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Part H: Research Recommendations

Physical Activity Guidelines Advisory Committee (PAGAC) members were requested to consider the research needed to help resolve unanswered or inadequately answered questions they identified during their review of the science. Although a substantial amount of research on physical activity and health has been published since 1995, major gaps still exist in our knowledge needed to establish cause and effect for various health outcomes and to better define dose response, especially at the low and high ends of the activity spectrum. At the end of many of the chapters in *Part G: The Science Base*, authors have included a listing or discussion directed at needed research for specific health outcomes included in their review. This section initially focuses on some overarching recommendations that are applicable to many of the outcomes considered during the PAGAC review. Following these general recommendations are priority recommendations specific to the outcomes considered by each subcommittee.

Overarching Research Recommendations

Participant Diversity

One issue that became evident during the PAGAC review was the lack of data on selected subpopulations, especially various race/ethnic groups, persons of low socioeconomic status (SES), individuals with specific cognitive and physical disabilities, and obese persons. Some of these groups have been excluded from participation based on study eligibility/exclusion criteria (e.g., ability to walk at a moderate pace, read or speak English), or because study logistics precluded them from easily participating (e.g., travel distances, study visits during work hours). Since 1995, many studies that included women as subjects have been published. However, only a few have provided within-study comparisons of the impact of physical activity on health outcomes between the sexes.

Recommendations

- Because of the scientific and logistical challenges of including adequate-sized samples of multiple groups in a study conducted at one institution, well-designed and executed multi-center studies are needed in which each research site can have access to subjects who represent various specific understudied populations. This is critically important in providing investigators with opportunities to examine interactions between sociodemographic factors, particularly sex and race/ethnicity or SES, and physical activity in relation to health and to make inter-group comparisons.

- Funding agencies should support well-designed studies of individual understudied populations, especially race/ethnic minorities, persons of low SES, and individuals with physical and cognitive disabilities, so that major questions regarding the effects of exercise and effectiveness of physical activity interventions in each of these populations can be answered. If an organization funded a number of such studies with at least a core of shared measures, they would have a well-diversified research portfolio on understudied populations. Such an approach would more likely answer key questions than would an approach that requires each investigator to include relatively small numbers of understudied populations in their studies.
- Journal standards for peer-reviewed articles should require a reporting of the race/ethnicity (in addition to sex and age) of the sample and presentation of subgroup analyses by race/ethnicity and/or SES if sample sizes are sufficient, rather than simply treating these as co-variates and adjusting for them.

Dose Response

In each of the review chapters, the dose-response data currently available are summarized. Based on these reviews, it is apparent that major unanswered issues still exist in response to the question, “How much of what type of activity is enough to improve health?” To have sufficient statistical power to appropriately evaluate dose response in experimental studies, the overall sample size needs to be relatively large. In observational studies, it has been difficult to isolate parameters other than overall activity amount from data collected using questionnaires. Many experimental studies have used one level of physical activity as the intervention (usually that included in recent recommendations) and, consequently, evaluation of any dose-response effects must rely on post-hoc comparisons. Given that the number of dose-response questions that can be asked are nearly limitless when considering various activity characteristics (type, intensity, frequency, duration, amount/volume), possible health outcomes, and different populations, it is important that some priority be developed for which dose response questions are most important.

Recommendations

- Some recently published data indicate that physical activity of a lower intensity and/or smaller amount than is currently recommended may provide significant health benefits for chronically inactive or unfit adults (who comprise a large proportion of the American population aged 18 years and over) and older adults. Both experimental and observational studies are needed to answer a variety of questions about the nature of benefits provided and characteristics of dose required at the low end. The range of physical activity used in the intervention should include a dose below that currently identified in physical activity recommendations to evaluate its impact and the stability of this level of physical activity behavior over time.

- There remains a lack of data defining both the shape of the dose-response curve at the higher amounts and intensities of activity for most health outcomes and whether an upper limit of benefit exists. Most current recommendations focus on a minimal or target amount/intensity of activity that is consistent with much of the population receiving some benefit, but don't address questions of "optimal" or "maximal" benefit. Studies are needed to clarify the amount of physical activity, defined by metabolic equivalent (MET)-minutes per week or some other measure, at which additional improvements in various health outcomes no longer occur or at which increases are negated by increased adverse medical events.
- To fill the gap in our knowledge about dose response, investigators should design and conduct studies that evaluate effects of the following variables at fixed volumes of physical activity: intensity, frequency, duration, and multiple bouts. Details related to these variables would allow more precise physical activity guidelines to be developed across the breadth of activity-related health outcomes.
- Reasonable evidence exists that activity accumulated in short bouts throughout the day can favorably alter selected biomarkers for cardiovascular and metabolic diseases and improve cardiorespiratory fitness. However, no evidence is available that such patterns of activity may be beneficial for musculoskeletal health. Experimental studies are needed to extend this research involving activity bouts of different durations, especially multiple bouts shorter than 10 minutes and a few long bouts per week (e.g., 2 x 75 minutes) on various health outcomes. Observational studies are needed using assessment methodologies that will allow accurate quantification of a range of types of activity in different population groups (e.g., abdominally obese, frail elderly) and an evaluation of the effect of accumulation of short bouts on clinical outcomes independent of activity intensity and amount.

Measurement Methodology

The ability of the PAGAC to draw strong conclusions for various outcomes was limited by the wide variety of questionnaires used to assess physical activity and numerous different approaches to data analysis and presentation.

Recommendations

- Uniform data collection is needed with respect to the type of physical activity (e.g., leisure-time, occupational) and physical activity characteristics (e.g., intensity, duration, amount).
- The Compendium of Physical Activity has been very useful in assigning standardized values of absolute intensity to a wide range of activities, but it should be updated and expanded to children and youth.

- During the past decade, technology that provides for the objective assessment of physical activity in relatively large groups of subjects has increased rapidly, especially through the use of motion sensors and physiological monitoring. These technologies have the potential to greatly improve the accuracy and reliability of physical activity assessment in free-living populations leading to a better understanding of health benefits and dose response. Development and evaluation of these technologies are needed for assessing populations with different activity profiles and sociodemographic characteristics.
- A much better understanding is needed on how the results of physical activity assessed by new objective measurement methods can be compared to data collected by commonly used questionnaires.

Physical Activity and Physical Fitness Surveillance

Physical activity surveillance of the US population has been provided by the Behavioral Risk Factor Surveillance System (<http://www.cdc.gov/brfss/>), the Youth Risk Behavior Surveillance System (<http://www.cdc.gov/HealthyYouth/yrbs/index.htm>), and the National Health and Nutrition Examination Survey (<http://www.cdc.gov/nchs/nhanes.htm>), but the information provided by these surveys remains quite limited. Also, longitudinal physical fitness assessment of most population groups in the United States is non-existent. Lack of these data prevents evidence-informed decisions regarding the contribution any change in physical activity has on various health outcomes, such as the rapid increasing incidence of obesity, metabolic syndrome, and type 2 diabetes (T2D).

Recommendations

- Surveillance of the total activity energy expenditure of representative samples of the US population needs to be implemented once appropriate assessment tools have been developed and validated. Such tools could include either questionnaires or new objective measurement technology, or a combination of the two.
- Special attention needs to be given to the surveillance of both the physical activity and physical fitness of the US population at both ends of the age spectrum — toddlers/children and the oldest adults. These groups constitute a substantial portion of the US population and receive unique benefits from being physically active, but no national surveillance system for physical activity or physical fitness data exist for them.

Systematic Reviews and Meta-Analyses

During literature reviews by the PAGAC, it became evident that, for selected health outcomes in various populations, a large number of studies have been published since 1995, but neither quantitative systematic reviews nor meta-analyses have been published. Such

reviews would be very helpful in drawing conclusions about health benefits, modifiers of the effects of physical activity, and dose response.

Recommendations

- Experts investigating specific health outcomes from physical activity should assess the nature and volume of recent publications and determine whether quantitative reviews of the data would contribute to existing knowledge, help formulate guidelines and policy statements, and help set research priorities.

Research Recommendations of PAGAC Subcommittees

In the review chapters in *Part G: The Science Base*, each subcommittee highlighted areas in which data are lacking and provided guidance regarding research needs for specific populations and health outcomes. The following section provides a consolidation of the key recommendations from these chapters. The varying format and style of these recommendations reflects the different approaches that subcommittees took in identifying and articulating research needs in their topic areas.

All-Cause Mortality

- Empirical data are needed that are specific to minority populations – African Americans and Hispanics, in particular.
- Empirical data are needed that are specific to disabled populations, whether physically or intellectually disabled.
- Additional studies are needed to clarify whether all activities “count” equally, because limited data now suggest that vigorous-intensity activities are associated with additional risk reductions, beyond their contribution to total energy expended, when compared with moderate-intensity activities.
- Additional data are needed to help clarify the shape of the dose-response curve. An emphasis on two areas of data collection would be particularly useful: (1) uniform data collection to assess the same domains of physical activity (e.g., leisure-time, occupational, household, and/or commuting) across studies, and (2) collection of sufficient details on physical activity to assess different modes of exercise (e.g., aerobic versus strength training) as well as energy expenditure and intensity.
- Studies are needed to determine the point (if any) on the dose-response curve at which no further reduction in all-cause mortality occurs.

Cardiorespiratory Health

Studies are needed to answer the following questions:

- What is the time course of acquisition of the cardiovascular health benefits resulting from increases in habitual physical activity?
- What are the cardiovascular health benefits of varying exercise bout duration, frequency, and intensity, while controlling for total volume?
- What effects do daily exercise exposures accumulated in short bouts have on the acquired cardiovascular health benefits of habitual physical activity?
- What are the effects of resistance training on cardiovascular health and what is the nature of dose-response effects (varying intensity, bout volume, and frequency of programs)?
- Are there sex differences in cardiovascular health benefits of habitual physical activity when controlling for activity volume?
- What are the specific harmful effects of physical inactivity on cardiovascular health and what are the characteristics of the inactivity most likely to produce harm?
- What are the specific effects of aerobic training, resistance training, and a combination on selected biomarkers of vascular health, such as brachial artery flow mediated dilation? What are the dose-response effects?
- What are the main characteristics of an exercise program for preventing and treating peripheral arterial disease (PAD)? What are the exercise dose-response patterns, sex differences, exercise modality options, differential effects on diabetic patients with PAD, on asymptomatic patients and are biomarkers available to predict exercise responders?

Metabolic Health

- Available data indicate that regular physical activity is associated with reduced risk of metabolic syndrome. However, it is not clear whether physical activity and exercise can be used in treating or reversing metabolic syndrome, and additional studies will help to clarify this issue.
- Research is needed in diverse populations to determine whether the effects of physical activity across the range of metabolic health issues, including metabolic syndrome, T2D, type 1 diabetes (T1D), and gestational diabetes, differ with race and ethnicity.

- Further examination of the effects of physical activity on metabolic syndrome and T2D also is warranted to determine whether and how its effect differ in youth and adults.
- Additional research evaluating dose-response patterns of exercise in preventing diabetes and cardiovascular outcomes in diabetes would make a valuable contribution to the metabolic health literature.
- Randomized controlled trials (RCTs) are needed to examine the effects of exercise on treating T1D in children and adults. Good cardiovascular outcome data in response to physical activity in T1D is lacking and could potentially be obtained in adult-onset T1D.
- Clinical studies in post-exercise hypoglycemia are needed to further study the intermittent high-intensity exercise approach to prevention and to compare extra carbohydrate versus lower insulin-dosing approaches to treating T2D.
- Research is needed on several issues related to gestational diabetes. For example, RCTs are needed to determine whether physical activity can prevent gestational diabetes. It also would be useful to have additional dose-response data on the role of exercise and physical activity in treating gestational diabetes.

Energy Balance

- Additional large scale, multi-site RCTs are needed to more thoroughly characterize the dose response of physical activity on weight stability, weight loss, and body composition across a variety of population groups, especially for those in the normal body mass index range. Only a limited number of RCTs have addressed these outcomes. Large-scale multi-site RCTs would allow investigators to more effectively address issues related to susceptibility to weight gain or resistance to weight or fat loss that may vary by sex, race/ethnicity, and age. As mentioned in the overarching recommendations, various volumes should be evaluated within the same study design.
- Determine the most effective strategies for promoting and maintaining sufficient doses of physical activity to facilitate weight loss and/or weight stability. It is important to develop effective intervention strategies to promote and maintain the desired level of physical activity for weight loss and/or weight stability because adherence to this level of physical activity is currently less than optimal. Although some strategies have been shown to be effective for improving adherence to this level of physical activity, the success of these strategies has been demonstrated in limited samples and populations. Therefore, additional research in this area is needed.

- Determine how much physical activity is needed to prevent weight regain following weight loss. Most of the available literature related to this question is observational or has relied on retrospective analysis of self-selected and self-reported levels of physical activity. Use of state-of-the art technology and complete energy balance designs are absent from the literature. Specifically, it appears that no adequately powered studies of sufficient duration with randomization have been conducted to examine different levels of physical activity following weight loss.
- Determine the physical activity effects on total and regional fat loss from those of weight loss, per se, especially in those people very susceptible to weight gain in the current social environment and who thus may be most resistant to weight or fat loss with exercise. Additional RCTs are needed to distinguish physical activity effects from weight loss effect. In addition, the large-scale use of imaging techniques is necessary to distinguish between subcutaneous and visceral fat depots in their responsiveness to endurance and/or resistance training. The ability of studies to translate imaging findings into simple anthropometric measures such as the waist or the abdominal circumference would increase the clinical and personal utility of the research.
- More research is needed to establish the risks and benefits of various regimens of physical activity in men and women with a body mass index of 35 or greater.

Musculoskeletal Health

Bone Health

- Risk for osteoporotic fractures is strongly influenced both by bone fragility and by falling. Physical activity is the only therapeutic intervention that can both increase bone strength and reduce risk for falling. A large RCT of the effectiveness of physical activity versus anti-resorptive therapy (e.g., bisphosphonates) on the prevention of fractures is needed.
- Bone mineral density can be measured with a high degree of precision and remains the best predictor of risk for osteoporotic fracture. However, studies of animals provide evidence that small increases in bone mineral density in response to mechanical loading reflect very large increases in bone strength. Development of better technologies for the non-invasive assessment of bone strength in humans would provide additional insights into the relative effectiveness of physical activity to enhance bone strength and reduce fracture risk.

Joint Health

- Dose-response studies are needed to determine the optimal frequency, intensity and duration of physical activity associated with benefits (minimum dose) or increased

symptoms (maximum dose) among adults with arthritis and other rheumatic conditions.

- Longitudinal studies of the relationship of lifetime accumulation of moderate physical activity, particularly walking, and incident arthritis of all types among the non-elite athlete population are needed. Special attention should be paid to adequately capture potentially confounding and mediating variables.

Muscle Quantity and Quality

- Studies of the specific modes of physical activity that are most effective in preventing the age-associated decline in skeletal muscle mass and function are needed, with a focus on whether age-related changes in other factors (e.g., nutritional, hormonal) are important mediators of the response.
- Investigations should identify the underlying mechanisms that limit the capacity for muscle hypertrophy in response to resistance exercise with advancing age.

Functional Health

- Design large RCTs to determine whether physical activity can prevent or delay the onset of functional limitations and/or role limitations in older adults. Few controlled trials have confirmed the strong evidence from observational trials that physical activity prevents or delays the onset of functional and/or role limitations. Given the problem of confounding in observational studies, large RCTs are needed.
- Determine the dose response of multi-modal activities on improving functional health and reducing falls. Evidence suggests that moderate-intensity, multi-modal interventions can help improve functional health and reduce falls. However, we do not know whether physical activity has a threshold or dose effect. Studies are needed to determine whether a threshold below the current recommendations exists and whether higher-intensity interventions are more or less effective than moderate-intensity interventions.
- Determine whether the dose-response effect is relevant to single component versus multi-modal interventions. We need to know the dose response for each component of multi-component interventions, not just the dose response for the total intervention. This would provide information on how to mix components to achieve maximal benefit for a given amount of time and would help clarify whether single-mode physical activity interventions would be as successful at improving functional health as multi-modal interventions. No trials have addressed this question. Most trials have included multi-modal interventions in older adults.
- Determine whether physical activity reduces injurious falls (e.g., falls that result in fractures) in older adults at risk of falls. Physical activity reduces falls in older adults

at risk of falls; however, little is known about whether it can reduce injurious falls. An RCT is needed that has sufficient power to assess whether physical activity can reduce injurious falls.

Cancer

- Knowledge about the role of physical activity in reducing the risk of common cancers would benefit from additional evidence gathered from clinical trials. In the survivorship setting, clinical trials showing a benefit of physical activity interventions on reducing deaths, recurrences, and reducing the impact of late or long-term treatment effects also would make a valuable contribution to our understanding of the needs of this growing population.
- Studies are needed to clarify biological mechanisms linking physical activity to specific cancers in order to identify associations with less commonly studied cancers.
- Studies are needed to define the shape of the dose-response curve of the physical activity-cancer relation in order to determine the effect of low-intensity activities and accumulated bouts.
- Observational epidemiologic research is needed to identify the dose, type, and frequency of physical activity on risk of various cancer sites and subtypes, in addition to identifying the effect of physical activity on risk of specific cancers within particular population subgroups, including various races and ethnicities, ages, sexes, and groups at elevated risk of cancer.

Mental Health

- Additional prospective cohort studies and tightly controlled RCTs are needed, especially for anxiety and sleep disorders. Specifically:
 - Additional studies of under-represented groups and of people at high risk of mental health disorders are needed.
 - Selection of potential confounders specific to mental health risks need to be included in prospective cohort studies.
 - Reporting of adherence to and dropout from trials should be improved, particularly with respect to the impact on the trial's efficacy and likely population effectiveness.
 - Investigators should strive for convergence of subjective and objective measures of physical activity and should specify the social and environmental contexts in which physical activity occurs.

- Valid outcome measures need to be selected, refined, and used uniformly.
 - Physical activity exposures and outcomes need to be measured frequently to permit investigators to model change.
 - It would be helpful to conduct additional RCTs comparing the effects of exercise with other preventive interventions.
 - Novel designs that distinguish social moderators and mediators of outcomes from experimental contamination (i.e., placebo effects) would make a valuable contribution to the field.
- Studies are needed that manipulate or directly compare standardized features of physical activity, including type, intensity, and timing, with the settings in which activity takes place (e.g., group versus solitary, community versus home, indoor versus outdoor).
 - It would be helpful to accelerate the synergy between human brain imaging studies and neuroscience studies that use animal models of human disease. This improved synergy could help elucidate biological mechanisms underlying the benefits of physical activity to mental health. An increased emphasis on modeling of social-cognitive mediators of mental health outcomes and studies of gene-environment interactions also would be valuable additions to the field.

Youth

- Determine whether physical activity affects classroom behavior and academic achievement in children and adolescents.
- Determine whether physical activity affects depression, anxiety, and cognitive function in children and adolescents.
- Determine the types and amounts of physical activity that are needed to prevent the development of excessive adiposity during childhood and adolescence.
- Identify the optimal types and amounts of physical activity needed to maintain cardiorespiratory and metabolic health during childhood and adolescence.
- Establish the dose-response pattern for the relation between physical activity and bone health in children and adolescents.

Adverse Events

- Determine how one selects the initial increment (dose) of activity for individuals who have been inactive that will maximize continued participation and minimize

adverse events. Recommendations have been vague about the amount of activity a person should initially select.

- Determine how a person should select the size and frequency of increments to an activity plan for a previously inactive individual that will maximize continued participation and minimize adverse events. Although a 10% increase per week has been suggested for youth and young adults, and a 2 to 4 week interval for older adults has been suggested, little research exists to support such suggestions.
- Determine the incidence and risk factors for adverse events associated with walking.
- Current literature suggests that risks may be unrelated to either total volume of walking or intensity (using elevated treadmills). These findings need to be substantiated in other settings and populations.
- Research is needed on the rate of adverse events in various populations resulting from participation in various modes of physical activity, including weight-bearing and resistance training.
- Research is needed to provide evidence-based answers to the following questions regarding pre-participation medical screening. Does a recommendation for people to develop an activity plan with a health care provider prevent adverse events? Does it reduce participation in physical activity? If the answer to both questions is yes, what is the balance at the population level? Are such recommendations justified for certain population subgroups? If so, which ones?

Understudied Populations

People With Disabilities

- Prospective cohort studies should be conducted to determine the frequency, intensity, and duration of physical activity associated with key health outcomes, including reduction in certain secondary conditions associated with the specific disability subgroup (e.g., pain in spinal cord injury, fatigue in multiple sclerosis, reconditioning in intellectual disability). Studies should be stratified by age, functional level, and severity of disability.
- Multi-center clinical exercise trials should be conducted to achieve adequate statistical power and to be able to generalize findings to certain subgroups within the targeted disabilities (e.g., young adults with paraplegia). A high level of intervention fidelity must be established that employs the same testing instruments, procedures and training regimen. The heterogeneity between and within disability groups and the low incidence of many disabilities make it extremely difficult to obtain an adequate sample size when recruiting from only one location.

- RCTs are needed to examine the effects of various types of exercise in addition to the actual training volume (frequency, intensity, duration). Group exercise such as tai chi or yoga may have additional social benefit, which may improve outcomes but may also confound the benefit of the specific dose of exercise. Future studies should control for the social aspect of exercise so as to obtain accurate data on the exercise regimen itself versus the social benefits associated with exercising in a group.
- Improved self-report assessment tools should be developed to measure changes in health in disabled populations. It is difficult to make comparisons between studies when instruments are not the same or not explained well enough to make critical comparisons between them. Given the small numbers of many disabled subgroups, it would be helpful to have a recommended set of instruments for each targeted outcome with good psychometric properties so that data from various studies can be compared.
- Development of new and innovative strategies for recruiting disabled individuals who generally do not volunteer for research studies must become a high priority. Because most experimental research is conducted with volunteers, it is difficult to generalize a study's findings to the entire subgroup. People who volunteer for exercise-related research may be younger and/or have a higher functional level than the broader population of people with disabilities.
- Determine how self-report measures of social integration and/or quality of life are associated with objective measures, such as quantifying an increase in community participation (i.e., increased number of outdoor and/or social activities, greater amount of time outside the home for social events, increased employment). The fact that physical activity can improve mental health and quality of life is an intriguing concept that should be examined in future research on disabled populations with a more objective and standardized measurement of these outcomes.
- Develop research designs that categorize subjects by function rather than disability to increase recruitment and identify key health outcomes that generalize across disability groups. Given the difficulty in identifying and recruiting certain populations whose disabilities have low incidence (e.g., spina bifida, muscular dystrophy, cerebral palsy), use of the International Classification of Functioning Disability and Health (ICF) model would allow researchers to identify specific eligibility criteria by impairments (e.g., lower extremity paralysis) and/or activity limitations (e.g., unable to walk) rather than by disability.

Women During Pregnancy and the Postpartum Period

- Additional RCTs are needed evaluating activity regimens with different dose patterns on the course of labor and delivery.

- RCTs are needed to determine whether physical activity will help prevent gestational diabetes.
- More research is needed on dose response looking at the role of exercise/physical activity in treating gestational diabetes.
- Studies to compare effects of physical activity during pregnancy and the postpartum period in diverse race-ethnic groups are needed.
- Research is needed to examine the effect of physical activity in reducing risk of T2D in women with a history of gestational diabetes.

Racial and Ethnic Diversity

- An increased number of Federally-funded studies should be powered to include sufficient representation of at least one ethnic/minority or lower SES population, with sufficient sample size to permit subgroup analyses by race/ethnicity or SES. Strict exemption criteria should be rigorously applied.
- Cultural proficiency of recruitment and retention approaches and adequacy of resources directed toward recruitment and retention should be scrutinized by grant review committee members with special expertise in this area, similar to the separate assessments of adequacy of study methods and analytical approaches by review committee statisticians.
- Federal program officers should manage and balance their portfolios to ensure that racial/ethnic differences in physical activity-related exposures and outcomes are under active investigation, and should use requests for applications (RFAs) and other mechanisms to direct funding toward disparities examination and elimination.
- Journals should require reporting of race/ethnicity, sex, and SES of samples in the abstract as well as the body of the text.
- Subgroup analyses should be requested when sample size is sufficient, and further data desegregation should be encouraged to examine interactions between sociodemographic characteristics, e.g., sex-ethnicity, SES-ethnicity.
- Abstraction databases should include search criteria that permit ascertainment of inclusiveness (i.e., subgroup analyses by race/ethnicity or SES).
- Specific research questions deserve particular emphasis, such as the precise role in weight maintenance of racial anthropomorphic variations in resting or activity-related energy metabolism (as opposed to or in concert with age- or sex-related differences) in body composition.