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Lessons Learned from the HEALTHY Primary Prevention Trial of Risk Factors for Type 2 Diabetes in Middle-School Youth

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Abstract

The HEALTHY trial was designed to take a primary prevention approach to risk factors for type 2 diabetes in youth, primarily obesity. The study involved over 6000 students at 42 middle schools across the US. Half received an integrated intervention program of components addressing the school food environment, physical education, lifestyle behaviors, and promotional messaging. The intervention was designed to be more comprehensive than previous efforts and the research was amply funded. Though the primary objective of reducing percent overweight and obese in schools that received the intervention program compared to control schools was not obtained, key secondary outcomes indicated an intervention effect. In retrospect, senior investigators involved in the study's design, conduct, and analysis discuss weaknesses and strengths, and offer recommendations for future research efforts that address prevention of childhood obesity from a public health perspective.

Keywords

obesity; metabolic risk; cardiovascular risk; prevention; school-based health promotion; pre-adolescence; cluster design trial; diabetes; HEALTHY

Introduction

The increase in childhood obesity and the concomitant rise in type 2 diabetes (T2D) in youth [1,2] have been the impetus to develop and evaluate interventions to prevent obesity and to

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lower diabetes risk factors. Schools traditionally have been the target of pediatric health promotion efforts because the majority of US children spend a significant amount of time in school and school personnel are capable of influencing student behavior and learning [3–5]. Nevertheless, school-based obesity prevention programs have yielded mixed results, and overall, findings on the prevention of weight gain have been disappointing [6].

The HEALTHY study was funded by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) as part of an initiative to address the alarming increase in T2D rates in youth, and was designed with the explicit intent to maximize the potency of school-based obesity prevention by addressing the shortcomings of previous investigations. Specifically, HEALTHY was amply funded, included substantive preparatory formative work and pilot testing, was planned by a multidisciplinary group of investigators with expertise in obesity prevention, diabetes and school-based research, employed a multi-component intervention designed to integrate evidence-informed elements that targeted all aspects of the environment, and was delivered with high fidelity.

Surprisingly, despite the extensive planning, pilot work, and high fidelity in implementing the HEALTHY intervention, there was a similar reduction in the proportion of overweight and obese children (~4%) in both control and intervention schools, i.e., results were not significant [7]. There was, however, a significantly greater effect in intervention schools on a number of important secondary endpoints, including obesity (BMI ≥ 95th percentile), elevated waist circumference, BMI z-score, and fasting insulin, particularly among students who were overweight and obese at baseline. Although the favorable changes in secondary endpoints were encouraging, the failure to obtain a significant difference between intervention and control schools in reducing the combined prevalence of overweight and obesity was disappointing.

In light of the critical need to develop successful obesity prevention efforts and mitigate risk for T2D in youth, we think it is imperative to evaluate the HEALTHY study experience. In this paper we provide an overview of the participants and methods to highlight the carefully considered design features of the HEALTHY trial, detail the lessons learned from the multi-site cooperative investigation, and elucidate the implications of the HEALTHY study for future obesity prevention efforts.

HEALTHY Study

HEALTHY was conducted at seven US sites in 42 schools (three intervention and three control schools at each site) and included more than 6000 students over a period of 3 years between 2006 and 2009. Schools that were selected had 50% or more ethnic minority or students who qualified for free or reduced price lunch in order to engage a population known to be at high risk for T2D. Parents consented to youth participation and students provided assent for study assessments. Baseline assessments were conducted in the fall of 6th grade and the intervention began after winter holiday break in 6th grade and continued through the spring of 8th grade when final outcomes measures were obtained.

The primary prevention trial was planned by a group of investigators with diverse expertise related to obesity, obesity prevention, diabetes, and school-based research in conjunction with NIDDK. During a series of planning meetings that included a review of previous school-based prevention trials, the study group designed the HEALTHY trial with the intent to address the limitations found in previous school-based health promotion initiatives. The HEALTHY design and methods have been reported in detail [8–14], but major design features are summarized below.

HEALTHY focused on middle school children

Given the overarching goal of reducing risk factors associated with the development of T2D, the study group determined that middle school was the optimal environment for the intervention. Importantly, middle school children typically are undergoing pubertal changes that increase insulin resistance, alter body composition, and affect other risk factors for T2D [15–22]. Further, as children transition from childhood to adolescence they eat fewer meals at home, become more independent in choosing meals and physical activities, and are increasingly influenced by peers. Finally, middle school youth are developmentally capable of increasing personal responsibility for behavior change.

HEALTHY was designed to address previous research limitations related to the scope of the intervention

School-based trials typically have focused on a single environmental change such as the cafeteria, physical education, or health curriculum. For example, numerous trials have emphasized diet quality but not strategies to promote behavior change or moderate overall intake, which are necessary to reduce obesity. Similarly, there have been many studies that have focused on activity levels by targeting physical education [23–27]. The HEALTHY investigators concluded that most previous efforts that targeted physical education did not optimize efforts to obtain moderate-to-vigorous physical activity (MVPA), which has been associated with positive changes in diabetes risk factors [28–29]. In response, HEALTHY was designed to maintain MVPA for the duration of a physical education class in all students by providing training, equipment, and an innovative curriculum that was consistent with state mandates. Finally, although there were numerous school-based interventions that focused on health education, few previous studies provided instruction, practice, tools, and strategies for behavior change.

In summary, the study group concluded that in order to reduce the risk for T2D the program needed to intervene on multiple levels in the school, i.e., environmental, social, and individual, and implement a comprehensive multi-component intervention. The HEALTHY program was designed to involve the total school environment and included improving the quality of the foods and beverages offered in the school food service, utilizing the school cafeteria as a learning opportunity, restructuring physical education (PE) classes to maximize MVPA, delivering in-class education and behavior change lesson plans and materials, reaching out to parents and families, and conducting school-wide events and promotional activities and campaigns. Using an overarching theme each semester (Table 1), components were integrated to enhance synergistic opportunities and address targeted behaviors. Details of the intervention have been published, but the comprehensive components of the HEALTHY program are summarized in Table 2.

HEALTHY incorporated strong methodological features

First, the study group developed and conducted multiple formative, pilot, and feasibility studies that informed the study design. From winter of 2003 through fall of 2005, the study group conducted six pilot and feasibility studies and two formative research protocols. The pilot studies demonstrated the feasibility of conducting comprehensive health screenings and data collection in middle schools and provided rates and prevalence of various T2D risk factors, as well as developing and testing intervention components singly and in combination. Formative research data were collected in focus groups and interviews with students, parents, and school staff and faculty.

Second, the intervention was administered by school faculty and staff with training and guidance provided by experts on the local site study team. HEALTHY also used volunteer student leaders to help deliver certain intervention components and to take advantage of the

force of peer influence, and used social marketing principles to make “HEALTHY” a desired brand.

Third, the study incorporated process evaluation as part of study design [14]. Process evaluation staff were kept separate from intervention staff and trained to collect data in a consistent objective manner. Process evaluation data were collected in the intervention schools and analyzed in each semester to identify problem areas and modify program implementation as needed. Almost all components of the intervention were implemented at very high levels of fidelity to the original design. Specifically, there were 1101 PE observations, 210 cafeteria observations, and 449 behavior change classroom activity observations. Nutrition strategies were met approximately 90% of the time, PE class activities were implemented as planned 87% of the time, and behavior change activities 97% of the time [30,31].

Fourth, outcome measures were carefully defined and data collection instruments and assessment procedures carefully developed or selected. These included physical and metabolic laboratory assessments related to diabetes risk. A comprehensive health screening was developed utilizing uniform equipment and training to collect height, weight, waist circumference, blood pressure, and a fasting blood draw. Standard self-report instruments were used to collect food frequency data, physical activity levels, quality of life, and pubertal maturity status. Parents received a feedback letter with their child’s physical and laboratory values along with norms and interpretation and recommended follow-up if appropriate.

Lessons Learned, or Where Do We Go From Here?

In light of the strengths of HEALTHY described above, we asked ourselves why we failed to obtain more robust results and how the HEALTHY experience can inform future work. Below we discuss the implications of HEALTHY-specific design choices, followed by consideration of more general questions related to obesity prevention including secular trends and the role of school-based research.

Should we have evaluated the primary outcome in the highest risk subgroup only?

The HEALTHY intervention was delivered to all students in the cohort grade to avoid stigmatization of overweight or obese students. Moreover, HEALTHY was conceived as a population-based intervention, and the primary outcome was assessed in the entire cohort participating in the study. In retrospect, results documented that the vast majority of children who were in the healthy weight range at baseline simply stayed at low risk [32]. Therefore, although we recommend that primary prevention programs continue to target all children, perhaps the primary outcome analysis should have focused on students who were at highest risk of T2D, i.e., those who started the study in the overweight or obese ranges. Indeed, although the combined prevalence of overweight and obesity was not different between control and intervention schools at the end of the period of study, there were significant decreases in the prevalence of obesity and BMI z-score in the intervention schools, and these changes were even more pronounced in the subset of students (comprising 50% of the cohort) who were overweight or obese at the beginning of the study.

Were the intervention components effective?

The HEALTHY intervention was designed to target the school milieu comprehensively. Consequently, it is not possible for us to tease out the efficacy of individual components of the intervention. For example, the extent to which the observed decreases in obesity were due to increased physical activity, improved nutrition, or both is not known.

Moreover, although the data would not be conclusive given the multiple intervention targets, evaluation of individual components was hampered by a lack of objective measures of behavior that can easily be applied in large field studies. For instance, the child-reported data on dietary intake and physical activity indicated no change in either domain from baseline to end of study in treatment or control schools [33,34]. However, there was a 4% decrease in BMI percentile in overweight and obesity, leading to the conclusion that there are significant limitations to the questionnaires used. The limitations associated with the self-report of dietary intake [35] and physical activity [36] are well documented. Researchers should give priority to developing new, innovative measures of diet and physical activity that can be used in large studies. Such measures are critical to understanding how best to design future interventions. With the above noted caveats in mind, it is nevertheless useful to comment briefly on specific HEALTHY intervention components.

Physical education component—Although the PE intervention component was delivered with high fidelity [30], changes in overall activity and fitness levels were not encouraging. At the end of HEALTHY, there were no overall differences between intervention and control school students in fitness as estimated by the 20 meter shuttle run or in self-reported overall MVPA. Moreover, although fitness levels in boys were essentially unchanged, girls demonstrated decreases in fitness during the period of study [34]. These data document compellingly that new approaches are needed. Although efforts to maximize the impact of PE are relevant, energy balance over time is more strongly related to overall levels of physical activity and sedentary behavior. Consequently, future studies to evaluate creative efforts to increase activity during the entire school day, such as standing classrooms [37] are indicated. There also is an urgent need to develop and evaluate innovative ways to mitigate decreases in fitness in girls, and evaluate physical education activities such as dance [38] that may be particularly appealing to girls. Finally, ways to combine in-school PE interventions with after-school, and home- and community-based efforts are needed to enhance overall lifestyle activity.

Dietary intervention component—The HEALTHY nutrition intervention component targeted the total school food environment of cafeteria, a la carte lines, school stores, fundraisers, and parties [10]. The intention was to improve the quality and appeal of foods and beverages offered, while engaging in educational and behavior change efforts to improve student selection. HEALTHY data showed that significant changes were made in the fat and sugar content and portion size of foods offered in the cafeteria and vending [39,40], but the dietary intake data collected from the students by food frequency questionnaire cannot be separated according to whether the food was eaten during or out of school.

A larger question about the school food environment involves the federally funded meal programs, which mandate a certain calorie level and food groupings, as well as providing surplus items at considerably reduced prices. The HEALTHY nutrition intervention component involved collaboration and coordination with school and district food services to operate within the federal rules that were operative at the time that the HEALTHY intervention was designed. Guidelines for the National School Lunch and School Breakfast Programs recently were revised to eliminate trans fats and reduce saturated fats, sodium, and calories [41]. These are positive changes and federal policies will need more frequent review to keep pace with public health goals for sound nutrition in children.

Classroom activities and behavior change strategies—The classroom activities that were developed into a program for teachers and students, called Fun Learning Activities for Student Health (FLASH), were developed to incorporate principles of social learning and

health-related behavior change [12] and informed by results of HEALTHY pilot studies. FLASH was designed to enhance student knowledge, decision-making, and self-management, and to take advantage of peer involvement for changes in eating and activity. Family outreach included newsletters (provided in English and Spanish) and periodic delivery of packages including materials for behavior change projects for holiday breaks and summer vacation. Process evaluation data indicated that the behavior change activities were delivered with fidelity and that FLASH was deemed feasible and effective by teachers and students (manuscript under review).

Nevertheless, we do not know how well students practiced self-management and did not evaluate the impact of family outreach efforts. We think that future work on the dissemination of evidence-based strategies for youth self-management and development of creative ways to involve parents and guardians in school-based programs will be crucial for future obesity prevention programs.

Was participation in the HEALTHY initiative and health screenings sufficient to impact rates of overweight and obesity in the control schools?

Participating schools may have been more receptive than schools in general to the objectives of the HEALTHY initiative. Moreover, control and intervention schools received monetary incentives that increased each year to enhance retention, and control schools may have used their incentives to make health-related changes. Finally, parents who consented to child participation in health screenings may have been more cognizant of the importance of healthy behaviors than those who did not. The same comprehensive baseline health screening was conducted in control as well as intervention schools, followed by a letter of results sent home to parents. This assessment of a child's BMI and other health risks may have motivated parents in control and intervention schools to take action. A recent natural experiment with a large sample showed no effect from a letter about BMI [42]. However, the HEALTHY letter provided significantly more feedback than BMI, including information about blood pressure, lipids, and glucose as well as guidelines to interpret the provided information. Families were encouraged to seek medical follow-up if abnormalities were present, and medical referrals were made for those who had no health care provider. More research is needed on whether health screening information provided to high risk families is sufficient to motivate behavior change. It is possible that some of the students at baseline had visits to health care providers and were placed in programs or on medical interventions. An understanding of how medical information is translated in public health studies would be valuable for designing future studies. We did not collect such data.

Should we have selected a different age group to target?

A recent systematic review concluded that obesity prevention efforts have a beneficial impact on BMI for 6- to 12-year-old children [6]. In this context, and given our focus on reducing T2D risk factors including obesity, middle-school children were the optimal age to document the impact of intervention on BMI and metabolic status. Nevertheless, HEALTHY participants were adolescents by the end of the intervention, and much less is known about the impact of intervention on children older than 12 years [6]. Additional work to identify optimal periods for learning and maximizing adoption of particular health behaviors is needed. We conclude that to prevent obesity and minimize risk for T2D, we will require prevention efforts to target youth and adults at all developmental levels.

Did secular trends catch up with us?

At the beginning of the long process to design a primary prevention trial such as HEALTHY, the study group believed that, based on available NHANES data [43], obesity rates in youth, particularly among minority youth in the US, were going to continue to

increase. In addition, no other study had described a reduction in overweight and obesity prevalence in the control group. It was, therefore, remarkable that the combined rate of overweight and obesity declined in the control as well as intervention schools. There was a long duration (2002–2009) from initial planning through pilot and feasibility studies and finally the trial itself, during which time national, state, and local secular trends occurred in combating childhood obesity. We planned for and implemented data collection on non-study environmental changes related to nutrition and physical activity in both control and intervention schools. We have reported that both control and intervention schools were subjected to similar secular trends in school policies and mandates meant to increase physical activity and decrease energy intake [44]. Given that future studies also will occur within a context of nationwide focus on obesity prevention, closer attention should be paid to assessing the impact of temporal efforts and campaigns to increase public awareness, influence health practices, and mandate environmental change to distinguish study impact from external forces on both control and intervention groups. Indeed, the challenge will be to capitalize on the current Zeitgeist, in which there is increasing momentum for health-related behavior changes as well as industry or corporate recognition of the need to develop pro-active strategies.

Are schools the right targets for obesity and diabetes prevention efforts?

Despite the limited impact of school-based studies to date, there are compelling reasons to continue to develop and evaluate school-based interventions. Schools continue to present unparalleled opportunities for obesity prevention and diabetes risk reduction. First, no other institution has as much contact time with children. Moreover, schools can implement environmental changes to impact available foods, physical education, class curricula, and the acceptability of healthy behaviors. Nevertheless, it is time to consider new ways to extend the impact of prevention efforts.

For example, advocates of social ecological models have argued that the environment has rapidly evolved toward being more obesogenic (i.e., promoting intake of readily available, inexpensive and highly palatable foods, decreasing physical activity, and increasing sedentary behavior) and these environmental changes overwhelm a finite capacity to self-regulate energy balance. Similarly, several studies also have indicated that greater increases in BMI occurred during the shorter summer months than throughout the school year and fitness gains during the school year were lost during the summer [45]. Thus, despite the extensive efforts in HEALTHY to modify the school environment to increase the likelihood of healthier choices and to preclude on-site unhealthy choices, it seems fair to conclude that changes in schools alone were insufficient to maintain HEALTHY efforts and accomplishments.

In this context, we think that although schools will remain an important nexus for health promotion efforts in youth, future programs will need to target multiple domains that influence eating and activity in youth. Changes in public policy, the health care sector, community, and media are indicated. Logical next steps in school-based prevention research might include evaluations of carefully considered programs that extend the focus of intervention to more than one sphere of influence, such as the neighborhood and home environment. Future interventions may want to reach out to the family to a greater extent than HEALTHY to help influence the child's diet and physical activity behavior outside of school and maximize parent involvement in school-based initiatives. Similarly, efforts to target environmental factors such as neighborhood stores that sell calorie dense snacks and sugared beverages to children leaving school [46], evaluate strategies to encourage activity such as mentored walking to school programs [47], or increase use of schools as sites for community activities, may be useful. Schools, as a primary institution concerned with child welfare, are a logical center of a web of interconnected community resources.

Conclusions

The strengths of the HEALTHY trial were the comprehensive nature of the focus on behaviors that influence energy balance, the well-funded support for the multiple components of the intervention, and the documentation of high levels of program delivery. Despite these strengths, the program had no differential effect by randomized treatment assignment on the primary outcome, although there were significant effects on multiple secondary outcomes including obesity, particularly among youth at highest risk. Even small changes in obesity prevalence in a population-based intervention could translate into significant public health benefit.

As delineated above, the HEALTHY design choices, although carefully considered, had limitations, which included a constrained ability to affect eating or activity behaviors outside of school, a primary focus on PE class rather than total youth activity and sedentary behavior, and limited ability to ensure practice of behavioral self-management skills. Other inherent limitations to the HEALTHY design included minimal family involvement and breaks in intervention exposure during school vacations and over the summer. Given the ubiquity of calorie dense foods and barriers to physical activity, it is clear that schools can be a nexus of change, but addressing the obesity epidemic will require cultivation of community partnerships to extend the influence of school-based programs. This may be particularly important for minority and low socioeconomic youth like those enrolled in the HEALTHY schools who may face more significant barriers to the adoption of healthy lifestyle.

Partnerships may need to extend to government agencies, as well. The HEALTHY investigators were constrained in the development of the intervention by current policies governing (1) federal meal programs mandating calorie value of meals, nutrient distribution, and use of surplus agricultural commodities, and (2) PE class curricula that mandate skill development drills that limit continuous participation and movement during class. Efforts to combat childhood obesity are likely to require a coordinated public health campaign modeled after smoking cessation.

HEALTHY was designed to mitigate the limitations of previous school-based obesity/diabetes prevention research by designing a comprehensive intervention that incorporated evidence-supported components from previous clinical studies in children and adults. Because the HEALTHY intervention had a limited impact on the combined prevalence of overweight and obesity in middle-school youth, additional work is needed to understand better how to promote behavior change in children with a population-based approach. This may involve understanding better the utility of individual intervention components, the most appropriate outcomes to track in a population-based study, how to manage an intervention occurring in the face of changing policies and public awareness, and how to integrate school-based efforts with those that target other aspects of children's environments.

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HEALTHY intervention materials are available for download at <http://www.healthystudy.org/>.

Disclosure

Conflicts of interest: M.D. Marcus: has received a sub-contract from George Washington University (part of Cooperative agreement from NIDDK) has been on the Scientific Advisory Board for United Health Care; K. Hirst: has received grant support from NIDDK; also travel to study meetings was covered; the NIDDK grant covered all activity, including committee work and data analysis, but not under a fee-under a cost-reimbursable grant.; F. Kaufman: has received grant support from NIDDK; also travel to study meetings was covered; G.D. Foster: has received grant support from NIH/NIDDK; also travel to study meetings was covered; and received salary support from grant; has been on the Scientific Advisory Board for United Health Group, ConAgra Food, Tate and Lyle; T. Baranowski: received grant support from NIDDK; also travel to study meetings was covered; he also serves on the Publications and Presentations Committee for the HEALTHY trial (NIDDK)

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Table 1

Intervention Themes and Targeted Behaviors

A. THEMES	
Winter/Spring 6th Grade	Water versus Added Sugar Beverages
Fall 7th Grade	Physical Activity versus Sedentary Behavior
Winter/Spring 7th Grade	High Quality versus Low Quality Food
Fall 8th Grade	Energy Balance: Energy In/Energy Out
Winter/Spring 8th Grade	Strength, Balance, and Choice for Life
B. TARGETED BEHAVIORS	
<ul style="list-style-type: none"> • Increasing water consumption • Substituting water for added sugar beverages • Drinking water for health, nutrition, and hydration • Choosing healthier foods and drinks for meals and snacks • Substituting nutrient dense, lower caloric foods for low nutrient, higher caloric foods • Self-monitoring, goal setting, and problem solving to increase intake of water, fruits, and vegetables • Increasing movement and accumulation of time spent being active • Decreasing time spent in sedentary behavior • Substituting physical activity for sedentary behavior • Self-monitoring, goal setting, and problem solving to increase physical activity and decrease sedentary behavior 	

Table 2

HEALTHY Intervention Program Contents

<p>Nutrition and School Food Environment</p> <ul style="list-style-type: none"> • \$3000 per year to the food service department to defray costs • hands-on monitoring and guidance from a dietitian expert on the staff of each field center • food service staff training to deliver the intervention <ul style="list-style-type: none"> ○ manager received \$50 for 4–6 hour initial training and \$25 per semester for 2 hour booster training, plus \$100 per semester for time spent in data collection procedures related to documenting delivery of intervention ○ workers received \$50 for 4–6 hour initial training and \$25 per semester for 2 hour booster training • semester theme-related messaging posted along the cafeteria line • 1–2 taste tests per semester to introduce new or unfamiliar products • 1 cafeteria learning laboratory per semester to provide a fun and engaging educational activity
<p>Physical Education</p> <ul style="list-style-type: none"> • PE teacher handbook of lesson plans and classroom management for each of 6th, 7th and 8th grades • PE teacher training to deliver the intervention <ul style="list-style-type: none"> ○ 6-hour training at beginning of each school year (reimbursed at hourly rate) ○ 6-hour booster training in second half of school year (reimbursed at hourly rate) ○ \$100 per semester for time spent in data collection procedures related to documenting delivery of intervention • ~\$15,000 over 3 years in PE class equipment required to implement intervention • hands-on monitoring and guidance from a physical education expert on staff of each field center • physical education teacher aide at each school
<p>Behavior Change</p> <ul style="list-style-type: none"> • theme-based educational program materials for each of 5 semesters <ul style="list-style-type: none"> ○ teacher manual ○ student handbook (English and Spanish versions) ○ materials to enhance the lessons and engage in a creative project • classroom teacher training to deliver the educational program <ul style="list-style-type: none"> ○ 4-hour training at beginning of each school year (reimbursed at hourly rate) ○ 1-hour booster training in second half of school year (reimbursed at hourly rate) ○ \$100 per semester for time spent in data collection procedures related to documenting delivery of intervention • 7 issues of a newsletter sent to families with first-person stories, tips, Q&A, etc. • school break packages of materials to engage the family and maintain lifestyle and behavior change (1) during summer between 7th and 8th grades and (2) over 8th grade winter holiday break • hands-on monitoring and guidance from a health promotion expert on the staff of each field center • health activities aide at each school
<p>Communications, Promotion, and Social Marketing</p> <ul style="list-style-type: none"> • intervention launch event materials • exterior banners • semester theme-related posters, flyers, and PA announcements • semester theme-related school-wide activity • recruitment and training of a corps of student peers who assisted with study events

- distribution of incentive and premium items to students, both branded (e.g., t-shirts, pedometers, water bottles, backpacks) and donated (e.g., coupons, health care products, tapes and DVDs)

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