Economic Evaluation of a Primary Care Trial to Reduce Weight Gain in Overweight/Obese Children: The LEAP Trial

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Background.—A common policy response to the childhood obesity epidemic is to recommend that primary care physicians screen for and offer counseling to the overweight/obese. As the literature suggests, this approach may be ineffective; it is important to document the opportunity costs incurred by brief primary care obesity interventions that ultimately may not alter body mass index (BMI) trajectory.

Methods.—Live, Eat and Play (LEAP) was a randomized controlled trial of a brief secondary prevention intervention delivered by family physicians in 2002–2003 that targeted overweight/mildly obese children aged 5 to 9 years. Primary care utilization was prospectively audited via medical records, and parents reported family resource use by written questionnaire. Outcome measures were BMI (primary) and parent-reported physical activity and dietary habits (secondary) in intervention compared with control children.

Results.—The cost of LEAP per intervention family was AU $4094 greater than for control families, mainly due to increased family resources devoted to child physical activity. Total health sector costs were AU $873 per intervention family and AU $64 per control, a difference of AU $809 ($P < .001$). At 15 months, intervention children did not differ significantly in adjusted BMI or daily physical activity scores compared with the control group, but dietary habits had improved.

Conclusions.—This brief intervention resulted in higher costs to families and the health care sector, which could have been devoted to other uses that do create benefits to health and/or family well-being. This has implications for countries such as the United States, the United Kingdom, and Australia, whose current guidelines recommend routine surveillance and counseling for high child BMI in the primary care sector.

KEY WORDS: cost effectiveness; obesity; primary care; randomized controlled trial; secondary prevention

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Childhood obesity is now endemic in almost all industrialized countries.[1] Effective prevention and management strategies are urgently needed to reduce the associated psychosocial[2] and physical morbidity.[3,4] To date, the more effective interventions for childhood obesity have been of relatively high intensity, delivered over more than 6 months to treatment-seeking parents and children attending hospital-based obesity programs.[5,6] However, the sheer scale of the epidemic would seem to preclude their provision to all those that might benefit. In 2006, the estimated prevalence of obesity in American school-age children was 13.2% and the estimated prevalence of those overweight was 26.8%[1] using International Obesity Taskforce cutpoints,[7] equating to more than 9 million obese children and 19 million overweight children aged 2 to 18 years in the United States alone.[8]

Therefore, a brief, secondary prevention, primary care intervention would be extremely attractive if effective. Such is the level of policy and public concern about the childhood obesity epidemic that family practitioners may be encouraged to offer counseling and other interventions[9]—even when the evidence does not support the effectiveness of such efforts[10,11]—so long as it is perceived that they are not harmful. Thus, national policies in many countries, including the United Kingdom,[12] the United States,[13] and Australia,[14] now explicitly endorse primary health care providers as central to identification of and counseling for childhood overweight and obesity. It is therefore important that the harms of such approaches are evaluated and reported. One aspect of harm is opportunity costs—the investments in a program required by health care providers and families that could instead have been devoted to some alternative use or program that creates greater benefits to health and/or family well-being.

For the 25% of Australian elementary school children who are overweight or obese (International Obesity Taskforce definitions),[15–17] the only universally accessed, individualized health care service is that delivered by family (general) practitioners (GPs). The prevalence of overweight and obesity in children attending family practice

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settings is known to mirror or exceed that in the general population.[18,19] Therefore, GPs could potentially make an important contribution within a primary health care setting, both in ongoing surveillance and in delivering a targeted individualized intervention within the existing health care system. However, no reported trials have yet examined the costs that would be associated with such an intervention.

We report a cost-consequence analysis to compare costs borne by families and the health care system to outcomes of the Live, Eat and Play (LEAP) program. LEAP was a randomized controlled trial of a brief, secondary prevention intervention delivered by GPs to reduce weight gain by targeting physical activity and dietary habits in overweight/mildly obese Australian children aged 5 to 9 years. Though in some aspects encouraging, ultimately it did not meet its primary aim of achieving lower body mass index (BMI) in the intervention group relative to control children.[20]

METHODS

The LEAP randomized controlled trial was conducted during 2002–2003 in 29 family medical practices in Melbourne, Australia. Detailed methods and processes of the randomized controlled trial are reported elsewhere.[21] Briefly, in early 2002, 34 GPs were recruited into LEAP and took part in a series of three 2.5-hour educational sessions at local venues; a range of adult learning styles were used. All 34 GPs attended at least 2 of the 3 education sessions and 75% attended all 3, with 85% reporting good or very good relevance to general practice. Subsequently, 2112 children aged 5 to 9 years attending participating practices for any reason during June to December 2002 were prospectively weighed and measured by practice staff. Of the 412 overweight/obese children identified and subsequently contacted by LEAP, parents of 163 (40%) provided written informed consent and were individually randomized into the randomized controlled trial on return of baseline questionnaires.[7] Very obese children ($n = 85$, UK BMI z score ≥ 3.0[22]) were excluded on the basis that a brief secondary prevention approach was not supported by the literature. Parents were asked to attend 4 consultations with their GP over a 12-week period (1 "long" of 30–40 minutes duration and 3 "standard" of 15–20 minutes duration), with or without their child present. The project was approved by the Royal Children's Hospital Ethics in Human Research Committee.

The primary outcome was the children's BMI (kg/m^2), measured by trained, blinded researchers 9 months and 15 months after the first consultation baseline measurement, adjusted for baseline BMI. The 2 secondary outcomes for this economic analysis were child physical activity and dietary habits, both reported by parents at 9 months and 15 months by using 4-day food and activity diaries over 2 weekdays and 2 weekend days. Afternoon child physical activity was measured prospectively using a modified Bouchard parent-rated activity diary completed between 3:30 PM to 6:30 PM daily for the 4 days,[23] from which was calculated percentage of time spent being active (light, moderate, and intense activities). Average daily activity scores were calculated from parent ratings of children's activity on a scale of 1 (sedentary) to 7 (intense activity) at 15-minute intervals between 3:30 PM and 6:30 PM over 4 days. Parents reported their children's consumption of 14 "healthy" (eg, fruit, vegetables, low-fat milk) and "less healthy" (eg, whole-fat milk, sweetened drinks) food and drink categories over the four 24-hour periods (0 = none, 1 = once, 2 = twice or more). After reverse coding the less healthy categories, an average daily dietary habits score was derived (possible range, 0–28) with a higher score indicating a better diet.

Resource Use

Our objective was to estimate the resource use that would be required to repeat the intervention. Therefore, the costs of the initial development of the LEAP intervention, training materials, and all research costs are excluded. Relevant resource use includes both investment of health care resources (such as GP visits) and family resources (such as additional time and money required to meet changed dietary and physical activity practices). Resource use and costs of the LEAP intervention were derived from 3 main sources: the LEAP team records, practice audit, and parent written questionnaires at 9 months.

LEAP Team Records

Program delivery costs include staff time and materials required to recruit and train GPs in the LEAP intervention, as well as the equipment required for each GP to measure baseline BMI, and all travel and communication costs associated with the running of the intervention. The time of GPs and other practice staff invested in training activities is not included. Thirty-four GPs from 29 practices took part, and it is this scale of GP involvement that largely determines the intervention provision costs rather than the actual number of parent and child participants. Staff time costs, travel costs, and costs of communication (GP newsletters, phone calls, etc) were taken from the records of the LEAP study team.

Practice Audit

The practice records of all LEAP children were audited after the 9-month follow-up. LEAP visits were recorded separately from other GP attendances. All other GP visits were assumed to be of average length (15–20 minutes duration, determined by using Medicare Benefits Schedule B).[24] All visits were costed according to the Medicare Benefits Schedule fee rates current for the year 2003. Around 30% of families in Australia pay an additional out-of-pocket "gap fee" when they visit a GP. In this study, all GPs received a AU $10 additional payment from study funds for each LEAP visit, and this AU $10 average additional fee is assumed to reflect any gap fee that would be charged if the intervention were rolled out in practice. We did not collect data on gap fees charged for other GP visits, so family resource use estimates exclude this aspect of the cost of accessing health care.

Parent Questionnaire

In the 9-month written questionnaire, parents reported time and travel costs associated with LEAP visits. Time and travel costs borne by families associated with non-LEAP GP visits were imputed at the mean value for standard LEAP consultations. At 9 months and 15 months, parents reported weekly family expenditure on groceries/food shopping and meals bought outside the home, child physical activity and sports and estimated time spent by each member of the household helping their child be physically active or play sports in a typical week, and costs of any new sports or activity equipment purchased since the beginning of LEAP. Parents reported any additional assistance sought to help their child achieve a healthier lifestyle and/or weight. Missing data were imputed at mean values; because findings were similar for the imputed and nonimputed data, only the former are presented here. Parent time was valued at the 2003 average Australian full-time wage of AU $900 per week[25] and travel costs accrued by car travel valued at 50 cents per kilometer. No value was placed on the time of the children.

Statistical Analysis

Costs and outcomes are reported separately. Analysis methods for outcome data have been detailed elsewhere.[20] Economic analysis was conducted in Microsoft Excel (Microsoft Corporation, Bellevue, Wash) on an intention-to-treat basis. All costs are shown in 2003 Australian dollars. Sensitivity analysis was conducted to assess the robustness of results to variation in unit cost estimates used (average wage rates, GP visit costs) and to variation in intervention costs (assuming greater numbers of children treated per GP).

RESULTS

Audit data were available for all 82 intervention and 81 control children, and parent questionnaire data were available for 65 (79%) intervention and 72 (89%) control children at 9 months and for 64 (78%) intervention and 70 (86%) control children at 15 months.

Table 1 summarizes LEAP program delivery costs. The total cost of providing the LEAP intervention was AU $57 812. This equates to AU $1994 per participating practice, AU $1700 per GP trained, or AU $705 per intervention child (Table 2). The monetary value of resources used by families associated with or due to the LEAP program is shown in Table 2.

Table 2 also shows the costs of visits to the GP for the health care sector and for families. The 82 intervention families had a total of 319 visits over the 9-month audit period, of which 229 were LEAP visits, with 41%, 21%, 17%, 17%, and 4% attending 4, 3, 2, 1 and no GP LEAP sessions, respectively; because there was no strong evidence that number of sessions influenced outcomes,[20] no stratified analyses were conducted. Of 81 controls, 54 had at least 1 visit to the GP, with a total of 177 visits. LEAP visits (travel, waiting, and consultation time inclusive) took, on average, 80 minutes for the first visit and 50 minutes for each subsequent visit. Of the 61 intervention parents reporting mode of transport, all traveled by car (80%), foot (10%), or both (10%); none used public transportation. Table 2 reports the total GP costs per family; the underlying average travel cost per GP visit was AU $6, and average time cost was AU $28 for a standard (15–20 minute consultation) visit.

Table 1. Costs to LEAP Team of Program Delivery*

Component	Value, $†
General communication	413
GP‡ recruitment (3 sessions)	1980
GP training (8 sessions)	12 122
Practice costs (29 practices)	29 994
Practice set-up (staff time and travel)	7075
Scales, stadiometers, and weights	14 415
Stationery, etc for BMI§ measurement (2000 children)	8504
Family materials (200 families)	13 303
Total LEAP provision costs	57 812
Average cost per child/family in LEAP	705

*LEAP indicates Live, Eat and Play program.
†Currency is given in 2003 Australian dollars.
‡GP indicates general practitioner.
§BMI indicates body mass index.

Also shown in Table 2 is the value of time and money invested by families in child physical activity and dietary habits, according to intervention or control status. Purchases of new equipment for child physical activity or sports were similar between groups over the 15-month period and were reported by 71% of intervention parents (mean purchase cost, AU $251) and 74% of control parents (mean purchase cost, AU $162). The amount of money spent for adults to help the child to be physically active or to play sports were similar in the 2 groups. However, there were statistically significant differences in adult time spent on child physical activity and sport in the first 9 months, with adults in the intervention families spending on average 7.8 hours helping their child be physically active or play sports in a typical week, compared with 4.9 hours by adult family members of control families. At the average Australian wage rate, this represented a family weekly time investment of AU $259 and AU $163 per child for intervention and control families, respectively. This additional time investment by intervention families was not sustained; over the following 6-month period the amount of time spent by adults helping their child be physically active or play sports was similar in intervention (4.8 hours) and control families (5.3 hours). The amount spent by the family in a typical week on groceries/food shopping and meals bought outside the home was similar between groups over the 15-month period. Average reported time invested in grocery shopping and meal preparation was also similar between groups over the 15-month period (8.3 hours for intervention parents and 8.7 hours for control parents, valued at a family weekly time investment of AU $278 and AU $292 per child for intervention and control families, respectively).

Sixteen percent of intervention families and 17% of control families sought additional assistance to help their child achieve a healthier lifestyle and/or weight. Most of this

Table 2. Average Costs Per Child/Family Associated with the LEAP Program*

Type of cost	Mean Cost		*P* Value
	Intervention†	Control†	
1. LEAP intervention	705	0	.001
2. Total LEAP visit costs	284	0	<.001
GP‡ costs	136	0	<.001
Time costs	133	0	<.001
Travel costs	15	0	.001
3. Total other GP visit costs	68	138	.008
GP costs	32	64	.01
Time costs	29	61	.006
Travel costs	6	12	.07
4. Total GP visit costs (item 2 + item 3)	352	138	.001
5. Additional assistance sought over 15 mo	6	12	.30
6. Sports/physical activity purchases over 15 mo	181	121	.06
7. Total weekly expenses	223	212	.33
Sports/physical activity expenses over first 9 mo	44	25	.12
Sports/physical activity expenses over next 6 mo	28	24	.34
Food/meal expenses§	185	187	.77
8. Total weekly adult time costs	497	460	.04
Adult time in child physical activity over first 9 mo	259	163	<.001
Adult time in child physical activity over next 6 mo	160	177	.39
Adult time in shopping/meal preparation§	278	292	.52
9. Weekly expenses and time costs over 15 mo ([item 7 + item 8] × 65)	46 803	43 682	.03
10. Total cost (items 1 + 4 + 5 + 6 + 9)	48 047	43 953	.01

*LEAP indicates Live, Eat and Play program.
†Currency is given in 2003 Australian dollars.
‡GP indicates general practitioner.
§Because time and expenses did not vary within groups between the 2 reporting periods, average for the 15-month period is given.

assistance was provided free of charge from family and friends or from information sourced through books, television, or the Internet. Additional help and advice was associated with additional expenditure for 6% of intervention families (mean AU $103) and 8% of control families (mean AU $122).

Mean total cost for all parties combined is AU $48 047 for intervention and AU $43 953 for control families (Table 3). This difference is driven by 3 factors: the cost of providing the LEAP intervention, which is spread over 82 cases (2.4 cases per GP), the cost of GP visits to the health sector and to families, and the value of adult time invested in child physical activity and sports during the first 9 months of the intervention. An economic evaluation conducted from the perspective of the Australian government would include only costs borne by Medicare and health providers and exclude family time costs and expenses. For these revised cost estimates, mean cost is AU $873 for intervention and AU $64 for control families.

As a cost-consequence analysis, the cost-effectiveness of the LEAP program depends on whether the outcomes attained are judged to be worth this additional investment of government and family resources. The primary outcome in LEAP was child BMI, adjusted for baseline BMI. At 9 months, the BMI of the intervention group, adjusted for baseline BMI, was 0.25 kg/m^2 less than the control group (95% CI, 0.6–0.1; $P = .25$), and at 15 months there was no difference in adjusted BMI (Table 3) or daily physical activity. However, LEAP had a sustained positive impact on dietary habits scores.

Table 4 shows a series of "what if . . . ?" or sensitivity analyses for the additional cost associated with LEAP by altering the main aspects of costing methods for which a viable alternative exists. The impact of changing these costing assumptions is shown first individually (items 1–4) and then combined. Time spent on GP visits would otherwise have been spent largely on household and childcare tasks, with only 9% of parents reporting that they would otherwise have been working. In sensitivity analysis, we therefore assess the impact on cost results of valuing parents' time at 50% and 0% (instead of 100%) of the Australian average wage. In case the increased intervention family time spent on child physical activity was due to a Hawthorne effect, we also assess the contribution of this family time difference between groups by setting this to zero. Table 4 also

Table 3. Cost-Consequence Analysis for the LEAP* Program†

Measures at 15 months	Intervention Mean (SD)	Control Mean (SD)	Difference Between Groups	
			Mean (SD)	*P* Value
Mean total cost	$48 047	$43 953	$4,094 ($864 to $7324)	.01¶
Mean health care cost	$873	$64	$809 ($784 to $833)	<.001¶
BMI‡ (kg/m^2)	21.7 (3.1)	21.2 (2.4)	−0.0 (−0.5 to 0.5)	1.00**
BMI *z* score	2.00 (0.68)	1.92 (0.59)	−0.03 (−0.17 to 0.10)	.62**
Activity time in MVPA, %§	39.2 (19.3)	35.2 (20.5)	3.2 (−2.8 to 9.5)	.29**
Daily physical activity||	3.3 (0.5)	3.2 (0.5)	0.2 (−0.0 to 0.3)	.08**
Daily dietary habits||	18.7 (2.0)	16.1 (2.7)	1.6 (0.9 to 2.3)	<.001**

*LEAP indicates Live, Eat and Play program; SD indicates standard deviation.
†Intervention and control groups are compared on outcome measures. Currency is given in 2003 Australian dollars.
‡BMI indicates body mass index.
§MVPA indicates moderate to vigorous physical activity.
||Higher scores indicate greater activity level and healthier dietary habits.
¶Student's *t* test.
**Outcome values compared using analysis of covariance, adjusted for baseline values.

Table 4. Sensitivity Analysis on Costs of LEAP*

	Mean Total Cost†	Mean Health Care Cost†
Baseline	\$4,094 ($P = .01$)	\$809 ($P < .001$)
1. Value of parents' time		
(a) 50% average wage	\$2,828 ($P = .009$)	\$809 ($P < .001$)
(b) Valued at \$0	\$1,562 ($P = .03$)	\$809 ($P < .001$)
2. Equal parents' time on physical activity	\$756 ($P = .53$)	\$809 ($P < .001$)
3. Unit cost of GP‡ visit		
(a) All visits \$20	\$4,024 ($P = .02$)	\$739 ($P < .001$)
(b) Other visits \$100	\$4,017 ($P = .02$)	\$732 ($P < .001$)
4. Economies of scale		
(a) 5 cases per GP	\$3,778 ($P = .02$)	\$492 ($P < .001$)
(b) 10 cases per GP	\$3,658 ($P = .03$)	\$372 ($P < .001$)
(c) 30 cases per GP	\$3,585 ($P = .03$)	\$300 ($P < .001$)
Combinations		
1(b) + 4(c)	\$1,053 ($P = .14$)	\$300 ($P < .001$)
1(b) + 3(b) + 4(c)	\$976 ($P = .18$)	\$223 ($P < .001$)
2 + 4(c)	\$247 ($P = .84$)	\$300 ($P < .001$)
2 + 3(b) + 4(c)	\$170 ($P = .89$)	\$223 ($P < .001$)

*LEAP indicates Live, Eat and Play program.

†Cost difference between groups (intervention-control) under alternate costing assumptions. Currency is given in 2003 Australian dollars.

‡GP indicates general practitioner.

shows the effect of using lower and higher estimates of the cost of a GP visit (AU \$20, AU \$100) to incorporate the excluded category of GP charges borne by families, and the difference in costs associated with providing the intervention to 5, 10, and 30 children per GP.

In all scenarios, there remains a significant additional health care cost associated with the LEAP intervention. However, additional costs to families are dependent on the reported difference in family time spent on child physical activity.

DISCUSSION

From a combined health sector and family perspective, the cost of LEAP per intervention child was AU \$4094 greater than for children of control families, largely as a result of increased family resources devoted to child physical activity. Total costs borne by the health sector were AU \$873 per intervention family and AU \$64 per control. This investment did not improve the primary outcome measure of child BMI in the intervention group relative to controls at 9 or 15 months, although there was some evidence of modest improvement in parent-reported dietary habits. The cost-effectiveness of LEAP depends on the value placed on this secondary outcome achieved for the additional investment of government and societal resources. It also depends on the reproducibility, longevity, and sustainability of these findings in larger trials.

The additional costs to both the health care sector and families demonstrated a high opportunity cost of this intervention. The comparison of costs and effects suggests that resources could be better used elsewhere within the obesity-prevention and/or broader public health budget. This does not mean that efforts to develop effective primary care interventions should cease—far from it—and these authors are currently completing a larger trial (LEAP 2, ISRCTN52511065), following a similar approach but incorporating learnings from the trial reported here. However, the fact that this and other[10] brief targeted child obesity prevention interventions have so far demonstrated minimal effectiveness shows just how important it is that primary care does not simply adopt untrialed approaches because they seem sensible. Rather, new primary care approaches must be developed, all should be rigorously trialed, and collection of economic data to understand the relative costs and consequences should become routine. Such efforts should carefully consider the existing primary care context. Many family practitioners in both the United States[26] and Australia[27] believe that they could potentially be effective in obesity management, and there is some evidence that obesity-related counseling has increased over the last decade.[28] However, even the introduction of routine measurement of BMI—apparently so simple—has proved surprisingly challenging,[27,29] and it should not be assumed that, even if achieved, the ensuing counseling would be helpful.

Strengths of this study include its randomized design and resource use and costs for both the health care sector and for families were reported. Limitations include the self-selected nature of the GPs. The LEAP program delivery cost per intervention child was relatively high due to the artificially small number of intervention children seen (2.4 per GP); if this rose to 30 children per GP per year, this cost would fall to AU \$196 per case. To limit respondent burden, data were not collected on GP fees charged in excess of Medicare Schedule fee rates or on parent time and travel costs for other GP visits or for other assistance sought, but the sensitivity analysis suggests that these items would have had only a minor effect on results. Although one could argue that total time spent on shopping and activities with children incurs some fixed minimum cost in our modern society, there is a valid opportunity cost of the additional time investments made by families in the intervention arm (compared with the control arm) as a result of the intervention, as these are hours that could be productively spent elsewhere. It is also possible that the true LEAP health care costs were slightly overestimated, because Table 2 suggests some cost-shifting of general health care into the LEAP visits for the intervention group.

The lack of evidence on the cost-effectiveness of interventions to promote health is nowhere more evident than in the field of childhood obesity.[30] Therefore, this study offers valuable new information. Very few studies have assessed the cost-effectiveness of a child obesity intervention.[31,32] Of these, 1 trial-based economic analysis assessed an intensive 13-week program of family therapy, which may not be widely available or generalizable to all families with overweight/obese children.[31] The other was a model-based cost-utility analysis of a child obesity prevention program that estimated program costs retrospectively and modeled future health benefits and associated cost savings to the health system and to society from reduced obesity-related morbidity and mortality.[32] We believe the current epidemiological evidence on long-term sequelae of childhood obesity is insufficient to support such modeling with any strength, so we prefer to present cost-effectiveness results in the basic form chosen here.

Given the policy and health relevance of the child obesity epidemic, it is essential that any assessment of potential interventions includes measures of monetary and other costs to evaluate outcomes relative to intervention inputs from providers, families, and society. This will allow governments and families essential information to make choices as to which, if any, programs they invest in.

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