

Examining the link between program implementation and behavior outcomes in the lifestyle education for activity program (LEAP)

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Abstract

Lifestyle Education for Activity Program (LEAP) was a comprehensive, school-based intervention designed to promote physical activity in high school girls. The intervention focused on changes in instructional practices and the school environment to affect personal, social, and environmental factors related to physical activity. Multiple process evaluation tools and an organizational assessment tool were developed to monitor program implementation from a framework called the LEAP essential elements, which characterized complete and acceptable intervention delivery; secular trends were also monitored. Using process data, LEAP intervention schools were categorized into low- and high-implementing groups and compared with control schools on nine essential elements assessed at the organizational level. The Wilcoxon scores test revealed that low- and high-implementing intervention, and control schools differed significantly on two of nine administrator-reported organizational-level components: having a physical activity team and having a faculty-staff health promotion program. A mixed-model analysis of covariance indicated that, compared to control schools, a greater percentage of girls in high-implementing schools reported engaging in vigorous physical activity. Process evaluation can be used to understand the relationship between level of implementation and successful program outcome.

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1. Introduction

Researchers have noted the great variability in health promotion program implementation and policy adoption in community and school settings (Dusenbury, Brannigan, Falco, & Hansen, 2003; Harachi, Abbott, Catalano, Haggerty, & Fleming, 1999; Helitzer, Yoon, Wallerstein, & Garcia-Velarde, 2000; Lillehoj, Griffin, & Spoth, 2004; McGraw et al., 2000; Scheirer, Shediak, & Cassady, 1995); in fact, few studies achieve full implementation of the intervention in field settings (Shadish, Cook, & Campbell,

2002). Program implementation can be influenced by many factors, including the implementers' level of motivation and skill, access to resources, and other unanticipated factors and barriers (McGraw et al., 1994). Further, an intervention's size (e.g., large or small), coverage (e.g., single or multi-site, local or national), and complexity (e.g., standardized or tailored intervention) affect implementation (Viadro, Earp, & Altpeter, 1997). Yet, outcome analyses are frequently conducted without an assessment of program implementation. This "black box" approach to evaluation assumes uniform implementation of the intervention (Harachi et al., 1999; Scheirer et al., 1995) and may result in a "Type III error" or concluding that a program was not effective when, in fact, it was not implemented completely and/or correctly (Dusenbury et al., 2003; Green & Kreuter, 1999; Harachi et al., 1999). Consequently, there

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has been increasing emphasis on the importance of measuring intervention implementation (Dusenbury et al., 2003; Harachi et al., 1999; Helitzer et al., 2000; Lillehoj et al., 2004; McGraw et al., 2000; Scheirer et al., 1995).

Process evaluation can play a key role in monitoring and ensuring successful implementation of a health promotion program (Baranowski & Stables, 2000; Bartholomew, Parcel, Kok, & Gotlieb, 2001; Green & Kreuter, 1999; Windsor, Baranowski, Clark, & Cutter, 1994). It can help prevent a “Type III” error through on-going monitoring to keep the program “on track” (formative use) (Devaney & Rossi, 1997; Helitzer & Yoon, 2002; Helitzer et al., 2000), and render a final judgment about the extent to which the program was implemented as planned (summative use) (Helitzer & Yoon, 2002; Helitzer et al., 2000). Carefully planned and collected process evaluation data can also be used to help clarify relationships among theoretical constructs and enhance understanding of program effects by linking intervention exposure to study outcomes (Baranowski & Stables, 2000; Helitzer & Yoon, 2002; McGraw et al., 1996; Scheirer et al., 1995; Steckler & Linnan, 2002). One analytic approach is to supplement “intent to treat” analytic approaches (which yields an unbiased estimate of the effects of being assigned to, but not of actually receiving, treatment) with analysis based on the amount of treatment received (Shadish et al., 2002). Studies that incorporate assessments of intervention implementation into outcome analyses often find stronger effects associated with a greater degree and/or fidelity of implementation, particularly when implementation is assessed by objective observers (Dusenbury et al., 2003; Harachi et al., 1999; Lillehoj et al., 2004; Resnicow et al., 1998).

Despite the potential benefits of conducting process evaluation, few studies report details of intervention implementation and even fewer use implementation data in the analysis of the primary study outcome. A recent summary of reviews about assessing intervention implementation in treatment, prevention, and education programs, revealed that only 6–24% of published reports described details of implementation (Dusenbury et al., 2003). Common problems identified in this review included lack of consistency in operational definitions of implementation constructs (e.g., what constitutes fidelity of implementation), limited use of methods (e.g., using provider reports only or a single observation), and use of measures without reported validity and/or reliability (Dusenbury et al., 2003; Lillehoj et al., 2004). Similarly, a recent review of studies measuring implementation of school programs and policies to promote physical activity and healthful eating found a lack of consistency and clarity in terminology, great variety in methods, and few reports of validity and reliability for measures (McGraw et al., 2000). However, some of the variability in measurement approaches across studies may be inherent to the task of measuring implementation because measures must be tied to the specific intervention (McGraw et al., 2000).

Furthermore, different methodologies may be needed for assessing classroom instruction compared to assessing adoption of policies (McGraw et al., 2000).

Recommendations for improvement in measuring intervention implementation include clearly defining what constitutes implementation by operationalizing the necessary program elements (Bartholomew et al., 2001; Harachi et al., 1999; Lillehoj et al., 2004; Scheirer et al., 1995); using a guide such as a logic model to guide planning and process data collection (Scheirer et al., 1995; Steckler & Linnan, 2002); developing multi-item indexes rather than single measures (Scheirer et al., 1995); and using multiple data sources (Bouffard, Taxman, & Silverman, 2003; Dusenbury et al., 2003).

The purpose of this paper is to describe, in the Lifestyle Education for Activity Program (LEAP), the use of process and organizational data to assess school-level program implementation in intervention schools and secular trends in control schools, and to examine the relationship between such implementation and the primary study outcome (self-reported vigorous physical activity (VPA) in high school girls). LEAP was a 2-year, comprehensive intervention designed to create instructional and environmental change in school settings to promote physical activity in girls in 12 high schools in South Carolina. LEAP intervention staff trained and provided on-going support to teachers and staff in the schools, who implemented LEAP in their schools. Specifically, this paper describes the (1) LEAP process evaluation framework, (2) use of process and organizational data to measure school-level implementation of LEAP in the 12 intervention schools and related secular trends in the 12 control schools, (3) relationship between school type (high- and low-implementing intervention schools and control schools) and administrator-reported change in organizational-level components, and (4) relationship between group membership and the primary study outcome of VPA in girls.

2. Background

2.1. Overview of the LEAP study design

The details of the design, methods, and outcomes of the LEAP are reported elsewhere (Pate et al., 2005). LEAP used an experimental cohort design with school as the unit of randomization and analysis for the primary study outcome (physical activity in high school girls). Twenty-four schools were paired by enrollment size, percent of enrolled girls who were African American, urban/suburban or rural location, and class structure (60- or 90-min classes), resulting in 12 intervention and 12 control schools. Schools from each pair were randomly assigned to control or intervention groups.

VPA was assessed using questionnaire data collected in two successive class cohorts, or “waves,” of students. Baseline measures were administered during the spring of the girls’ 8th grade year (middle school); exposure to the

physical education component of the intervention took place during the 9th grade year (high school). Follow-up measures were administered during the spring of the 9th grade year. The study was approved by the University of South Carolina Institutional Review Board.

The intervention was aimed at increasing the percentage of girls meeting physical activity guidelines by increasing the intensity and duration of physical activity during physical education classes and by promoting physical activity in other settings. The primary outcome variable was the percentage of girls in each school who reported participating in VPA (≥ 6 metabolic equivalents or METS) during an average of one or more 30-min blocks per day over the 3-day reporting period.

2.2. Overview of the LEAP intervention

An ecological model (Stokols, 1996) provided the organizing framework for the LEAP intervention and drew primarily from social cognitive theory (Bandura, 1986). In addition to using theories that could explain physical activity behavior at the individual level, the LEAP intervention model included influences on the school as an organization and activities needed for organizational and environmental change, including the eight-component coordinated school health program (CSHP) model (Allensworth & Kolbe, 1987; Wechsler, Devereaux, Davis, & Collins, 2000) with an emphasis on organizational infrastructure development (Allensworth, Lawson, Nicholson, & Wyche, 1997).

The LEAP intervention focused on changing personal, social, and environmental factors related to physical activity and involved changes to the school environment and instructional programs. Instructional program components included changes in physical education and health instruction to enhance physical activity self-efficacy and enjoyment and to help girls learn the physical and behavioral skills needed to adopt and maintain a physically active lifestyle. Schools were not required to implement a specific LEAP curriculum. Rather, to change instructional practice, teachers at all intervention schools received standardized training in the principles of LEAP (e.g., make PE fun and interesting for girls, develop lessons on goal-setting or seeking friends' support for activity), and then adapted their classes to create LEAP PE. Exposure to physical education took place during the 9th grade; approximately 80% of the girls in control and intervention schools were enrolled in 9th grade PE.

The environmental strategy involved changing school practices that encouraged and supported physical activity and included changes to school health services, faculty-staff health promotion, school environment, and school-community linkages. To change the school environment, LEAP provided standardized training for the LEAP teams. These teams assessed their own schools and adapted the LEAP elements to change the school environments to create their own, unique LEAP school. In addition to

providing training, LEAP staff facilitated adoption of LEAP in the schools by providing consultation and on-going support, as well as facilitating linkages between schools and local resources. The public health approach of LEAP focused on environmental change in the school setting; individuals in the target population (high school girls) were presumed to be in the school environment.

The LEAP intervention, as well as process evaluation results pertaining to LEAP intervention staff delivery of the intervention, are described in detail elsewhere (Ward et al., 2006). To summarize briefly, two full-time LEAP interventionists provided training primarily through 15 centralized workshops over 2 years with the 12 intervention schools (mean number of schools represented at each workshop = 9.6, ranging from 6–12) on the core topics of LEAP, such as working effectively as a team for environmental change and changing physical education class to incorporate LEAP PE instructional practices. Additional training and demonstrations were made for individual schools upon request. LEAP intervention staff created numerous resource materials for LEAP schools and maintained on-going contact with LEAP schools through scheduled visits, phone calls, and email. Communication was also maintained through newsletters and a listserv.

In summary, LEAP was a unique school-based intervention in that the intervention: (1) was adapted by teachers and staff at each school; (2) was based on a public health approach that emphasized change in the school environment and instructional practice; (3) involved LEAP intervention staff developing relationships and having on-going contact with the teachers and staff in the schools to facilitate LEAP implementation; and (4) had administrator-reported change in organizational-level components as an expected part of the intervention.

3. Measuring implementation

3.1. LEAP process evaluation framework and logic model

Process evaluation planning should be guided by defining “complete and acceptable delivery” of the intervention (Bartholomew et al., 2001) which, in turn, should be guided by a conceptual framework (McGraw et al., 1994) or logic model (Scheirer et al., 1995; Steckler & Linnan, 2002). Using theory to inform the development of process evaluation, ensures that key constructs underlying the intervention and corresponding key elements of the intervention are measured and documented (Israel et al., 1995; Steckler & Linnan, 2002).

Accordingly, in the first step in framework development, LEAP investigators and staff identified characteristics of the ideal LEAP program based on theory, literature, program experience, and intervention expertise. Through this process, investigators and staff conceptualized complete and acceptable delivery of LEAP (Bartholomew et al., 2001), the components of which became known as the LEAP “essential elements.” The original six components of

LEAP from the Coordinated School Health Program model were expanded to 16 “essential elements”, described in Table 1. The “essential elements” framework guided the development of the LEAP intervention, and the organizational assessment and process evaluation instruments. Schools were expected to implement all instructional

elements and three environmental elements (school administrator support, school physical activity team, and media messages promoting physical activity). All schools received training and strong encouragement to implement the remaining environmental elements (school nurse counseling, adult modeling through faculty/staff health

Table 1
The essential elements of the LEAP intervention and process evaluation data collection tools used for assessment

Essential element	Description	Data collection tools
<i>School environment components</i>		
● School administrator supports physical activity promotion	Tangible support from the principal for physical activity (PA) promotion, such as providing time and resources physical education (PE) classes and PA programs; participates on PA team	Process evaluation: record review, and LEAP criteria; organizational assessment
● School physical activity team	A team that regularly plans, implements and evaluates student and faculty PA programs	Process evaluation: record review, and LEAP criteria; organizational assessment
● Messages promoting physical activity are prominent in the school	School media used to promote PA, including newsletters, school announcements, television, video, stall talkers, bulletin boards, etc.	Process evaluation: record review, observational checklist, and LEAP criteria
● School nurse counseling for physical activity (health services)	School nurse regularly counsels students about PA and has materials related to PA in health room	Process evaluation: record review, and LEAP criteria; organizational assessment (have school nurse)
● Adult modeling of physical activity through faculty/staff health promotion	School has an active wellness program in place which sponsors PA programs for staff	Process evaluation: record review, and LEAP criteria; organizational assessment
● Health education reinforces messages and skills taught in physical education	Instructional activities in health education complement and reinforce those taught in PE	Process evaluation: record review, and LEAP criteria; organizational assessment (have health education beyond sex education)
● Girls have chances to be active outside of physical education class	Students frequently linked to PA opportunities in the community through school media	Process evaluation: record review, and LEAP criteria
● Family involvement	Families are provided information about PA, PA resources, and PA opportunities	Process evaluation: record review, and LEAP criteria; organizational assessment
● Community agency involvement	School collaborates with community agencies to provide PA programs and resources for students, faculty/staff, and families	Process evaluation: record review, and LEAP criteria; Organizational assessment
<i>School instructional components (primarily PE)</i>		
● Gender-separated classes	Gender-separate classes provide a supportive environment for girls; ranges from gender dominant (separation by choice of activity within coed class) to scheduling separate classes for males and females	Process evaluation: record review, observational checklist, and LEAP criteria
● Includes cooperative activities	PE has cooperative games, activities, and team-building, along with the traditional, competitive sport activities	Process evaluation: record review, observational checklist, and LEAP criteria; organizational assessment
● Emphasizes lifelong physical activity	Classes emphasize a variety lifetime PAs girls enjoy, such as dance, aerobics, strength training, etc	Process evaluation: record review, observational checklist, and LEAP criteria; organizational assessment
● Classes are fun and enjoyable	Fun/enjoyment facilitated by positive interactions with PE teacher, interaction with other girls, and enhancements such as music and a variety of activities	Process evaluation: record review, observational checklist, and LEAP criteria
● Classes are physically active	Students are engaged in moderate-to-vigorous PA for at least 50% of class time	Process evaluation: record review, observational checklist, and LEAP criteria
● Teaching methods are appropriate (e.g., emphasize small group activities)	The use of small enduring groups is consistent with emphasis on enjoyment and fun	Process evaluation: record review, observational checklist, and LEAP criteria
● Behavioral skills are taught (in physical education, health education, or designated class)	Behavioral skills training to adopt and maintain an active lifestyle include decision-making, goal-setting, overcoming barriers to PA, time management, and communication (support-seeking) provided	Process evaluation: record review, observational checklist, and LEAP criteria

promotion, health education reinforcement of messages, family involvement, and community involvement); however, these elements were not required, as many schools did not employ the additional personnel (e.g., school nurse, health education teacher, wellness coordinator) needed for these areas.

The LEAP Process Evaluation Logic Model, shown in Fig. 1, presents the chain of events that link intervention activities, school-level implementation, organizational-level components, and individual behavior outcomes (self-reported VPA in girls).

3.2. Purpose and scope of LEAP process evaluation

LEAP process evaluation included the following elements:

- (1) documenting dose of external intervention delivered (LEAP staff activities including training and all contacts with schools);
- (2) documenting reach (school teacher and staff participation and attendance in training);
- (3) getting school participant feedback (e.g., school staff and teachers and students);
- (4) providing feedback on program implementation for corrective action by LEAP staff;
- (5) monitoring fidelity and completeness of LEAP implementation;
- (6) monitoring the organizational-level implementation of LEAP components in intervention schools; and
- (7) monitoring environmental and policy factors in intervention and secular trends in control schools that could potentially affect program outcomes.

Items (1)–(4) are reported elsewhere (Ward et al., 2006). This article focuses on items (5)–(7). This comprehensive approach enabled us to assess the relationship of school implementation of intervention (process data) with organizational-level intervention components (organizational

data reported by school administrator), and to assess the impact of level of implementation (process data) on self-reported physical activity in high school girls (primary study outcome).

3.3. Process evaluation and organizational assessment instruments

The LEAP “essential elements” guided the development of three process evaluation instruments (record review, direct observation checklist, and LEAP criteria) and one organizational assessment instrument (organizational assessment interview). The instruments tapped into different data sources and assessed varying essential elements, as appropriate for a given data source (see Table 1). For example, the direct observation checklist was designed specifically to observe PE class, as well as limited aspects of the environment (e.g., school media promoting PA), and the organizational assessment interview was designed to tap into school-level policy and practice related to PA from the school administrator’s perspective. Table 2 provides an overview of LEAP process evaluation and organizational assessment data sources, methods, sample items, and rating scales and sample items for each instrument. As shown, all instruments had either 3- or 4-point response formats; each was summarized as an index. Content validity of each instrument was established by the investigators and staff based on the essential elements framework, and instruments were pilot-tested for clarity and appropriateness. A single independent process evaluator skilled in qualitative methods conducted all record reviews, direct observations, and organizational assessment interviews after receiving training. LEAP intervention staff conducted the LEAP criteria assessment, which included the LEAP PE criteria assessment as a subscale.

3.3.1. Record review

The record review was a 35-item instrument used to review LEAP intervention staff documentation for

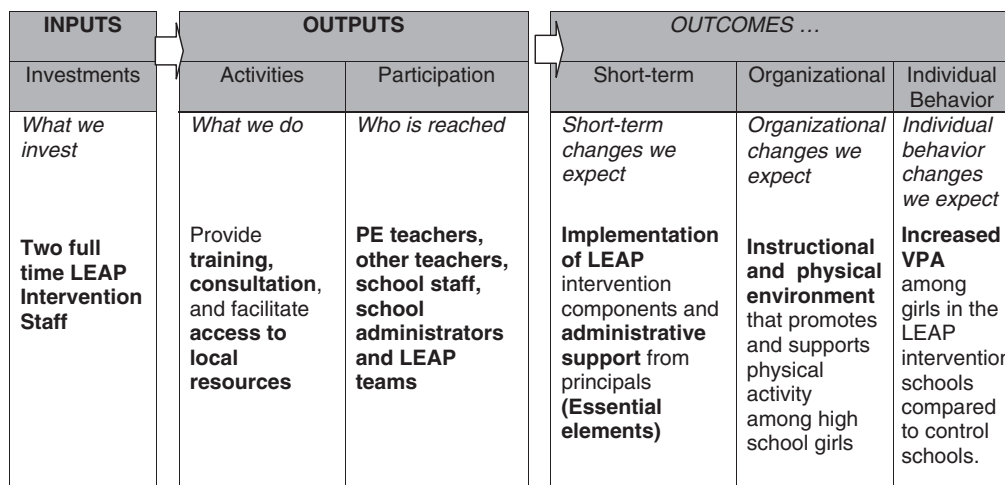


Fig. 1. LEAP process evaluation logic model.

Table 2
Data sources, methods, sample items, and rating scales from LEAP process evaluation and organizational assessment measures

Data collection tool and data source	Method and timing of data collection	Sample items	Rating scale
Record review: LEAP intervention staff records ^a	Independent process evaluator reviewed and rated progress on LEAP Essential Elements once per year	<p><i>Rate evidence for:</i></p> <ul style="list-style-type: none"> ● School physical activity team ● Administrative support for PA ● Lifetime PA is emphasized ● Active wellness program for staff 	<p>0 = Not found in records 1 = Documents indicate some activity 2 = Documents indicate organized activity 3 = Documents indicate organized activity highly consistent with LEAP philosophy and theory</p>
PE observational checklist: observation of selected PE classes and school environment	Independent process evaluator observed and rated two PE classes and selected aspects of school environment each semester	<p><i>Instruction</i></p> <ul style="list-style-type: none"> ● Most girls appear to be physically activity for at least 50% of class time. ● Students are organized into small, enduring groups <p><i>Environment:</i></p> <ul style="list-style-type: none"> ● Girls are linked to out-of-class physical activity opportunities via school media messages. 	<p>0 = No or none 1 = Sometimes 2 = Most of the time 3 = All of the time</p>
LEAP criteria: LEAP intervention staff	LEAP intervention staff rate progress on LEAP Essential Elements once per year based on observations and impressions	<ul style="list-style-type: none"> ● Does the school have a team that regularly plans, implements, and evaluates PA programs? ● Does the school have an active wellness program in place? ● Does the school collaborate with community organizational to provide PA programs and resources? 	<p>0 = No 1 = Partially 2 = Yes, completely</p>
LEAP PE criteria: LEAP intervention staff (subscale of LEAP criteria)	LEAP intervention staff rate progress on LEAP PE Essential Elements once per year based on observations and impressions	<ul style="list-style-type: none"> ● Is PE gender separate to provide a safe and supportive environment for girls? ● Does the curriculum provide variety and choice of lifetime activities popular among girls? ● Do instruction and management techniques include the use of small, enduring groups? 	<p>0 = No 1 = Partially 2 = Yes, completely</p>
Organizational assessment: school administrator	Process evaluator interviews assistant principal once per year	<ul style="list-style-type: none"> ● Does your school have a committee that meets regularly to plan events related to PA for students or staff? ● Does your school have an active wellness program in place? ● Does your school's PE program emphasize lifelong PA? 	<p>0 = No plans 1 = In planning stages 2 = Partially in place/partial support/minimal or new 3 = Fully in place/strong support/strong</p>

^aLEAP intervention staff records include contacts with schools, phone and email communication, school visitation logs, field notes, observations from site visits and phone consultations, information about training and training participation, descriptive information from the schools, and summaries of schools' LEAP accomplishments.

evidence on all 16 essential elements (see Table 1) in intervention schools; additional items on the scale assessed details such as having adequate space and budget for PE, availability of physical activity facilities on school grounds, and recognition of physical education program (PE award). LEAP intervention staff maintained extensive documentation of intervention activities, including contacts with schools, phone and email communication, school visitation logs, field notes, and observations from site visits and phone consultations. School records also contained information about staff training and training participation, descriptive information from schools, and summaries of schools' accomplishments. The independent process evaluator went through the records annually, rating each school's progress on LEAP intervention elements. Sample items are shown in Table 2; also reflected in Table 2 is the 4-point rating scale for this instrument, ranging from 0 (not found in records) to 3 (documents indicate organized activity highly consistent with LEAP philosophy and theory).

3.3.2. Direct observation checklist

The direct observation checklist was a 25-item observational tool used to assess seven essential elements specific to physical education and one environmental essential element (messages promoting physical activity) in the 12 intervention schools (see Table 1). Additional items on the scale assessed details such as the inclusion of warm-up activities and reinforcing girls for out-of-class physical activity. The independent process evaluator observed two PE class-sessions per semester for each intervention school during spring semester of each intervention year; to avoid schedule conflicts at the school, observations were scheduled in advance. Sample items are provided in Table 2; each item was rated on a 4-point scale from 0 (no or none) to 3 (all of the time).

3.3.3. LEAP criteria and LEAP PE criteria—ratings by intervention staff

LEAP intervention staff used the LEAP criteria to assess all 16 essential elements in the intervention schools; the PE subscale focused specifically on the seven LEAP instructional essential elements, which was a major emphasis of the intervention (see Table 1). These instruments were completed at the end of each academic year based on staff records, observations, and interactions with the intervention schools, as a way to summarize each intervention school's progress on LEAP essential element implementation. Sample items are provided in Table 2; each item was rated on a 3-point scale: 0 (no), 1 (partially), or 2 (yes, completely).

3.3.4. Organizational assessment interview

The organizational assessment interview was a 22-item interview (administered in 10–15 min) conducted by the independent process evaluator in all intervention and control schools with a school administrator (usually

assistant principal), to assess organizational-level components (i.e., school environment and instruction practices consistent with the LEAP intervention). This tool assessed organizational-level factors and, unlike the process tools described in the previous section, was not designed to measure implementation. Because it was administered in all schools, items in this instrument were worded without specific reference to the LEAP intervention components. As a result, the wording of some items differed from the wording in the other data collection tools. In intervention schools, the administrator interviewed was not directly involved in LEAP intervention implementation. As shown in Table 1, the organizational assessment rated nine of the essential elements, including seven environmental factors and two instructional factors. Additional items assessed events and activities (secular events) that could affect project outcomes such as participation in physical education teacher training and receiving an award in school health, and organizational resources such as budget for physical education. As shown in Table 2, each item was rated on a 4-point scale, from 0 (no plans) to 3 (fully in place/strong support/strong); also shown are sample items.

3.4. Data analysis for measuring implementation

Data obtained during the second year of the 2-year intervention were used for process evaluation and organizational outcome analyses. The rating scales from all instruments, including the organizational assessment, were considered ordinal level measurement. Data were summarized or analyzed by process evaluation objective, as described below.

3.4.1. Assessing fidelity and completeness of LEAP intervention implementation

Fidelity and completeness of LEAP implementation were examined in two ways: implementation of the LEAP essential elements considering all intervention schools combined, and implementation of the LEAP essential elements in each intervention school individually. Fidelity and completeness of LEAP implementation for all 12 intervention schools combined was determined by tallying the number of schools in which a given element had been “adopted” based on the record review. An element was “adopted” if records indicated “organized activity” or “organized activity highly consistent with LEAP theory and philosophy”. This resulted in a list of LEAP components from most to least adopted in all 12 intervention schools.

Fidelity and completeness of LEAP implementation for each school individually was assessed using multiple data sources via the three process evaluation data collection tools: record review (comprehensive assessment of extensive LEAP intervention staff documentation), direct observation checklist (observation of instructional practices and one environmental element), and LEAP criteria, including the LEAP PE criteria used as a separate subscale

(LEAP intervention staff comprehensive assessment). The ratings for the essential element items in each scale were summed to create a single index score for each of these four scales, resulting in four scores for each school. The 12 intervention schools were then rank-ordered by total score according to each data source from highest to lowest level of implementation. Because the data sources and specific essential elements assessed varied for each instrument, we did not expect directly comparable scores; rather, we used information from these multiple data sources collectively to assess level of implementation. Based on the rank ordering with these scores, schools were sorted into two groups, high- and low-implementers. Low-implementers were defined as schools that were consistently ranked in the lowest third in all data sources.

3.4.2. Assessing school implementation of LEAP and organizational-level components

We examined the relationship between fidelity and completeness of LEAP implementation (assessed through process evaluation) and organizational-level components (assessed by the organizational assessment). Schools classified into the high- and low-implementation and control groups were compared on nine essential elements measured by the organizational assessment using the non-parametric Wilcoxon rank scores test: Administrative support for physical activity, active physical activity team, health services, faculty-staff health promotion, health education, family involvement, community agency involvement, cooperative options in physical education, and an emphasis on lifelong physical activity in physical education. A significance level of $p \leq .05$ was accepted for all tests.

3.5. Results for measuring implementation

3.5.1. School resources and secular trends

Organizational assessment interviews conducted in the first year of LEAP indicated that intervention and control schools did not differ on organizational resources that could affect LEAP implementation or outcomes, such as PE budget, space for PE, or availability of health education teacher and school nurses. Secular trends assessment during the second year indicated that three control schools scored highly on three LEAP essential elements: physical activity team, active health promotion for faculty and staff, and emphasis on lifelong physical activity in PE. These schools were retained in the sample; this conservative strategy would tend to reduce the ability to detect differences between control and intervention schools.

3.5.2. Fidelity and completeness of LEAP intervention implementation

The most frequently adopted essential element for all intervention schools combined, based on the record review, was physical education (five PE essential elements were implemented in eight or more schools). The majority of

schools (eight) also adopted two of the four environmental essential elements community linkages and active LEAP team. The least frequently adopted essential elements (recommended) pertained to components in health education, health services, and family involvement (reported in four or fewer schools) (see Table 3). On average, the 12 intervention schools implemented eight of the 10 required essential elements.

Table 4 presents the rankings of each intervention school using multiple data sources and process evaluation instruments (record review, PE observational checklist, LEAP criteria, and LEAP PE criteria). As shown in the table, four intervention schools were consistently ranked in the bottom third on at least three of the four scales. A fifth school was ranked in the bottom third two out of four times, was never ranked in the top third, and was ranked very low in PE (based on LEAP PE criteria). This school was also put into the low-implementing group, resulting in five of the 12 schools being classified as “low implementers.”

3.5.3. Relationship between school implementation of LEAP and organizational-level components

A comparison of high- and low-implementing intervention and control schools on administrator-reported organizational elements using the Wilcoxon rank scores test is

Table 3

Levels of implementation of essential elements across schools from most to least number of schools implementing based on project records ($n = 12$)

Essential Element	Review of project records: number of schools adopting
Emphasizes lifelong physical activity in physical education	12
Physical education classes are fun and enjoyable	10
Girls are physically active in physical education	10
Messages about physical activity are prominent in the school	10
Gender separation in physical education classes	9
Physical education includes cooperative activities	8
Community agency involvement	8
Active LEAP team	8
Faculty/staff health promotion	6
Teachers use appropriate methods in physical education (e.g., small group interaction)	6
Administrative support	6
Behavioral skills for physical activity are taught	6
Girls have opportunity to be active outside of class	5
Health education reinforces messages and skills from physical education	4
Health services: school nurse provide counseling for physical activity	3
Family involvement	3

presented in Table 5. School administrators in the high-implementing, compared to low-implementing and control groups, reported significantly higher organization level practices for two of the nine essential elements: having a physical activity team and having a faculty-staff health promotion program.

4. Relating implementation to outcomes for participants

4.1. Physical activity assessment

Physical activity was assessed using a self-reported questionnaire, the 3-day physical activity recall (3DPAR), a modification of the previous day physical activity recall (PDPAR), which has been shown to be valid and reliable

Table 4
LEAP intervention schools (n = 12) ranked from highest to lowest index score for level of implementation of essential elements (year 2) using multiple data sources

Rank	Record review	PE observations	LEAP criteria	LEAP criteria PE
1	G	G	I	C, G, L
2	C	L	G	B, J
3	A, B	F	C, J	A, F
4	F	A	B, L	H
5	D*	B	F	K*
6	J, L	D*	A	I*
7	H*	J	D*	E*
8	K*, E*	C	K*	D*
9	I*	I*	H*	
10		H*	E*	
11		K*		
12		E*		

Note: Homes ranked in the lower third are italic; schools in bold* are assigned to low implementation group
Alphabetical list of school codes: A, B, C, D*, E*, F, G, H*, I*, J, K*, L.

(Trost, Ward, McGraw, & Pate, 1999; Weston, Petosa, & Pate, 1997). In a recent validity study, VPA as measured by the 3DPAR was correlated ($r = .41, p < .001$) with log transformed accelerometry in 70 8th and 9th grade girls (Pate, Ross, Dowda, Trost, & Sirard, 2003). Our correlation of .41 is typical for studies using motion sensors to validate self-report instruments in youth (Kohl, Fulton, & Caspersen, 2000; Sirard & Pate, 2001). The 3DPAR showed good reproducibility and validity in a sample of Brazilian youth (Goulart et al., 2001), and has also demonstrated factorial validity and invariance in adolescent girls using confirmatory factor analysis (Motl, Dishman, Dowda, & Pate, 2004).

The 3DPAR was administered by trained research staff to 1604 ninth grade girls; participants providing previous consent were scheduled for survey administration in small groups (for ease of administration) in each school. Participants recalled their physical activity behavior for each of the three previous days, beginning with the most recent day. The 3DPAR is administered with a standardized script along with graphic figures to explain the intensity level of common activities. The instrument was always administered on a Wednesday; participants were asked to complete a separate form for each day recalled (Tuesday, Monday, and then Sunday). A subject reported the predominant activity she performed during each of 34 30-min blocks (7:00 am to midnight), choosing from a list of 55 that were grouped into six categories: sleeping/bathing, eating, work, after-school/spare-time/hobbies, transportation, and physical activities/sports. The 3DPAR includes a rating of intensity because many activities can be performed at varying intensities; including an intensity rating for each reported activity enhances the validity of the instrument (Weston et al., 1997).

Each activity was assigned a MET value using the Compendium of Physical Activities (Ainsworth et al., 2000). The MET value assigned to an activity was based on the typical intensity range for that activity adjusted for the

Table 5
Comparing high implementing intervention schools, low implementing intervention schools, and control schools on organizational assessment using Wilcoxon scores (Rank Sums)

Essential element	Rank sum score		χ^2	P	
	Intervention				
	High (n = 7)	Low (n = 5)			
Active physical activity team	18.0	11.6	9.7	7.34	.03
Administrative support	13.9	9.5	13.2	2.44	.29
Emphasizing lifelong PE	15.5	8.6	12.4	4.84	.09
Cooperative options in PE	15.4	10.9	11.4	3.13	.21
Provide health services	14.7	14.4	10.4	2.86	.24
Health promotion for staff	19.0	10.6	9.5	9.59	.01
Provide health education	12.8	12.1	12.5	.07	.35
Coordinate physical activity events with community	15.4	12.7	15.6	2.09	.39
Family involvement	12.0	10.0	13.8	1.46	.48

Bolded item showed statistically significant differences

Table 6
Comparison of physical activity variables in girls attending high- and low-implementing intervention schools and control schools

Variable	Unadjusted means (\pm SD)						Adjusted means at follow-up (+SD)				
	Control ($n = 740$)		Low ($n = 336$)		High ($n = 527$)		Control	Low	High	P group	P trend
	Pre	Post	Pre	Post	Pre	Post					
1 block VPA/day (%)	45.6 (3.4)	39.1 (2.9)	41.7 (5.2)	37.1 (4.4)	39.1 (4.3)	47.0 (3.7)	36.4 (2.8)	39.8 (3.9)	47.6 (3.2)	.05	.02

Controlling for wave, wave \times group interaction, baseline BMI, race, and school.

subject's intensity rating (light, moderate, hard, or very hard). Data from each day were reduced to the number of moderate to vigorous (≥ 3 METs; MVPA) and vigorous (≥ 6 METs; VPA) 30-min blocks, and an average was calculated for each of these variables over the 3 days. Only data from the primary study outcome, VPA (e.g., running, very active sport participation), are presented in this paper. Data were collected by trained, university-based research staff.

4.2. Analysis: school implementation of LEAP and VPA in girls

As noted previously in the study design overview section, VPA was assessed using data collected in two successive "waves" or cohorts of students. Baseline measures were administered during the spring of the girls' 8th grade year (middle school) and follow-up measures were administered during the spring of the 9th grade year.

We used a mixed-model analysis of covariance (ANCOVA) to examine the relationship among the three groups (high implementation, low implementation, and control) and the primary study outcome (self-reported VPA in girls). Level of implementation was the independent variable and the follow-up value of physical activity was the dependent variable with baseline physical activity as a covariate. Analyses were adjusted for wave, interaction of wave and group, baseline BMI, race and school. A test for trend or linear dose response was calculated for each of the physical activity variables. Because the girls were from 24 different high schools and students within a school share a unique social and physical environment, the statistical analysis was designed to control for the influence of school. In all analyses, school was treated as a random variable and the student-level covariates were fixed. A significance level of $\leq .05$ was accepted for all tests.

4.3. Results: school implementation of LEAP and VPA in girls

Seventy-six percent of girls ($n = 2111$) who were measured at baseline were also measured at follow-up. Girls who were measured at follow-up did not differ from those who were lost to follow-up in age, BMI, or proportion reporting regular VPA at baseline. A slightly higher percentage of girls lost to follow-up were African American than white (53.7% vs. 47.4%). Girls were lost to

follow-up because they transferred to another school, had a class schedule that conflicted with the measurement schedule, or declined to participate. After excluding 506 girls who were missing data for physical activity, BMI, and/or race, complete data on 1604 girls were available for analysis. For those girls there were no significant differences in the demographic variables (age, BMI, and percentage of African American girls) between girls in the control and intervention schools. Detailed results of the LEAP intervention are reported elsewhere (Pate et al., 2005).

As shown in Table 6, the prevalence of girls participating in an average of one or more 30-min blocks of VPA differed significantly among the three groups after adjusting for baseline data and other covariates. Pair-wise comparisons showed that girls in the high implementation schools had a higher prevalence of participation in VPA (48% with an average of one or more 30 min blocks of VPA) than girls in control schools (36% with an average of one or more 30 min blocks of VPA). The test for a linear dose–response was also significant, indicating a dose effect in proportions of participation in VPA from control, low implementers to high implementers. As reported elsewhere (Pate et al., 2005), the overall effects of the intervention on percentage of girls reporting VPA remained significant even after adjusting for the intensity of activity in PE class. This indicates that the intervention effect was due to increased overall physical activity, and not solely attributable to increased activity in physical education.

5. Discussion

5.1. Measuring implementation in an environmental intervention

LEAP, a multi-component public health intervention, was designed to promote physical activity in high school girls by targeting personal, social, and environmental factors related to physical activity through changes to the school environment and instructional programs. Three important considerations defined the LEAP approach to measuring program implementation. First, LEAP engaged in a systematic process to develop a framework that was used to guide process evaluation and organizational assessment. The essential element framework operationally defined high quality and complete implementation of LEAP. Based on this framework, multiple instruments

tapping into multiple data sources were developed to objectively assess intervention implementation. Second, the intervention and the process evaluation framework were focused on the school organization and environment as the unit of analysis (rather than on reaching individual girls, who were presumed to be within the environment). Finally, LEAP was implemented by existing personnel in each intervention school, who adapted the LEAP intervention after receiving staff development and with on-going consultation from LEAP staff. Due to the complexity of the LEAP intervention, it was essential that we examine the chain of events or causal pathway guided by the LEAP logic model from LEAP staff activities, to school teacher and staff activities (fidelity and completeness of school implementation), and organizational-level variables (instructional and physical environment in schools as reported by school administrators). Additionally, process evaluation data were used to help understand the impact of the intervention implementation on self-reported VPA in high school girls, the primary outcome for the study.

5.2. Fidelity and completeness of the LEAP intervention implementation

Fidelity and completeness of implementation in the LEAP intervention was defined by the essential elements framework, which described “complete and acceptable” delivery of LEAP at the school level. As recommended, we used multiple process evaluation data sources to assess fidelity and completeness (Bouffard et al., 2003; Helitzer & Yoon, 2002). In contrast to many school-based studies, LEAP focused on changing the school environment and instructional practice, and did not provide a specific LEAP curriculum. Therefore, fidelity and completeness pertained to changes in the school environment and instructional practice, as guided by the essential elements. Process data sources to assess implementation were records and documents to assess environmental and policy approaches, observations of instructional practices to assess classroom instruction (McGraw et al., 2000), and the ratings of LEAP intervention staff. Data were gathered using objective rating instruments, which were scored as indexes.

Considering all 12 intervention schools combined, LEAP documented the greatest change in physical education, with an average of five of the seven PE elements rated as implemented. This result is expected since LEAP PE was a primary focus of the intervention. The least-documented areas of organizational activity were health education and health services. This can be explained in part because LEAP relied on the schools’ existing resources to implement these components, and most schools were not fully staffed with health education teachers or nurses. As noted previously, less intervention emphasis was placed on these elements due to the documented variability in schools’ having schools nurses and certified health teachers.

Process evaluation data on implementation of the essential elements was used to group schools into high- and low-

implementing groups. The seven schools in the high-implementing group had higher total index scores for fidelity and completeness of intervention implementation; whereas the five schools in the low implementing groups had lower scores. Variability in intervention implementation has been consistently reported in a variety of settings (Dusenbury et al., 2003; Harachi et al., 1999; Helitzer et al., 2000; McGraw et al., 2000; Scheirer et al., 1995), and incomplete implementation of interventions in “real world” settings is well documented (Shadish et al., 2002). Although greater implementation could likely have been achieved by providing additional resources to the schools (e.g., LEAP intervention staff directly implementing certain elements), this was not consistent with the LEAP staff development and organizational change approach, nor would it result in sustainable changes in the school environment.

5.3. Relationship between school implementation of LEAP and organizational-level components

Schools grouped into high- and low-implementing (based on level of intervention implementation) and control schools were compared on organizational assessment scores. The organizational assessment interview with the assistant principal as key informant was used to measure organizational-level factors consistent with the intervention. The three groups differed significantly on two of the nine essential elements, both of which pertained to the school environment: having a LEAP team and an active faculty-staff health promotion program. Thus, in high-implementing schools, a school administrator not directly involved in the intervention reported changes in several organizational elements extending beyond physical education. This result is consistent with developing a school psychosocial environment that supports physical activity through school policies, role modeling by school staff, and environmental cues (Wechsler et al., 2000), and illustrates the development of some organizational infrastructure to promote physical activity (Allensworth et al., 1997). These differences suggest that some of the LEAP effects were obtained from intervention elements outside of physical education, and are consistent with the results of the LEAP outcomes paper (Pate et al., 2005).

The difficulty of making environmental and organizational practice change is reflected in that the three groups differed on only two of the nine elements assessed at the organizational level. However, this is not a measure of implementation, but rather is a reflection organizational change, which possibly resulted from LEAP implementation in the intervention schools.

5.4. School implementation of LEAP and self-reported VPA outcome in girls

An important, but underused, application of process evaluation data is to explain the effects of intervention implementation on the primary study outcome (Baranowski

& Stables, 2000; McGraw et al., 1996; Steckler & Linnan, 2002). To our knowledge, LEAP is the first physical activity intervention in a school setting to show better program outcomes (increased prevalence of self-reported VPA) directly associated with greater school level program implementation. Girls in the high implementing schools showed a higher prevalence of participation in VPA compared to girls in the control schools. The CATCH intervention (in elementary schools) was successful in producing significant increases in physical activity, largely through increased activity in physical education (Luepker et al., 1996; McKenzie et al., 1996). CATCH also conducted an extensive process evaluation (McGraw et al., 1994); however, the relationship between implementation and outcomes was examined only for the curriculum component in CATCH (McGraw et al., 1996). The LEAP results are also consistent with the results of most previous studies focused on curriculum implementation in health education and drug abuse prevention, particularly when intervention implementation was assessed by objective observers (Dusenbury et al., 2003; Harachi et al., 1999; Lillehoj et al., 2004; Resnicow et al., 1998).

5.5. Lessons learned

The LEAP essential elements provided an effective framework for a comprehensive assessment of LEAP implementation, including the selection of data sources and development of data collection instruments and methods early in the intervention process. The framework provided an effective structure for prioritizing, collecting, and summarizing process evaluation data from multiple data sources. Going through the structured process for developing the essential elements enabled LEAP investigators and staff to come to consensus about what LEAP should be and required investigators and staff to make specific linkages between the underlying theory of LEAP and strategies used in the intervention. The framework also provided a clear and concrete way to characterize complete and acceptable delivery of LEAP, which guided training for the teachers and school staff who implemented LEAP with LEAP intervention staff guidance. Finally, the essential elements framework enabled us to organize, synthesize and use an extensive amount of documentation and data for formative and summative purposes (Cooksy, Gill, & Kelly, 2001).

The full essential elements framework contained 16 elements, which were identified prior to intervention implementation based on the ideal scenario. We did not expect the ideal scenario to be realized in all schools, and as expected, determined that many schools lacked regular access to school nurses and health education teachers. Therefore, we indicated to the schools that all instructional (seven elements) and three environmental elements were required, whereas the remaining six elements were strongly encouraged. This strategy preserved the integrity of the framework, while allowing school adaptation based on

local resources. School adaptation of the intervention was planned as part of the LEAP intervention.

Using intervention staff records as a data source is an effective approach if the records are consistently kept for all schools, and are detailed as well as current; fortunately with LEAP, this was the case. However, it should be noted that the quality of data from a record review are only as good as the records themselves. Use of multiple data sources was a strength of this study. However, different data sources (e.g., intervention staff, administrators, observations of teachers) tap into different perspectives and different elements of the intervention, and cannot be compared directly. The triangulation approach we used to rank order schools in implementation is an effective use of multiple, valid, and different points of view.

5.6. Limitations

The LEAP process evaluation instruments were assessed for content validity based on the essential elements framework and are pertinent only for this intervention. The essential elements framework was specific to LEAP and, therefore, these tools apply uniquely to the LEAP intervention. However, tailoring tools for specific intervention needs is appropriate, and this approach could be utilized in subsequent intervention models. The process instruments used in this study need further reliability assessment. Because a single, independent process evaluator collected process and organizational data, it was not possible to assess inter-rater reliability. The 3DPAR, shown to be valid and reliable for assessing physical activity in this population, is a self-report measure of physical activity. The unit of analysis for assessing organizational implementation was the school, resulting in a small sample size ($n = 24$) for comparisons among intervention and control schools. Finally, the three groups (high- and low-implementing and control schools) differed significantly on relatively few organizational-level components to promote physical activity as reported by a school administrator (two of nine). Even so, there were significant differences in VPA in girls in high- and low-implementing and control schools. This paper illustrates the importance of process evaluation, not only to monitor program implementation, but to compare program implementation to program outcomes.

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