and reliable alternatives for a national survey in which space limitations are a concern, but extensive training is feasible. The validity and reliability of distance runs are more variable and in general lower than has been reported for the heart rate extrapolation and progressive shuttle run methods; however, these tests are appropriate for a school setting for practical reasons.

Musculoskeletal Fitness

Musculoskeletal fitness is a multidimensional construct that encompasses three related components: muscle strength (the ability of skeletal muscle to produce force under controlled conditions), muscle endurance (the ability of skeletal muscle to perform repeated contractions against a load), and muscle power (the peak force of a skeletal muscle multiplied by the velocity of the muscle contraction). Neither any of these components individually nor any single test can describe overall musculoskeletal fitness. Therefore, a number of tests that measure various dimensions of musculoskeletal fitness often are used in combination. As with other fitness components, a wide variety of tests, such as the curl-up, the push-up, the hand grip, and jumps, have been used to measure musculoskeletal fitness in the past.

The committee concluded that adequate experimental and prospective longitudinal evidence supports the relationship between the multidimensional construct of musculoskeletal fitness and health. Empirical evidence also is increasing for the importance of musculoskeletal fitness, especially muscle strength and power, to health outcomes in adults. There is, however, insufficient high-quality evidence to support a strong association between any single musculoskeletal fitness test item and health markers in youth. Based predominantly on evidence indicating a relationship to health outcomes in adults, the committee concluded that musculoskeletal fitness should be assessed in a national youth fitness survey.

Growing evidence supports use of the handgrip strength test and the standing long jump as health-related musculoskeletal fitness test items in youth. Studies reviewed show a relationship between performance on these tests and bone health and body composition. The handgrip strength test demonstrates moderate to strong validity when assessed against upper- and lower-body criterion muscle strength measures. The standing long jump, although not strictly a measure of muscle strength, demonstrates acceptable validity against lower- and upper-body criterion muscle strength measures and lower-body muscle power measures. The handgrip strength and standing long jump tests demonstrate strong and moderate reliability, respectively. The committee recommends that the handgrip strength and standing long jump tests be included in a national survey. While these tests should not be interpreted in a health context until their relationships with health outcomes have been established more firmly in youth, they can be included for their educational value. Other measures of muscular strength, such as the modified

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pull-up or push-up as an alternative for measuring upper-body musculoskeletal strength and power or the curl-up for measuring core strength, also can be used in schools.

Flexibility

Flexibility is the intrinsic property of body tissues, including muscle and connective tissue, that determines the range of motion achievable without injury at a joint or group of joints. Like musculoskeletal fitness, flexibility is specific; a person can have a good range of motion around a shoulder joint, for example, but lack range of motion in the hip. Such specificity precludes any relationship between a given measure of flexibility and any systemic health markers (e.g., back pain, risk of injury, posture problems). Moreover, clinical theory suggests that the complex interaction among multiple musculoskeletal components (e.g., flexibility, strength, endurance), rather than one component alone, is most likely to be associated with health markers. Further, possible associations with health are complicated by the fact that risk may be higher for those with low or exceptionally high flexibility than for those in the middle ranges. Finally, although evidence suggests a link between flexibility and health among adults (e.g., low-back pain), such evidence is more difficult to establish in youth given that the commonly used health risk outcomes may take years to manifest.

The literature review did not reveal a relationship between any flexibility test and health in youth. In addition to the challenges mentioned above, this could be due to the study designs included in this review. Specifically, in contrast to studies on other fitness components, there was a lack of quality longitudinal and experimental studies measuring the association between flexibility and health markers in youth. For example, many studies did not include health markers hypothesized to be related to flexibility and typically did not include a control. Future efforts to study the relationship of flexibility to health will require a multivariate approach. Although no relationship to health has been shown, the sit-and-reach test is feasible to implement and has acceptable validity and reliability.

Recommendations for National Surveys

A substantial body of evidence supports the idea that specific tests measuring cardiorespiratory endurance and body composition are related to health markers in youth. The evidence for an association between musculoskeletal fitness and health markers in youth is less extensive. The committee concluded that insufficient evidence has thus far been accumulated to support recommending a health-related measure of flexibility for youth at this time.

The committee concluded that a criterion-referenced approach using cut-points associated with health markers is the ideal approach for interpreting scores. There is, however, insufficient evidence with which to develop age- and gender-specific criterion-referenced cut-points for all measures except for BMI. Until data are collected with which to establish criterion-referenced cut-points, age- and gender-specific interim cut-points corresponding to percentiles for adults on tests related to the same component or for youth on tests related to a different or the same component should be used.

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RECOMMENDATION 8-1.[3] A national survey of health-related physical fitness in youth should include measures of cardiorespiratory endurance, body composition, and musculoskeletal fitness. The survey should include the following fitness test items: (1) measures of BMI, waist circumference, and skinfold thickness (triceps and subscapular sites) to assess body composition; (2) a progressive shuttle run, such as the 20-meter shuttle run (or a submaximal treadmill or cycle ergometer test if there are space limitations) to measure cardiorespiratory endurance; and (3) handgrip strength and standing long jump tests to measure musculoskeletal fitness.

RECOMMENDATION 8-2. Standard protocols for the administration of measures of youth fitness in national surveys should be developed and implemented. The focus should be on maximizing the measures' reliability, validity, and safety. Trained personnel should be used for test administration and data collection.

RECOMMENDATION 8-3. Developers of fitness test batteries should use age- and sex-specific cut-points to determine which individuals are at risk of poor fitness-related health outcomes. Optimum cut-points should be based on criterion values when population-based evidence is available on the relationship between the level of performance on a fitness test and a health outcome or marker. In the absence of criterion values, interim population-based percentile values should be applied. These values might be derived from adults on tests for the same component or from youth on tests for a different or the same component. Specifically, the guidance of the committee should be applied as follows:

- **Body composition: For BMI, the CDC-established cut-points for underweight, overweight, and obesity evaluations should be used. Interim cut-points for skinfold and waist circumference measures could be derived from the CDC-established percentiles for BMI.**
- **Cardiorespiratory endurance: For measures of cardiorespiratory endurance, interim cut-points could be derived from the lowest performers (e.g., 20th percentile) on the cardiorespiratory endurance distribution curve.**
- **Musculoskeletal fitness: For musculoskeletal fitness tests, interim cut-points could be derived by borrowing the percentile (e.g., 20th percentile) from the cardiorespiratory endurance tests.**

[3]The committee's recommendations are numbered according to the chapter of the main text in which they appear.

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Recommendations for Schools and Other Educational Settings

The preceding recommendations outline the optimum test items for measuring fitness in youth in national surveys. Conducting fitness tests in educational settings can yield further benefits, such as contributing to the body of evidence on the association between health-related fitness components and learning outcomes, improving individuals' fitness performance, and educating about the importance of physical fitness. The committee considered the strengths and weaknesses of the test items recommended for a national survey with regard to their practicality in schools and other educational settings.

School leaders and teachers should apply the following recommendation and select applicable test items in light of the contextual variables that characterize their schools, such as available equipment, space, and test administrators, as well as cost, as schools differ greatly on these variables. Factors related to culture and race/ethnicity, as well as how a test item aligns with the existing curriculum, should also be considered. Finally, perhaps the most important element of fitness testing in schools is the interpretation and dissemination of results. This element represents an opportunity to assist participants in preventing disease and understanding fitness, but can have detrimental effects on the individuals involved if not carried out appropriately. As mentioned above, training in the administration of protocols and the interpretation and communication of test results is essential.

RECOMMENDATION 9-1. Developers and administrators of fitness test batteries in schools and other educational settings should consider including the following test items:

- **standing height (measure of linear growth status) and weight (measure of body mass) to calculate BMI as an indicator of body composition;**
- **a progressive shuttle run, such as the 20-meter shuttle run, to measure cardiorespiratory endurance; and**
- **handgrip strength and standing long jump tests to measure upper- and lower-body musculoskeletal strength and power, respectively.**

Additional tests that have not yet been shown to be related to health but that are valid, reliable, and feasible may also be considered as supplemental educational tools. For cardiorespiratory endurance, alternatives to the shuttle run include distance and/or timed runs, such as the 9-minute or 1-mile run, while the modified pull-up and push-up are possible alternatives for measuring upper-body musculoskeletal strength. The curl-up may be considered in addition to the suggested musculoskeletal fitness tests for measuring core strength and endurance. Although the committee does not recommend a flexibility measure as a core component of a fitness test battery, administrators in schools and other educational settings may wish to include the sit-and-reach test or its alternatives (e.g., backsaver sit-and-reach) to measure flexibility. Experts who establish cut-points for interpreting performance on these fitness test items should follow the guidance provided earlier (Box S-2 and Recommendation 8-3).

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Recommendations for Future Research

Altogether, the CDC's literature review revealed many gaps in understanding of the relationship between fitness measures and health in youth. Although the review revealed a number of associations between the two, many of the studies reviewed were not designed to assess the independent association between performance on a fitness test and a health outcome or marker. Moreover, while not included in the search strategy, studies predicting health outcomes in adulthood would be valuable in characterizing the importance of a health marker. For example, it remains to be determined whether changes in muscle strength and power during youth are predictive of health outcomes in later life.

The committee offers the following recommendations for designing and conducting research on some of the most pressing questions that must be answered if progress is to continue in selecting the best measures of fitness in youth. It should be noted that the committee is recommending research only for those test items that have been studied well enough to justify their inclusion here. At the same time, it is not the intent of the committee to eliminate from future consideration those test items that currently do not meet the level of evidence necessary for inclusion in a battery of tests.

RECOMMENDATION 10-1. Well-designed research studies aimed at advancing understanding of the associations between fitness components and health in youth should be undertaken. Researchers should ensure that the interventions studied are both specific and sufficient (i.e., appropriate dosage and duration) to induce a change in fitness. In addition, studies should be designed so that the effect of potential confounders (e.g., nutrition, physical activity, demographic variables, maturity status) and the potential for adverse events can be analyzed.

RECOMMENDATION 10-2. Longitudinal studies should be conducted to provide empirical evidence concerning how health markers related to fitness track from youth into adulthood.

RECOMMENDATION 10-3. Randomized controlled trials and longitudinal studies should be undertaken to understand the following issues regarding the relationships between (1) specific fitness tests and health, and (2) fitness components and health:

- **Studies should examine the relationship between changes in cardiorespiratory endurance as measured by field tests, including the shuttle run and timed and distance runs, and subsequent changes in health risk factors in youth beyond weight status and cardiometabolic risk factors. Examples include bone health and neurocognitive function and behavior.**
- **Studies should explore the relationship between body composition measures and physical fitness tests and the potential interactions among body composition, fitness, and health in youth.**

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- **Studies should address the relationship between specific musculoskeletal fitness test items and health markers in youth. Priority should be given to test items for which there is growing evidence, such as the handgrip strength or standing long jump test, or others that are promising. Since musculoskeletal fitness is a multivariate construct, the studies should be designed so that a variety of tests are conducted.**
- **Studies should investigate the relationship between specific flexibility test items (e.g., sit-and-reach and its modifications), either by themselves or in combination with musculoskeletal fitness test items, and potential health markers (e.g., back pain, posture, injury prevention). Such studies should include stretching interventions specifically designed to produce changes in joint-specific flexibility. Since flexibility is a multivariate construct, the studies should be designed so that a variety of tests are conducted. Researchers should investigate the development and validation of a general marker of musculoskeletal systemic flexibility and its relationship to health markers and risk factors.**
- **Studies should examine the potential effects of modifying factors (i.e., age, gender, race/ethnicity, body composition, maturity status, training status/practice, motor skill, socioeconomic factors) on fitness components and on the relationship between a change in a health-related fitness component and health markers in specific populations.**

RECOMMENDATION 10-4. Developers of national surveys of health-related physical fitness in youth should consider the inclusion of measures of cardiometabolic health, bone health, and neurocognitive function. The collection of fitness and health data in the same individuals would allow investigators to further confirm whether direct relationships between specific test items and health markers and risk factors exist.

RECOMMENDATION 10-5. When an association between a fitness test and a health marker is confirmed, research should be conducted to establish and validate health-related cut-points for that test. For example, given the association of skinfold measures with health markers, large national studies should be conducted to establish health-related cut-points for skinfold measures in youth.

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Introduction

Protecting health is a major priority of society, families, and individual parents. Over the past 100 years there has been a revolution in the ability to protect health in the developed world, where there are resources to enable this to happen. In 1900, among every 1,000 babies born in the United States, 100 would die before their first birthday, and five before 5 years of age (Guyer et al., 2000). By 2007, fewer than seven were expected to die before their first birthday, and only 0.29 per 1,000 before 5 years of age (DHHS, 2010). Diseases severe enough to kill children and adults can also leave survivors disabled in some way, and as mortality has fallen, so has the chance of severe disability from these diseases.

Among the dangers for children and adults that have greatly diminished over the past century are infectious diseases. For bacterial diseases, antibiotics have been developed to treat infections before permanent harm can occur. For many viral and bacterial diseases, vaccines now exist.

In the early 20th century, smallpox (which has 30 percent mortality and a very high rate of disfigurement and other less common sequelae including blindness and encephalopathy) and rabies (virtually 100 percent fatal) could be prevented with immunization (CDC, 2001, 2008). With the fast growing understanding of microbes and immunity from 1920 onward, the development of immunizations became a race to "conquer" infectious disease. Beginning with the combination diphtheria, pertussis, and tetanus immunization during World War II and most recently with immunization to prevent cervical cancer (the human papillomavirus vaccine), immunizations have changed our expectations for child and adult health. Infections are less of a terror, and we now expect our children to survive to adulthood.

Vaccines function by stimulating the immune system and prompting a primary immune response to an infecting pathogen or to molecules derived from a particular pathogen. The immune response elicited by this primary exposure to vaccine pathogen creates immunological memory, which involves the generation of a pool of immune cells that will recognize the pathogen and mount a more robust or secondary response upon subsequent exposure to the virus or bacterium. In successful immunization, the secondary immune response is sufficient to prevent disease in the infected individual, as well as prevent the transmission of the pathogen to others. For communicable diseases, immunizations protect not only the individual who receives the immunization, but also others with whom he or she has contact. High levels of vaccination in a community increase the number of people who are less susceptible or resistant to illness and propagation of the infectious agent. Unvaccinated individuals or those who have not developed

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immunity to this pathogen are afforded an indirect measure of protection because those with immunity reduce the spread of the pathogen throughout the entire population. The larger the proportion of people with immunity, the greater the protection of those without immunity. This effect is called "herd immunity." Herd immunity is an important phenomenon as immunization programs rarely achieve 100 percent immunization in a population; and in some cases, previously vaccinated persons may not exhibit effective immunity and disease may result from exposure to the pathogen. For protection, we rely on immunizing not only ourselves but also our neighbors.

The overwhelming safety and effectiveness of vaccines in current use in preventing serious disease has allowed them to gain their preeminent role in the routine protection of health. Before an immunization is introduced for population-wide use, it is tested for efficacy and safety. However, immunization is not without risks. For example, it is well established that the oral polio vaccine on rare occasion causes paralytic polio and that vaccines sometimes lead to anaphylactic shock. Given the widespread use of vaccines; state mandates requiring vaccination of children for entry into school, college, or day care; and the importance of ensuring that trust in immunization programs is justified, it is essential that safety concerns receive assiduous attention.

Congress passed the National Childhood Vaccine Injury Act (NCVIA, P.L. 99-660) in 1986. The legislation was intended to bolster vaccine research and development through federal coordination of the vaccine efforts in government and by providing relief to vaccine manufacturers who reported at the time that financial burdens from awards in the tort system threatened their financial viability. The legislation was also intended to address concerns about the safety of vaccines by instituting a compensation program financed by an excise tax on covered vaccines, setting up a passive surveillance system for vaccine adverse events, and by providing information to consumers (CDC, 2010). Key provisions of the 1986 legislation include:

- The establishment of the National Vaccine Program Office, which coordinates immunization-related activities between all Department of Health and Human Services (HHS) agencies including the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration, the National Institutes of Health, and the Health Resources and Services Administration (HRSA).
- The requirement that all health care providers who administer vaccines provide a vaccine information statement (VIS) to the vaccine recipient, or his or her parent or legal guardian, prior to each dose. Each VIS contains a brief description of the disease as well as the risks and benefits of the vaccine. The CDC develops VISs and distributes them to state and local health departments as well as individual providers.
- The requirement that health care providers must report certain and are encouraged to report other adverse events (health effects occurring after immunization that may or may not be related to the vaccine) following vaccination to the Vaccine Adverse Event Reporting System.
- The creation of the National Vaccine Injury Compensation Program (NVICP) to compensate those injured by vaccines on a no-fault basis. Importantly, this compensation system has two parts:
- The Secretary of Health and Human Services has created a Vaccine Injury Table (Table) that "lists and explains injuries/conditions that are presumed to be caused by

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vaccines. It also lists time periods in which the first symptom of these injuries/conditions must occur after receiving the vaccine. If the first symptom of these injuries/conditions occurs within the listed time periods, it is presumed that the vaccine was the cause of the injury or condition unless another cause is found," [http://www.hrsa.gov/vaccinecompensation/table.htm] and compensation is awarded.

- Individuals who assert that they suffered an injury from a vaccine that is not on the Table ("off-Table" or "causation-in-fact") must pursue their claim before Special Masters, who are appointed by the United States Court of Federal Claims, which hears any appeals. Claimants bear the burden of proving that the vaccine caused their injury, although the burden of proof is lower than that in the tort system.

A key component of the legislation, found in Sections 312 and 313, required the HHS secretary to consult with the Institute of Medicine (IOM) to review the scientific literature on vaccine safety. Two reports were issued (Institute of Medicine, 1991, 1994). These reports contain a framework for causality assessment of vaccine adverse events.[1] The reports addressed the vaccines covered by the VICP up to that point: diphtheria- and tetanus-toxoids and whole cell pertussis vaccine and other tetanus toxoid-containing vaccines; measles, mumps, and rubella vaccines; *Haemophilus influenzae* type B vaccine; hepatitis B vaccine; and both inactivated and oral polio vaccines.[2] The reports informed the secretary's review of the Vaccine Injury Table. The reports have also been referenced extensively as a source of definitive scientific understanding of the evidence by Special Masters in decisions regarding injuries not listed on the Vaccine Injury Table.

The IOM was subsequently asked to review specific vaccine safety concerns in a series of reports requested by the CDC. These reports (Institute of Medicine, 2001a, 2001b, 2002a, 2002b, 2003a, 2003b, 2004a, 2004b) included causality assessments similar to the previous IOM reports, but included other conclusions and recommendations regarding research, communications, and policy review.

CHARGE TO THE COMMITTEE

In 2009 HRSA requested that the IOM convene a committee of experts to review the epidemiological, clinical, and biological evidence regarding adverse health events associated with specific vaccines covered by the Vaccine Injury Compensation Program. The committee was charged with developing a consensus report with conclusions on the evidence bearing on causality and the evidence regarding the biological mechanisms that underlie specific theories for how a specific vaccine is related to a specific adverse event. The vaccines to be reviewed include varicella zoster vaccine, influenza vaccines (but not 2009 H1N1 vaccine), hepatitis B vaccine, human papillomavirus vaccine, tetanus-containing vaccines other than those containing the

[1] Adverse *events* are distinguished from adverse *effects* in that an event is something that occurs but may not be causally associated, whereas an adverse "effect" implies causation. All adverse effects are adverse events, but not all adverse events are adverse effects.

[2] Vaccines are included in the VICP if they are recommended by the Centers for Disease Control and Prevention (CDC) for routine administration in children and are subject to an excise tax. Adults who experience an adverse reaction to one of these "childhood" vaccines are also covered by the program.

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whole cell pertussis component, MMR vaccine, hepatitis A vaccine, and meningococcal vaccines. It is expected that the report will provide the scientific basis for review and adjudication of claims of vaccine injury by the VICP.

HRSA presented a list of specific adverse events for the committee to review (see Table 1-1). The selection criteria was described at the first committee meeting (Johann-Liang, 2009) as including the vast majority of adverse events in the claims for compensation. The committee added adverse events to the list if it identified epidemiologic studies or case reports for an adverse event not original assigned by HRSA. These additions were all-cause mortality and seizures following influenza vaccine; optic neuritis following MMR, influenza, hepatitis B, and DTaP vaccines; neuromyelitis optica following MMR vaccine; erythema nodosum following hepatitis B vaccine; and stroke and small fiber neuropathy following varicella vaccine.

The committee was also tasked with addressing, as time and evidence allowed, general considerations. These included: underlying (susceptible) populations, "immune dysfunction," vaccine administration issues, appropriate time intervals for anaphylaxis and autoimmune diseases, and sequential vaccination issues. The committee addressed some of these, as described in Chapters 4–12. It is important to note that the committee was *not* tasked with assessing the benefits (effectiveness) of vaccines or any policy issues related to vaccination. The task is clearly focused on an assessment only of the risk of vaccines.

COMMITTEE PROCESS

The committee was composed of individuals with expertise in pediatrics, internal medicine, neurology, immunology, immunotoxicology, neurobiology, rheumatology, epidemiology, biostatistics, and law. Appendix F includes biographical sketches of the committee members. The committee met eight times between April 2009 and March 2011. The committee held open sessions at three of these meetings. Appendix G includes agendas of these open meetings. The committee's methodology and approach to their task is described in Chapter 2.

OUTLINE OF THE REPORT

Chapter 2 details the committee's methodology. Chapter 3 discusses generally possible mechanisms of vaccine injury. Chapters 4–11 present the evidence reviewed by the committee for each of the eight vaccines covered and the conclusions it reaches. Chapter 12 presents causality assessments for adverse events that can occur with any injected vaccine regardless of the vaccine antigen and components. The committee discusses some special considerations of its work in Chapter 13.

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TABLE 1-1 Adverse Events Included in the Vaccine Chapters

Adverse Event	MMR Vaccine Chapter 4	Varicella Vaccine Chapter 5	Influenza Vaccine Chapter 6	Hepatitis A Vaccine Chapter 7	Hepatitis B Vaccine Chapter 8	HPV Vaccine Chapter 9	DT-, TT-, and aP-Containing Vaccines Chapter 10	Meningococcal Vaccine Chapter 11	Injected-Related Events Chapter 12
Disseminated Oka VZV without Other Organ Involvement		•							
Disseminated Oka VZV with Subsequent Infection Resulting in Pneumonia, Meningitis, or Hepatitis		•							
Vaccine Strain Viral Reactivation without Other Organ Involvement		•							
Vaccine Strain Viral Reactivation with Subsequent Infection Resulting in Meningitis or Encephalitis		•							
Measles Inclusion Body Encephalitis	•								
Encephalitis	•		•		•		•	•	
Encephalopathy	•	•	•		•		•	•	
Infantile Spasms							•		
Seizures	•	•	○		•		•		
Meningitis	•								
Cerebellar Ataxia		•							
Ataxia	•						•		
Autism	•						•		

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Adverse Event	MMR Vaccine Chapter 4	Varicella Vaccine Chapter 5	Influenza Vaccine Chapter 6	Hepatitis A Vaccine Chapter 7	Hepatitis B Vaccine Chapter 8	HPV Vaccine Chapter 9	DT-, TT-, and aP-Containing Vaccines Chapter 10	Meningococcal Vaccine Chapter 11	Injected-Related Events Chapter 12
Acute Disseminated Encephalomyelitis	•	•	•	•	•	•	•	•	
Transverse Myelitis	•	•	•	•	•	•	•	•	
Optic Neuritis	○		○		○		○		
Neuromyelitis Optica	○		•		•	•			
Multiple Sclerosis	•		•	•	•	•	•	•	
First Demyelinating Event					•				
Guillain-Barré Syndrome	•	•	•	•	•	•	•	•	
Chronic Inflammatory Disseminated Polyneuropathy	•		•	•	•	•	•	•	
Opsoclonus Myoclonus Syndrome	•						•		
Bell's Palsy			•	•			•		
Brachial Neuritis	•		•		•	•			
Amyotrophic Lateral Sclerosis						•			
Small Fiber Neuropathy		○	•						
Anaphylaxis	•	•	•	•	•	•	•	•	
Chronic Urticaria							•		
Serum Sickness							•		
Asthma			•						
Erythema Nodosum					○				

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Adverse Event	MMR Vaccine Chapter 4	Varicella Vaccine Chapter 5	Influenza Vaccine Chapter 6	Hepatitis A Vaccine Chapter 7	Hepatitis B Vaccine Chapter 8	HPV Vaccine Chapter 9	DT-, TT-, and aP-Containing Vaccines Chapter 10	Meningococcal Vaccine Chapter 11	Injected-Related Events Chapter 12
Systemic Lupus Erythematous			•		•				
Vasculitis			•		•				
Polyarteritis Nodosa			•		•				
Psoriatic Arthritis					•				
Reactive Arthritis					•				
Rheumatoid Arthritis					•				
Juvenile Idiopathic Arthritis					•				
Arthropathy (Arthralgia and Arthritis)	•	•	•			•	•		
Type 1 Diabetes	•				•		•		
Hepatitis (Autoimmune)				•					
Myocarditis							•		
Pancreatitis						•			
Hepatitis	•								
Thromboembolic Events						•			
Stroke		○	•						
Hypercoagulable States						•			
Myocardial Infarction			•						
Chronic Fatigue Syndrome	•								
Chronic Headaches								•	
Fibromyalgia	•		•		•		•		

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Adverse Event	MMR Vaccine Chapter 4	Varicella Vaccine Chapter 5	Influenza Vaccine Chapter 6	Hepatitis A Vaccine Chapter 7	Hepatitis B Vaccine Chapter 8	HPV Vaccine Chapter 9	DT-, TT-, and aP-Containing Vaccines Chapter 10	Meningococcal Vaccine Chapter 11	Injected-Related Events Chapter 12
Sudden Infant Death Syndrome							•		
Hearing Loss	•								
All-Cause Mortality			○						
Oculorespiratory Syndrome			•						
Thrombocytopenia		•							
Immune Thrombocytopenic Purpura							•		
Complex Regional Pain Syndrome									•
Deltoid Bursitis									•
Syncope									•

NOTE: Adverse events indicated by "○" were added to the list by the committee.

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REFERENCES

CDC. 2001. Vaccinia (smallpox) vaccine recommendations of the Advisory Committee on Immunization Practices (ACIP), 2001. *MMWR Recomm Rep* 50(RR-10).

CDC. 2008. Human rabies prevention. *MMWR Recomm Rep* 57(RR-3):1-36.

CDC. 2010. *History of vaccine safety*. http://www.cdc.gov/vaccinesafety/Vaccine_Monitoring/history.html (accessed August 1, 2011).

DHHS. 2010. Deaths: Final data for 2007. *National Vital Statistics Reports* 58(19).

Guyer, B., M. A. Freedman, D. M. Strobino, and E. J. Sondik. 2000. Annual summary of vital statistics: Trends in the health of Americans during the 20th century. *Pediatrics* 106(6):1307-1317.

Institute of Medicine. 1991. *Adverse effects of pertussis and rubella vaccines: A report of the committee to review the adverse consequences of pertussis and rubella vaccines*. Washington, DC: National Academy Press.

Institute of Medicine. 1994. *Adverse events associated with childhood vaccines: Evidence bearing on causality*. Washington, DC: National Academy Press.

Institute of Medicine. 2001a. *Immunization safety review: Measles-mumps-rubella vaccine and autism*. Washington, DC: National Academy Press.

Institute of Medicine. 2001b. *Immunization safety review: Thimerosal -containing vaccines and neurodevelopmental disorders*. Washington, DC: National Academy Press.

Institute of Medicine. 2002a. *Immunization safety review: Hepatitis B vaccine and demyelinating neurological disorders*. Washington, DC: The National Academies Press.

Institute of Medicine. 2002b. *Immunization safety review: Multiple immunizations and immune dysfunction*. Washington, DC: National Academy Press.

Institute of Medicine. 2003a. *Immunization safety review: SV40 contamination of polio vaccine and cancer*. Washington, DC: The National Academies Press.

Institute of Medicine. 2003b. *Immunization safety review: Vaccinations and sudden unexpected death in infancy*. Washington, DC: The National Academies Press.

Institute of Medicine. 2004a. *Immunization safety review: Influenza vaccines and neurological complications*. Washington, DC: The National Academies Press.

Institute of Medicine. 2004b. *Immunization safety review: Vaccines and autism*. Washington, DC: The National Academies Press.

Johann-Liang, R. 2009. Charge to the Institute of medicine committee review of adverse effects of vaccines. Paper read at Meeting of the Institute of Medicine Committee Review of Adverse Effects of Vaccines, Washington, DC.

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