

**A School-based Program to Improve Hypertension Awareness and
Blood Pressure Control in the Community:
Rationale, Design, and Planned Pilot Testing**

By

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A Master's Paper submitted to the faculty of
the University of North Carolina at Chapel Hill
in partial fulfillment of the requirements for
the degree of Master of Public Health in
the Public Health Leadership Program.

Chapel Hill

2006



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Acknowledgments: This project was conducted while Dr. Viera was a Robert Wood Johnson Clinical Scholar at UNC Chapel Hill. Funding was provided by the Robert Wood Johnson Foundation. Kristen Rake and Halle Amick provided valuable research assistance. Dr. Viera would also like to extend special thanks to Principal Carrie Little, and the fifth grade teachers Lisa Lowing, Judy Bennett, and John McLean, all of North Chatham School, Chatham County, NC. Without their support, this project would not have been possible.

Abstract

Context: Despite the existence of national guidelines and over 70 antihypertensive medications, 42% of hypertensives are not being treated, and up to 75% of those treated are not at goal blood pressure. Over 30% of adults are not even aware that they have hypertension. Innovative strategies aimed at the community level might lead to improved hypertension awareness and control.

Objectives: (1) To describe the rationale behind a school-based intervention designed to raise children's awareness of the health risks of high blood pressure as well as strategies that can help reduce those health risks and to serve as an innovative means of deploying home blood pressure monitors in an effort to raise community awareness of high blood pressure. (2) To describe planned pilot testing of the program.

Design: Pilot, crossover trial.

Setting: Public school in a suburban community.

Participants: Fifth grade students and their parents/guardians.

Intervention: (1) Classroom didactic about hypertension followed by an in-class laboratory consisting of measurement of blood pressure using automatic oscillometric devices. (2) Automatic blood pressure devices taken home by students for measurement of parent/guardian blood pressures with a form of immediate feedback.

Main and Secondary Outcomes: (1) Child and parent/guardian knowledge about high blood pressure, (2) Parent/guardian intent to have blood pressure checked by health professional, (3) Parent/guardian reported control of blood pressure.

Results/Conclusions: The pilot study (n=60 students) is currently ongoing. Results will not be available until June/July 2006. Importantly, as a pilot study, the goal is not to demonstrate effectiveness but to assess feasibility in preparation for a larger trial.

Burden of Suffering

Hypertension, or elevated blood pressure, is a chronic condition that currently affects over 65 million Americans, and its burden has been described as “a rising tide.”¹

Hypertension is responsible for 35% of all myocardial infarctions and strokes as well as half of all episodes of heart failure.² Furthermore, hypertension is a major contributor to peripheral vascular disease, end-stage renal disease, aortic aneurysm, and retinopathy.²

⁵ Nearly one out of four premature deaths is due to hypertension.⁶ Hypertension is the most common primary diagnosis in the United States, and annual costs associated with its treatment are estimated to be nearly \$56 billion.^{7,8}

Benefits of Treatment

Decades of research have demonstrated the benefits achieved with blood pressure reduction. For example, lowering the systolic blood pressure (BP) to 150 mm Hg decreases the incidence of strokes of all types.⁹ Lowering diastolic BP by 10 mm Hg reduces the number of strokes by as much as 56% and the incidence of coronary heart disease by 37%.¹⁰ Overall, antihypertensive therapy leads to a 35% to 40% mean reduction in stroke incidence, 20% to 25% mean reduction in myocardial infarctions, and greater than 50% reduction in incidence of congestive heart failure.⁷ In patients with stage 1 hypertension (systolic BP 140-159 mm Hg and/or diastolic BP 90-99 mm Hg) and additional cardiovascular disease risk factors, it is estimated that a sustained reduction of 12-mm Hg in the systolic BP for 10 years prevents 1 death for every 11 patients treated. In the setting of preexisting cardiovascular disease or target-organ damage, only 9 patients need to be treated to prevent 1 death. Blood pressure lowering itself appears to be more important than which pharmacologic agent is used.¹¹

Current Guidelines

The United States Preventive Services Task Force (USPSTF), in its most recent review of the evidence for screening for high blood pressure, found substantial indirect evidence

supporting the effectiveness of screening adults to detect hypertension and treating them to reduce cardiovascular disease.⁶ The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7) recommends initiating pharmacologic therapy for adults with Stage 1 hypertension.⁷ Additionally, JNC 7 added the new category of prehypertension for individuals with BP less than Stage 1 but above 120 mm Hg systolic or 80 mm Hg diastolic. JNC 7 recommends lifestyle modification for individuals with prehypertension.

Strategies to Improve Blood Pressure Control

In addition to recommending lifestyle modifications and prescribing antihypertensive medications, additional strategies that clinicians can take to help patients achieve blood pressure control include simplification of medication regimens and prescribing lower cost medications.⁷ Still, it is ultimately the patient who decides what recommendations to follow, including whether or not to fill a prescription and take medication(s) the rest of his/her life.¹² There is a growing body evidence for interventions aimed at promoting self care among patients with hypertension. Examples of such interventions include (1) patient education or counseling, (2) self-monitoring of blood pressure, and/or (3) interventions to improve adherence to treatment. A self-management 'program' usually combines two or more interventions designed to promote self-care.

The demonstrated effectiveness of interventions for promoting self-care for hypertension varies depending on the specific component(s) of the intervention. The results from published systematic reviews suggest small reductions in systolic blood pressure (1-5 mm Hg) and varied levels of improvement in blood pressure control. However, the pooled estimates from the meta-analyses must be viewed with caution because of the heterogeneity between studies as well as publication bias.

Self-management programs. A meta-analysis of chronic disease self-management programs for older adults included 13 studies on hypertension self-management that reported blood pressure changes as outcomes.¹³ The pooled results suggest a reduction in systolic blood pressure of approximately 5 mm Hg and a reduction in diastolic blood pressure of approximately 4.3 mm Hg. The 95% confidence intervals (reported as effect sizes rather than mm Hg) around these pooled point estimates did not contain the null value, indicating statistically significant results. It was not clear which characteristic(s) of self-management programs (e.g., tailoring, group setting, feedback) actually lead to benefit. Again, this review was limited to older adults. The effect sizes are likely smaller as the estimates are affected by the heterogeneity between studies as well as publication bias.

Educational interventions. A Cochrane review of interventions used to improve blood pressure control in patients with hypertension included 17 RCTs (14 of which reported relevant outcome data) assessing the effect of educational interventions directed to the patient.¹⁴ For the outcomes of mean systolic and diastolic BP differences, because of heterogeneity between studies, pooling of results was not appropriate. For the outcome of uncontrolled BP (defined as not below target) pooled results of 5 trials (530 subjects) suggested a trend toward improved blood pressure control, but this did not reach the level of statistical significance (OR 0.66 in favor of treatment, 95% CI 0.44-1.01).

Self-monitoring. The same Cochrane review included 15 RCTs assessing the effect of self-monitoring on systolic blood pressure, diastolic blood pressure, and/or blood pressure control.¹⁴ For the outcome of diastolic BP differences, pooled results showed a net reduction of 2 mm Hg [95% CI 1.4-2.7]. Pooled results for systolic BP showed a net reduction of 2.5 mm Hg [95% CI 1.1-3.9], but there was again significant heterogeneity between these studies in evaluating this outcome, so pooled results must be viewed with caution. For the outcome of uncontrolled BP, there was no significant heterogeneity

($p=0.51$), and pooled results demonstrated a non-significant odds ratio in favor of self-monitoring (0.88, 95% CI 0.67-1.15).

Another meta-analysis included 18 RCTs of self-monitoring of blood pressure and found similar results in terms of heterogeneity between studies when assessing the outcomes of systolic and diastolic BP differences.¹⁵ For the outcome of uncontrolled BP, there was no significant heterogeneity, and a relative risk of 0.90 (95% CI 0.80-1.00) in favor of self-monitoring. When adjusting for publication bias, this equates to approximately a 10% greater proportion of hypertensive patients with BP under control. The size of the actual BP effect is estimated to be a 2.2/1.9 mm Hg reduction attributable to self-monitoring.

Promoting adherence. A 2004 Cochrane review specifically sought to assess the evidence for interventions to improve treatment adherence in patients with hypertension.¹⁶ As with studies in the Cochrane Review described above, the 38 studies included in this review also included multiple interventions and methods of assessing outcomes. For example, patient education strategies ranged from written material to lectures to group education. Patient motivation and support strategies included self-recording of BP, teaching on self-determination, and telephone-linked computer counseling. Because of heterogeneity between these studies, the results were not pooled. By itself, patient education did not seem to improve adherence. When combined with motivational strategies or more complex interventions, adherence to hypertension treatment might be improved, which in turn might lead to improved blood pressure control. However, the evidence is insufficient at this time to draw a firm conclusion.

Dietary advice. RCTs that assess the effectiveness of advice to reduce sodium intake on blood pressure also contain varying levels of interventions, from verbal and/or written instructions to individual counseling to nutritionist led family salt-restriction programs.¹⁷ Thus, pooled results must be viewed with caution. Patients given low sodium advice

appear to have a small reduction in systolic BP compared to controls. At just over a year of follow-up, systolic BP appears to be reduced by 2.5 mm Hg (95% CI 1.2-3.8) and diastolic by 1.2 mm Hg (95% CI 0.6-1.8). Longer term results (5 year follow-up) seem less substantial, with a systolic BP reduction of approximately 1.1 mm Hg (95% CI 0.4-1.8) and diastolic BP reduction of only 0.6 mm Hg (-0.3-1.5). Some trials in this review included normotensive individuals, and subgroup analyses demonstrated a greater effect of low sodium advice on blood pressure for hypertensives. Patients given more general dietary advice seem to have similar reductions in blood pressure, at least in the short term.¹⁸

Stress management. There is insufficient evidence to state whether teaching stress management, autogenic training, or other relaxation techniques to patients with hypertension leads to improved BP control.

Quality Gap

Despite the availability of periodically updated, widely distributed national guidelines⁷ and the availability of over 70 antihypertensive medications, 42% of patients with hypertension are not being treated, and 69 to 75% do not have their hypertension under control.^{19, 20} An estimated 30% of people with hypertension are not even aware of their illness.¹⁹ Table 1 shows estimates of blood pressure control among treated hypertensives by subgroups.

Table 1. Percentage of Treated Hypertensive Patients Not at Goal

Caucasians	44%
African Americans	55%
Hispanics	56%
Patients >= 60 years old	56%
Patients with diabetes	75%

Healthy People 2010 goals include reducing the proportion of adults with high blood pressure to 16%, reducing the proportion of adults with hypertension whose blood pressure is not under control to 50%, and increasing the proportion of adults with hypertension who are taking action to help control their blood pressure to 95%.²¹

A recent study of 1953 hypertensive patients found that only 57% received optimal care and 42% had their blood pressure controlled.²² Younger patients without cardiac risk factors were noted to be at greatest risk for poorer care.²² My colleagues and I also recently published work based on secondary analysis of national data affirming that certain subgroups, such as younger men, are particularly vulnerable to not receive preventive services such as blood pressure screening.²³ This effect is partly explained by the difference between younger men and women in their number of ambulatory care visits.

Thus, one strategy to improve blood pressure screening for such people would be to increase their visits for ambulatory care. Presumably, such visits would be health maintenance visits. However, this strategy is not ideal as a population approach because even if people could be persuaded to increase their visits, such a strategy would not only be costly and resource-consuming, but because of disparities in access to care, would also not likely reach those most likely to benefit. A second strategy would be to develop alternative methods of health promotion and preventive services delivery that reach people in their communities.

Community Based Heart Health Projects

There have been a variety of community based projects aimed at improving cardiovascular health. Numerous papers have been published from these projects.²⁴⁻⁷³

The programs are summarized in Table 2 below.

Project	Intervention / Duration	Intervention Provider	Setting	Follow-up
Puska et al 1985. North Karelia Project	<ul style="list-style-type: none"> • Mass media • Educational materials • Workshops • TV programs, videos • Screening • Local fairs 10 years	<ul style="list-style-type: none"> • Professional • Researcher • Lay person • Peer • Volunteer • Community groups 	<ul style="list-style-type: none"> • Community • Home • Hospital • School • Worksite • Clinic • Local dairies • Local butcher • Restaurants Urban & rural	15 years post-intervention
Farquhar et al 1985. Stanford Five City Project	<ul style="list-style-type: none"> • Mass media • Educational materials • School curriculum • Workshops 6 years	<ul style="list-style-type: none"> • Professional • Lay person • Peer • Volunteer • Community groups 	<ul style="list-style-type: none"> • Community • Home • Hospital • School • Worksite • Clinic Urban	End of intervention
Mittlemark et al 1986, Luepker et al 1994. Minnesota Heart Health	<ul style="list-style-type: none"> • Mass media • Educational materials • Workshops • School curriculum • TV programs, videos • Screening • Counseling • Contests • Self-help groups 6 years	<ul style="list-style-type: none"> • Professional • Researcher • Lay person • Volunteer • Community groups 	<ul style="list-style-type: none"> • Community • Home • School • Worksite • Clinics • Churches • Grocery stores • Restaurants Urban & rural	End of intervention. Second outcomes at 10 years post-intervention

<p>Nutbeam et al 1987, Tudor-Smith et al 1995. Heartbeat Wales</p>	<ul style="list-style-type: none"> • Mass media • Educational materials • Workshops • School curriculum • Screening • Counseling • Support groups <p>5 years</p>	<ul style="list-style-type: none"> • Professional • Lay person • Volunteer • Community groups 	<ul style="list-style-type: none"> • Community • Hospital • School • Worksite • Clinic • Restaurant <p>Urban & rural</p>	<p>End of intervention</p>
<p>Lefebvre et al 1988, Carleton et al 1995. Pawtucket Heart Health Project</p>	<ul style="list-style-type: none"> • Mass media • Educational materials • Workshops • School curriculum • TV programs, videos • Screening • Counseling <p>6 years</p>	<ul style="list-style-type: none"> • Professional • Researcher • Lay person • Volunteer • Community groups 	<ul style="list-style-type: none"> • Community • Hospital • School • Worksite • Clinic • Churches • Libraries • Grocery store <p>Urban</p>	<p>End of intervention</p>
<p>Norman et al 1990. County Health Improvement Program</p>	<ul style="list-style-type: none"> • Mass media • Educational materials • Workshops • School curriculum <p>2 years</p>	<ul style="list-style-type: none"> • Professional • Lay person • Volunteer 	<ul style="list-style-type: none"> • Community • School • Worksite <p>Rural</p>	<p>End of intervention</p>
<p>Goodman et al 1995. South</p>	<ul style="list-style-type: none"> • Mass media • Educational 	<ul style="list-style-type: none"> • Professional • Lay person 	<ul style="list-style-type: none"> • Community • Clinic 	<p>End of intervention</p>

Carolina Heart to Heart	<ul style="list-style-type: none"> materials Workshops Screening <p>5 years</p>	<ul style="list-style-type: none"> Volunteer Community groups 	<ul style="list-style-type: none"> Worksite Church <p>Urban</p>	
Tian et al 1995. China Sodium Intake Project.	<ul style="list-style-type: none"> Mass media Educational materials Workshops Counseling Nutrition guidelines Low sodium salt <p>3 years</p>	<ul style="list-style-type: none"> Professional Lay person Community groups 	<ul style="list-style-type: none"> Community Home Clinic <p>Urban</p>	End of intervention
O'Loughlin et al 1995. Coeur en Sante St Henri	<ul style="list-style-type: none"> Mass media Educational materials Workshops School curriculum TV programs, videos Contests <p>5 years</p>	<ul style="list-style-type: none"> Professional Lay person Community groups 	<ul style="list-style-type: none"> Community Grocery store Restaurants <p>Urban</p>	End of intervention
Brownson et al 1996. Bootheel Heart Health Project	<ul style="list-style-type: none"> Mass media Educational materials Workshops Screening Support groups <p>5 years</p>	<ul style="list-style-type: none"> Professional Lay person Volunteer Community groups 	<ul style="list-style-type: none"> Community School Church Clinic <p>Rural</p>	End of intervention

These interventions seem effective in raising people's awareness of their blood cholesterol levels as well as their risk for cardiovascular disease. Some interventions also led to a reduction in the proportion of the population with elevated cholesterol, partly because they increased the number of people who visited their primary care physician to have their cholesterol checked.

While some programs were also effective in reducing smoking prevalence in some groups (e.g., men, adolescents), they were not effective when measuring outcomes of smoking prevalence, physical activity, and cardiovascular disease mortality at the community level. These interventions were also not effective in reducing mean blood pressure in the community.

These community heart health projects were notably multi-pronged and multi-sectoral in scope. While these characteristics may have contributed to their relative effectiveness, they also contributed to their complexity. Importantly, the positive effects were not maintained when the intervention was discontinued. Thus, it is important to consider the long-term sustainability of any heart health intervention.

The Guide to Community Preventive Services⁷⁴ does not specifically address community interventions aimed at preventing cardiovascular disease but does address the topics of nutrition, obesity, smoking and physical activity. The Guide notes that more evidence is needed to determine the effectiveness of school-based programs to control overweight and obesity as well as to improve nutrition. The Guide makes no mention of the effectiveness of school-based education on reducing initiation of tobacco use but does recognize the effectiveness of school-based physical education as an approach to increase physical activity among young people.

Overarching Program Goals

I wanted to design a sustainable program with the potential to improve cardiovascular health at the community level by raising awareness of hypertension and its health hazards. Importantly, I also wanted a method to reach people who might otherwise have little or no means to receive health promotion messages and/or screening. I decided that a school-based program would allow me to blend primary and secondary prevention efforts at the community level.

The American Heart Association Guide for Improving Cardiovascular Health at the Community Level⁷⁵ provides a table of strategies including (1) assessment, (2) education, (3) community organization and partnering, (4) assuring personal health services, (5) environmental change, and (6) policy change. The goals in Table 3 are abstracted from this guide.

Strategy and Goal	How Addressed by Proposed Program
<i>General Health Education.</i> All communities should provide information to their members about the burden, causes, and early symptoms of CVD and stroke.	Directly: Fifth grade children will learn that high blood pressure can lead to heart disease, strokes, kidney disease, and other vascular diseases. Indirectly: Parents/guardians will learn from their children.
<i>General Health Education.</i> Communities should provide materials and programs to motivate and teach skills for changing risk behaviors that will target multiple	By delivering the program in the public school setting, all subgroups have the potential to be reached. Self-measurement of blood pressure is a technique (skill)

<p>population subgroups.</p>	<p>which will likely be increasingly utilized given the increasing amount of evidence supporting it. Self-measurement can promote self-management of a chronic condition such as hypertension.</p>
<p><i>School and Youth Education.</i> All schools should have research-based, comprehensive, and age-appropriate curricula about cardiovascular health and ways to improve health behaviors and reduce CVD risk.</p>	<p>This program is designed to teach middle-school children about high blood pressure. In doing so, the program reinforces healthy eating habits and the promotion of physical activity while discouraging smoking, inactivity, and high salt intake. The pilot evaluation is designed to guide future larger scale trial of the intervention to demonstrate effectiveness.</p>
<p><i>School and Youth Education.</i> All schools should implement age-appropriate curricula on changing dietary, physical activity, and smoking behaviors.</p>	
<p><i>Community Organization and Partnering.</i> All communities will have an action plan for CVD and stroke prevention and control with specific targets and goals.</p>	<p>This program creates the opportunity for health professionals, teachers, children, and parents/guardians to become involved in community activity for CVD and stroke prevention.</p>
<p><i>Community Organization and Partnering.</i> All communities will provide materials and services for risk factor change that are research based whenever possible.</p>	<p>Deployment of home blood pressure monitors in the community represents a service that can lead to risk factor reduction (i.e., improved blood pressure control). The pilot is designed with future evaluation in mind.</p>
<p><i>Assuring Personal Health Services.</i> Increase the percentage of people at risk</p>	<p>This program has great potential to reach people (e.g., middle-aged men) who may</p>

who will effectively reduce risk factors to goal levels for primary and secondary prevention of heart disease and stroke.	otherwise not receive CVD prevention messages and/or blood pressure screening.
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Prototype Curriculum

I designed the prototype curriculum with the following three aims in mind: (1) improve children's knowledge about high blood pressure, (2) raise parental/guardian knowledge and awareness of high blood pressure, and (3) serve as an innovative means to deploy home blood pressure monitors for potential blood pressure screening of parents/guardians. Designated the *Fifth-graders Initiating Family Talk about Hypertension (FIFTH) Project*, I wanted the program to serve as a fun way for children to learn about high blood pressure while reinforcing science, health, art, and teamwork skills. The prototype lesson guide is attached as Appendix 1.

The program components reflect several of the North Carolina Healthful Living Education standards for fifth grade students. For example, the following competency goals are addressed:

1. Competency Goal 1: The learner will direct personal health behaviors in accordance with own health status and susceptibility to major health risks.
2. Competency Goal 3: The learner will interpret health risks for self and others and corresponding protection measures.
3. Competency Goal 6: The learner will choose not to participate in substance use (includes tobacco products).
4. Competency Goal 8: The learner will exhibit a physically active lifestyle.

While the topic of high blood pressure is generally not taught to middle school students, it serves as a means to also reinforce the importance of maintaining a healthy lifestyle.

That is, physical activity and healthy diet are encouraged while smoking and unhealthy eating habits are discouraged.

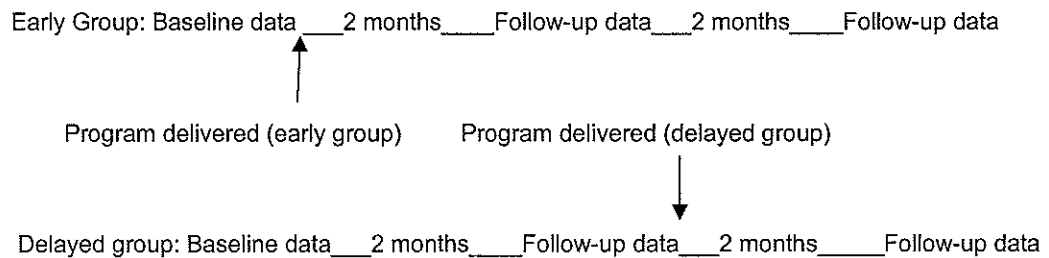
In addition to addressing Healthful Living Education standards, the FIFTH Project—mainly through the in-class laboratory activity—also allows incorporation of several science curriculum goals, including:

1. Nature of Science: This strand helps students understand the human dimensions of science and the role of science in society.
2. Science as Inquiry: This strand particularly emphasizes scientific investigations or laboratory experiments.
3. Science and Technology: This strand includes the ability to use scientific instruments and to measure things carefully.

The purpose of this research is to conduct pilot testing and evaluation of the FIFTH program in preparation for revision of the program and submission of future proposals on a larger scale.

Overall Design

The evaluation portion of the study is diagrammed below:



There will be at least one classroom assigned to the early group and at least one assigned to the delayed group. Prior to the designated time of the classroom portion of the project in the early group, informational letters and consent documents to be taken home and signed by parents/guardians will be distributed to students in both the early group and the delayed group. The letters will be accompanied by two questionnaires and a large, opaque return envelope. The letter will describe the project as well as methods of evaluation (Appendix 2). Via their signature, parents will have the option to opt their child out of the data collection and evaluation portion of the project (Appendix 3).

Parents/guardians who choose to participate will be asked to sign a consent form (Appendix 4) and complete a baseline parental questionnaire that will accompany the consent letter (Appendix 5). This questionnaire will ask parents/guardians questions to record basic demographics and will ask about whether they have high blood pressure, whether it is under control, whether they have seen or intend to see a health professional about their blood pressure, and basic knowledge about high blood pressure. The consent forms for both parent and child participation and the baseline parent/guardian questionnaire(s) will be returned to the teachers in a sealed envelope for pick-up.

The early group will then receive the educational program including the in-class laboratory. Automatic blood pressure monitors will be loaned to children (whose parents consent to participate) to take home so that parents can measure and record their blood pressure. During the classroom portion of the educational program, there are three episodes of data collection. A baseline student questionnaire (Appendix 6) will be given to students who have parental permission to participate in the evaluation portion of the program and who assent to participate. The questionnaire asks students to record information about age, race/ethnicity, language spoken at home, and basic knowledge about high blood pressure. Participating students will have their height and weight recorded in a private location with data recorded by a member of the research team or

the teacher. An in-class data collection form (Appendix 7) will be used to record students' blood pressure/pulse. These measurements will be conducted and recorded by students in pairs with one student using the automatic blood pressure machine to take the measurements on the other student and record the measurements on the form. Students will perform each measurement twice. In-class supervision and assistance will be provided by the instructor.

As "homework," students will be encouraged to talk to their parents about what they learned regarding high blood pressure. To help facilitate such discussion, children whose parents elect to participate in the study will be loaned an automatic blood pressure monitor to take home. Parents will be asked to measure and record their blood pressure/pulse on pre-printed forms (Appendix 8). Participating parents will send the data forms via their fifth grade children to the teachers in sealed envelopes that are provided. The principal investigator will collect the in-class data forms and the parent data forms. Two months after the educational portion of the program, students given permission to participate in the evaluation portion of the program in both the early and delayed groups will complete an in-class follow-up questionnaire (Appendix 9) which asks students the same questions as at baseline about knowledge of high blood pressure. Questionnaires will be collected by the teacher, placed in a sealed envelope, and held for pick-up by the principal investigator. The same day, students will take home a follow-up questionnaire (Appendix 10) to parents/guardians. This questionnaire will ask parents/guardians the same questions about whether they have high blood pressure, whether it is under control, whether they have seen or intend to see a health professional about their blood pressure, and basic knowledge about high blood pressure. Students will return the follow-up questionnaires sealed in envelopes provided. No portion of the students' performance or level of parental participation will be graded, and parents/guardians can cease participation at any time.

The delayed group will then receive the educational program including the in-class laboratory and the homework assignment in the same manner described above. Two months after the educational portion of the program, students given permission to participate in the evaluation portion of the program in both the early and the delayed groups will complete an in-class follow-up questionnaire which will be collected by the teacher and held for pick-up by the principal investigator. The same day, students will take home a follow-up questionnaire for parents/guardians. Students will return the follow-up questionnaires sealed in envelopes provided. Again, no portion of the students' performance or level of parental participation will be graded, and parents/guardians can cease participation at any time.

If a participating fifth grade child's blood pressure measurement is elevated above the 95th percentile for age and height, a letter (Appendix 11) will be sent to the parent/guardian via US mail. The baseline parent questionnaire has a space for parents to write their mailing address for such purposes. The letter will explain that the child had a blood pressure measurement that was higher than normal but that it needs to be verified by a health professional or in a health professional's office. The letter will advise the parent/guardian to make an appointment with a healthcare provider to be evaluated.

As part of the process during which participating parents measure and record their blood pressure, the parents will be able to determine a "zone" in which their blood pressure falls using Appendix 12. The three zones are: green (systolic blood pressure < 140 mm Hg, diastolic blood pressure < 90 mm Hg), yellow (systolic blood pressure 140-160 mm Hg, diastolic blood pressure 90-100 mm Hg), and red (systolic blood pressure > 160 mm Hg, diastolic blood pressure > 100 mm Hg). So that parents receive some component of immediate feedback, zones are explained on laminated cards that accompany the

automatic blood pressure monitors. Additionally, parents/guardians whose blood pressure readings are above 180 mm Hg systolic or 110 mm Hg diastolic will be sent a letter via US mail recommending that they be seen by a healthcare professional for evaluation (Appendix 13). The baseline parent questionnaire has a space for parents to write their mailing address for such purposes.

For this pilot project, questionnaires will not be translated into other languages, but data on languages other than English spoken by children at home will be collected to guide future evaluations.

A summary of the educational and evaluation portions is provided in the next table.

Educational Portion	Evaluation Portion
<i>All children in participating classrooms</i>	<i>Consented children only</i>
- Interactive lesson	- Baseline in-class questionnaire
- In-class activity with use of automatic blood pressure device	- Height and weight measurement
- Encouraged to talk to parents about what they learned regarding blood pressure	- Recording of blood pressure measurements with letter to parent/guardian if in-class blood pressure measurement above 95th %ile
- Art project (if done)	- Take home blood pressure device
	- 2-month follow-up questionnaire
	- 4-month follow-up questionnaire
	<i>Participating parents/guardians</i>

	- Baseline questionnaire
	- Blood pressure/pulse
	- Height and weight
	- 2-month follow-up questionnaire
	- 4-month follow-up questionnaire
	- Letter to parent/guardian if blood pressure measured at home above 180/110 mm Hg

Evaluation Instruments

I designed several instruments to be used for evaluation in pilot testing the FIFTH Project. The parent/guardian questionnaire contains demographic items as well as three outcome items: knowledge, blood pressure control, and intent to be screened. An obvious limitation with the latter two items is that they are by self report.

The knowledge items for the parent/guardian instrument were based in part on a 12-item questionnaire designed by the National Institutes of Health for the assessment of blood pressure knowledge my non-medical persons. I found no similar existing instrument designed to assess children's knowledge of high blood pressure. Therefore, I designed one through an iterative process based on concepts that would be taught in the classroom lesson.

The remaining data collection instruments are simple forms designed to allow easy recording of systolic and diastolic blood pressure as well as pulse.

Analysis Plan

The outcomes of this pilot study will consist of post-intervention assessments of:

- 1) Children's knowledge of high blood pressure assessed by five true/false questions,
- 2) Parent/guardian knowledge of high blood pressure based on ten Likert-scaled questions,
- 3) Parent/guardian intent to see a health professional about blood pressure,
- 4) Parent/guardian reported control of blood pressure if already known to be hypertensive.

Basic descriptive statistics will be used to analyze the frequency, means, and medians of demographic and baseline characteristics. We will perform paired t-tests comparing the pre- intervention assessments to the two-month post-intervention assessments. We will also compare the difference in outcomes in the early intervention group to the delayed intervention group. For example, using the outcome of one of the Likert-scaled knowledge questions, to detect a 1.5 point difference in the means between the parent/guardians of students in classroom 1 versus classroom 2, using a power of .80 and a standard deviation of 2, we only need 28 parent/guardians in each group. However, we must take into account the cluster effect of the household.

Using the outcome of proportion of children responding correctly to the true/false questions about hypertension, to demonstrate that an increase from 30% to 60% is statistically significant (with a power of 0.8), we need 20 students to complete pre- and post-intervention assessments. However, to demonstrate that an increase from 50% to 65% is statistically significant (with a power of 0.8), we would need 85 students to complete pre- and post-intervention assessments. Importantly, this is a pilot study whose goal is not necessarily to demonstrate effectiveness of the program. Nevertheless, the analyses will be helpful for planning future studies. Other outcomes assessed will include the parental/guardian opt-out rate and the percentage of children who speak another language at home (for purposes of determining if translation needed for future evaluations).

Initiating a School Based Program Involving Research

Designing a school-based curriculum complete with laboratory activity is only one complex task in this project. Organizing, implementing, and tracking the distribution to fifth graders of 20-25 automatic blood pressure devices also requires planning. One of the most important considerations in designing and carrying out a school-based program is the planning of the evaluation of its effectiveness. In order to evaluate the program, data has to be collected. The collection of data from children and their parents/guardians constitutes research, and that research must be done ethically and with consideration of the interests of all involved parties. The timeline below shows highlights as I went through the process of implementing this project. Some of the obstacles might explain why so few school-based interventions have been formally evaluated for effectiveness.

Timeline

Dates	Activities
June-July 2005	Designed curriculum including a cartoon worksheet (in conjunction with Medical Illustration)
July 2005	Contacted two Chatham County middle school principals, County Health Department Public School Liaison, school nurses
July 2005	Met with Principal of North Chatham School and garnered her support
August 2005	Initiated contact with fifth grade teachers at North Chatham School; initial Institutional Review Board (IRB) application submitted; maintain contact with North Chatham School principal; garnered School Board and Superintendent support
September 2005	Submitted revision of IRB application
November 2005	Submitted budget request; met with North Chatham fifth grade teachers

December 2005	Ordered materials and supplies; developed database for data entry
January 2006	Printed cover letters, consent forms, initial questionnaires, all packaged in large “confidential” envelopes. First classroom sessions with distribution of parental/guardian pre-intervention questionnaires and consent forms.
January/February 2006	Baseline children questionnaires; program delivered in “early” group.
April 2006	Classroom session for follow-up data collection in children and distribution for follow-up questionnaires for parents/guardians. Program to be delivered in “delayed” group.
May 2006	Final follow-up in both “early” and “delayed” groups.
June/July 2006	Data analysis planned

Sustainability

Even given the challenges in carrying out this project, I believe that if the program is found to be effective, it can be sustained with equal enthusiasm even without the intensive monitoring of the research setting. A school nurse, for example, could take the lead on the program within the schools, coordinating with teachers and delivering the program once per year. Home blood pressure devices could be maintained within the school nurse’s office or a central supply location. For the next version of the program, I plan on developing the training materials and working with school nurses to conduct a larger trial of the program. I will use what I learn from this pilot study to revise the classroom materials, evaluation instruments, and analysis plan.

Potential Public Health Impact

On the population level, even small reductions in blood pressure can lead to substantially decreased morbidity and mortality. The FIFTH Project has the potential to reach people in their communities with the message that controlling blood pressure is important.

Because the program also begins with children, it has the potential to serve as a means of primary prevention. That is, children who adopt certain lifestyle changes taught through the program (e.g., decrease table salt) may delay or prevent the onset of hypertension. If the program is effective and it is implemented in communities throughout the country, the public health impact could indeed be far reaching.

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Appendix 1

Prototype FIFTH Project Curriculum Components

Educational Portion

Science/Health Interactive Didactic

1. What is blood pressure?

Children will learn basic concepts of blood pressure and how it relates to the function of the heart as a pump

2. What happens when blood pressure is high?

Children will learn simplified definitions of heart failure, stroke, heart attack, and kidney failure

3. What can help people not have high blood pressure?

- a. Children will learn that other unhealthy behaviors such as smoking and not exercising are related to high blood pressure
- b. Children will learn that healthy eating and exercising are important not only for overall health but also for maintaining healthy blood pressure
- c. Children will also learn that medications can help control blood pressure

Laboratory

Materials needed:

One thermometer (supplied by Project)

1 scale (supplied by Project)

30 Automatic blood pressure machines (supplied by Project)

Data recording forms (supplied by Project)

Pens

Measures used in health

1. Children will be shown thermometer and discuss temperature as a health-related measurement

2. Children will have their height and weight measured and recorded, understanding that these are also health related measurements
3. Children will use an automated sphygmomanometer to measure blood pressure (students do in pairs with assistance from instructor, teacher, or research assistant)

Art (this could be a homework project or contest)

Materials needed:

Poster board

Markers, pencils, etc

Children will create posters about high blood pressure, for example, "Why [someone they care about] Should Make Sure His/Her Blood Pressure is Okay," or "The Dangers of High Blood Pressure." Posters could be displayed on a parent/teacher night or as a special section of the science fair. In addition, posters could be judged as part of a contest.

Evaluation Portion

“Homework” (for participating parents only, i.e., those whose parent/guardian provide consent)

Materials needed:

Automatic blood pressure machines (supplied by Project)

BP Zone Card (supplied by Project)

Data recording forms (supplied by Project)

Pen

Children whose parents/guardians indicated their desire to participate in the evaluation portion of the project will take home an automatic blood pressure machine. Children will be taught that automatic blood pressure machines are not toys and are to be treated with care. They will be instructed not to use them on smaller children in their home, or on pets, or inanimate objects. Parents are asked to measure and record their blood pressure two times. Children will be encouraged to “make sure their parents take their measurements correctly” and to talk to parents’/guardians’ about what they learned about blood pressure.

A card indicating three ranges of blood pressure will accompany the devices. These can provide immediate feedback to parents about their measurements. Automated blood pressure machines will be returned to school.

LESSON GUIDE

INTERACTIVE DIDACTIC

Opener

Show sphygmomanometer. “How many of you know what this is?”

Write “sphygmomanometer” on the board. Explain that this is a fancy word for the device used to take blood pressure. Ask, “Who knows what blood pressure is?”

Today we are going to learn more about blood pressure and even measure each other’s blood pressure!

What is Blood Pressure?

Show water hose without nozzle. “Have any of you used a water hose?” Walk around and have children press on the hose. They should note that they can compress it. Explain that they can compress it because right now it has no water in it. The water causes ‘pressure’ to be exerted on the inside of the hose. Ask if they think they can compress the hose as easily if the water was going full blast through the hose.

Now, “What happens if you barely turn on the water and then try to use the hose?”

Use the water hose idea to talk about pressure and what happens when there is too little pressure (water comes out too weak and slow) vs too much pressure (water comes out too hard and fast). Ask why we use a nozzle or has anyone placed a thumb over the end of the hose. Use this analogy to discuss blood pressure in the blood vessels (“hoses”) of the body. Explain how blood has to travel through blood vessels from the heart all around the body – up to the brain and down to the toes. The blood vessels get smaller and smaller the further they get from the heart, kind of like the way a nozzle makes the hose get smaller and smaller. Blood pressure then is how hard the blood is ‘pressing’ on the inside of the blood vessels. It can be measured by health workers like nurses and doctors using the sphygmomanometer.

Go back to the idea of the hose and ask what we need to do to get this hose working. (connect it to water source) But inside our bodies, instead of the blood vessels being connected to a water faucet, what are they connected to? (the heart) The heart is a muscle that pumps the blood through the blood vessels. If the heart stops pumping, what do you think would happen to our blood pressure? (it would be like the empty water hose) [Take out basketball and manual air pump] Now, what do you think happens if the heart has to work really hard to pump the blood? [Start pumping air into the basketball, and as more air goes in exaggerate how much harder it is to push the manual air pump.] That's right! Just like I have to work harder to pump the air into the ball, the heart would have to work harder to pump the blood if the blood pressure gets too high. If the heart has to work too hard for too long, it can become sick, and not pump as well. Doctors call that "heart failure," and it is dangerous to people's health. [write "heart failure" on board]

Other Dangers of High Blood Pressure

High blood pressure can also cause people to have "heart attacks." Does anyone know what a "heart attack" is? Explain that a "heart attack" happens when the blood does not get to the heart muscle properly and causes part of the heart to weaken or die. If that happens, the heart won't pump as well either, and that can lead to "...what thing you just learned about?" (heart failure)

Now we are going to learn about a few more dangers of high blood pressure. [Distribute the worksheet] On the worksheet, there is an outline drawing of a person with high blood pressure. His name is Liv N. Dangerously. Right now, he feels okay and does not think anything is wrong with his health. In fact, you cannot tell a person has high blood pressure just by looking at him or her. The only way to tell for sure is to measure it. People don't always feel bad when they have high blood pressure either. Most of the time, they feel just fine and have no symptoms of anything being wrong. The neat thing is that, because of this class, you can see inside Mr. Dangerously's body. Even though he

feels fine, the high blood pressure that has been building up over the years is causing him to have problems, and could cause him to become sick. Let's go through together and see if we can figure out what can happen from high blood pressure.

Heart: heart failure and heart attacks

Brain: strokes

Eyes: loss of vision

Kidneys: kidneys can stop working

Blood vessels: arteries can harden and cause poor blood flow

Talk bit more in depth about each of these things as children identify them.

Also, point out that high blood pressure does not cause cancer.

LABORATORY

Show thermometer. Ask, "Have any of you ever had your temperature taken?" Explain that temperature is one health-related measurement. Show scale. Explain that weight (and height) are other health related measurements. And of course, as we've learned today, blood pressure is a health related measurement. When nurses and doctors do any of these measurements, they write them down. Now for our laboratory, we are going to actually learn to take a blood pressure - just like a nurse or doctor might do. But before that, let's think about what might help people to not have high blood pressure

[Students in groups will be asked to look at the picture of Liv N Dangerously and write down ideas they have of what can help people not have high blood pressure. While they are doing this, individual students will be called to have their height/weight taken and recorded privately. Once heights/weights finished, talk with students about what they've written down that can help people not have high blood pressure:

Not smoking

Maintaining healthy weight

Eating healthy foods/lowering salt intake

Physical activity/exercise

The above measures are always good, not just for blood pressure, but for good health.

They may keep you from having high blood pressure, but many, many adults have high blood pressure. Much of the time, people with high blood pressure will also need medicines to help keep their blood pressure under control. You may even know someone who takes medicine for their high blood pressure.

NOW WE ARE GOING TO LEARN TO TAKE BLOOD PRESSURES

[Distribute data collection form]

One way is with special machines like this one.

Demonstrate how the blood pressure machine works and how to use it properly.

Demonstrate how to record blood pressure (as two numbers – a top and bottom) and pulse. Explain need to be careful with machines and distribute. Students will pair off and perform measurements. Instructor walks around helping. At conclusion, congratulate students and collect forms.

HOMEWORK

For homework, many of you will get to take home a blood pressure machine to show your parents or other adults living with you. There are also forms [show form] like this and there are spaces for two adults to write their blood pressures. Make sure they do it correctly. ☺ You may even want to talk to your parents/other adults about what you learned today about high blood pressure. Remember to take care of the equipment just like nurses and doctors do and return everything tomorrow with your forms.

ART PROJECT

If teacher would like to include art project, two ideas:

Students could do the poster on a day after the above lesson (the day they return their bags)

A contest could be offered and children would elect to participate or not. Those choosing to participate would do the poster at home and bring them in by certain deadline. Three winners could be selected with winners receiving a prize.

The children will do a poster about high blood pressure, e.g., "The Dangers of High Blood Pressure" or "Why (someone I care about) Should Make Sure His/Her Blood Pressure is Okay." Posters could be displayed at a parent/teacher night or as a special section of the science fair.

Appendix 2(a)

Date _____

Dear Parents/Guardians:

One of the exciting programs being delivered in our fifth grade classes this year is a health lesson designed to teach children about high blood pressure. The lesson plan was designed by Dr. Anthony Viera, a former middle-school teacher, now a practicing family physician and researcher at the University of North Carolina at Chapel Hill. Dr. Viera lives in Chatham County and is interested in helping residents of Chatham County have better health. He would like to collect some basic information from you and your child in order to see whether this program is helpful. If the program is helpful, it might one day be used all over North Carolina to help communities throughout the state have better health. Please see the attached letter from Dr. Viera to learn more about the program and to decide whether participation in his research study is something you and your child would like to do.

Sincerely,

Fifth Grade Teacher _____ School

Appendix 2(b)

Dear Parents/Guardians,

My name is Anthony Viera. I am a family physician interested in improving prevention, detection, and control of high blood pressure in the population through interventions in the community. I have designed the Fifth-graders Initiating Family Talk about Hypertension (FIFTH) Project as a way to add to the current school health curriculum some information about high blood pressure -- a problem that affects over 65 million adults in this country and is responsible for nearly 1 out of 4 premature deaths. It is my hope that childhood education can help prevent or delay this common health problem.

The FIFTH Project also has the potential to go beyond a classroom education project. Home blood pressure devices are tools that can potentially be used to help screen adults for high blood pressure, but not everyone has one or should go out and buy one. Therefore, innovative methods are needed to get them to people with some method of feedback. The FIFTH Project may represent one such approach. I ask that you consider participating in a research study that is designed not only to evaluate whether the classroom education is effective but also whether incorporating home blood pressure devices into this program can potentially help in detecting and controlling high blood pressure in the community.

What will the children be asked to do?

As a special addition to the health and science curriculum, all children in the classroom will be taught about the possible health consequences of high blood pressure as well as what people can do to help lower their risk of developing high blood pressure. As part of a classroom activity, children will take one another's blood pressures using a commercially available automatic blood pressure device.

The research component of the program for the children involves four things:

- (1) completion of a very simple questionnaire asking age, race/ethnicity, language spoken at home, and 6 true/false knowledge questions about high blood pressure
- (2) recording of the child's height and weight in a private location of the classroom
- (3) recording of the blood pressure measurements taken in the classroom
- (4) completion of a questionnaire asking the same 6 true/false knowledge questions about high blood pressure 2 months and 4 months after the program

What will parents/guardians be asked to do?

All children will be encouraged to talk to parents/guardians about what they learned about high blood pressure.

The research component of the program for parents/guardians involves four things:

- (1) completion of a baseline questionnaire (attached) returned to school in a sealed envelope
- (2) allowing your child to be loaned an automatic blood pressure device to take home over the weekend so that you can take and record your blood pressure
- (3) send your blood pressure measurements in a sealed envelope to school with your child
- (4) completion of shorter follow-up questionnaires at 2 months and at 4 months

You would be notified if your child's blood pressure measurement is higher than expected for his/her age and height. You would also be notified if your blood pressure measurements are above a level that warrants more immediate attention.

Two copies of the first questionnaire are attached, allowing information to be collected on two parents/guardians. If you and another adult would like to participate, we ask that you both complete the attached consent form as well as the questionnaire and return them to school in the sealed envelope. A second questionnaire, shorter than the first,

would be sent home to you in about three months, and a similar questionnaire about three months after that.

If you choose not to participate yourself - or not to allow your child to participate - in the evaluation portion of this project, that decision will in no way affect your child's grades. Additionally, he/she would still receive the educational portion of the program.

The attached consent form should be signed and returned to the school with your child in the sealed envelope.

Thank you in advance for your time and consideration.

Anthony J. Viera, MD
Robert Wood Johnson Clinical Scholars Program
University of North Carolina at Chapel Hill
(919) 966-3712

Appendix 4

University of North Carolina-Chapel Hill Consent to Participate in a Research Study Adult Subjects Biomedical Form

IRB Study # 05-2696

Consent Form Version Date: 11-2-05

Title of Study: Feasibility of a School Program to Improve Knowledge about Hypertension by Students and Their Parents

Principal Investigator: Anthony J. Viera, MD

UNC-Chapel Hill Department: Robert Wood Johnson Clinical Scholars Program, CB 7105, 5034 Old Clinic Bldg, UNC Chapel Hill, Chapel Hill, NC 27599

UNC-Chapel Hill Phone number: (919) 966-3712

Faculty Advisor: Joanne Garrett, PhD

Funding Source: Robert Wood Johnson Foundation

Study Contact telephone number: (919) 966-3712

Study Contact email: anthony_viera@med.unc.edu

What are some general things you should know about research studies?

You are being asked to take part in a research study. To join the study is voluntary.

You may refuse to join, or you may withdraw your consent to be in the study, for any reason.

Research studies are designed to obtain new knowledge that may help other people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies.

Deciding not to be in the study or leaving the study before it is done will not affect your relationship with the researcher, your health care provider, or the University of North Carolina-Chapel Hill. If you are a patient with an illness, you do not have to be in the research study in order to receive health care.

Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study. You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?

The purpose of this research study is to pilot test a prototype classroom-based program designed to achieve the following three aims: (1) improve children's knowledge about high blood pressure, (2) raise parental/guardian knowledge and

awareness of high blood pressure, and (3) serve as an innovative means to deploy home blood pressure monitors for blood pressure screening of parents/guardians

You are being asked to be in the study because you are the parent/guardian of a fifth grader at North Chatham School.

How many people will take part in this study?

If you decide to be in this study, you will be one of approximately 120 parents/guardians in this research study.

How long will your part in this study last?

Your total time in the study would be approximately four months.

What will happen if you take part in the study?

The first thing you will do is complete a questionnaire containing basic information about you and questions about blood pressure in general. Once your child receives his/her classroom instruction about blood pressure, he/she will be loaned an automatic blood pressure device to take home over a weekend so that you can measure your blood pressure. You would be given an instruction sheet on how to take your measurements and asked to record two measurements on a form. The form would be sealed in an envelope and returned to the school with your child for collection by the researchers. If the physician in charge of the study feels that your blood pressure measurements are in a particularly high range, you will be sent a letter. Approximately two months later, you will be asked to fill out a questionnaire similar to the first one but shorter. Then, two months later, you will be asked to fill out a similar questionnaire.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. The benefits to you from being in this study may be that you learn more about high blood pressure, or you decide to visit your physician who makes sure your blood pressure is in a healthy range.

What are the possible risks or discomforts involved with being in this study?

While risks of being in this study are minimal, you should be aware that blood pressure measurements can vary. It is possible that you could have a high blood pressure reading by the home device and have a normal measurement in your doctor's office. However, home blood pressure measurements tend to be more reflective of people's true blood pressure as long as the machines are accurate and the measurements are taken correctly. If you visit a physician based on a high blood pressure measurement at home and you are determined to not have high blood pressure, you might have lost time off of work in addition to the potential worry and medical expenses.

If you choose not to be in the study, what other treatment options do you have?

You do not have to be in this research study in order for your child to receive the health education portion of the program.

How will your privacy be protected?

No subjects will be identified in any report or publication about this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time.

Will you receive anything for being in this study?

You will not receive anything for taking part in this study.

What if you are a UNC employee?

Taking part in this research is not a part of your University duties, and refusing will not affect your job. You will not be offered or receive any special job-related consideration if you take part in this research.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

What if you have questions about your rights as a research subject?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Subject's Agreement:

I have read the information provided above. I voluntarily agree to participate in this research study.

 Signature of Research Subject

 Date

 Printed Name of Research Subject

<i>Please rate how strongly you agree or disagree with the following statements.</i>	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
<i>11. Most of the time, I will know if I have high blood pressure because I will feel bad or have symptoms.</i>	1	2	3	4	5
<i>12. High blood pressure can lead to heart attacks.</i>	1	2	3	4	5
<i>13. High blood pressure can lead to strokes.</i>	1	2	3	4	5
<i>14. High blood pressure can lead to heart failure.</i>	1	2	3	4	5
<i>15. High blood pressure can lead to kidney failure.</i>	1	2	3	4	5
<i>16. Too much salt can lead to high blood pressure.</i>	1	2	3	4	5
<i>17. Exercise can help lower high blood pressure.</i>	1	2	3	4	5
<i>18. Not smoking can help lower high blood pressure.</i>	1	2	3	4	5
<i>19. High blood pressure can lead to cancer.</i>	1	2	3	4	5
<i>20. Losing weight can help lower high blood pressure.</i>	1	2	3	4	5

A few final questions:

21. Do you currently smoke? Yes No

22. Do you exercise regularly? Yes No

23. What is your height? _____ 24. Weight? _____

25. Is there a particular doctor's office, clinic, health center, or other place you go to if sick or need advice about health? Yes No

26. How would you describe your overall health?

 Excellent Very good Good Fair Poor

27. Do you have access to the Internet from home? Yes No

28. Do you have access to the Internet from work? Yes No Not applicable

Is there anything else you would like to tell us?

Thank you very much for completing this questionnaire!

Preferred mailing address: _____

Telephone number: () _____

Appendix 6

Name _____ Date _____

Teacher _____ School _____

1. I am _____ years old.

2. I am a: Boy Girl (Circle one)

3. I am: Black Hispanic White Not sure (Circle one)

4. Do you speak a language other than English at home? Yes No

If you answered "Yes," what language do you speak at home?

5. For these statements, circle whether you think they are true (T) or false (F).

T F Smoking is bad for your health.

T F High blood pressure is bad for your health.

T F Eating a lot of salty food can make your blood pressure go higher.

T F You can tell someone has high blood pressure by looking at them.

T F Blood pressure gets higher if you exercise a lot.

T F High blood pressure causes cancer.

Appendix 7

Name _____ Date _____

Teacher _____ School _____

	First time	Second time
Blood pressure	/	/
Pulse		

Appendix 8

Student's name _____ Date _____

Teacher _____ School _____

Adult 1

Name _____ Relationship _____

	First time	Second time
Blood pressure	/	/
Pulse		

Adult 2

Name _____ Relationship _____

	First time	Second time
Blood pressure	/	/
Pulse		

Appendix 9

Name _____ Date _____

Teacher _____ School _____

1. For these statements, circle whether you think they are true (T) or false (F).

T F Smoking is bad for your health.

T F High blood pressure is bad for your health.

T F Eating a lot of salty food can make your blood pressure go higher.

T F You can tell someone has high blood pressure by looking at them.

T F Blood pressure gets higher if you exercise a lot.

T F High blood pressure causes cancer.

Appendix 10

Please answer the following questions. Again, your responses will be kept confidential and will not be shared with anyone.

Parent/guardian name: _____

1. Relationship to student: Father Mother Grandparent Aunt/Uncle
Other

2. Do you have hypertension (high blood pressure)? Yes No Not sure

3. Are you on any medications to control your blood pressure? Yes No
Not sure

4. If you answered 'Yes' to 3 or 4, is your blood pressure under control? Yes
No Not sure

5. Within the last 2 months, have you seen a health professional about your blood pressure? Yes No Not sure

6. Within the next 2 months, do you intend to see a health professional about your blood pressure? Yes No Not sure

7. Over the last 2 months, have you changed your diet? Yes No

If so, how? _____

8. Do you currently smoke? Yes No

9. Do you exercise regularly? Yes No

10. Is there a particular doctor's office, clinic, health center, or other place you go to if sick or need advice about health? Yes No

Please rate how strongly you agree or disagree with the following statements.	Strongly disagree	Disagree	Not sure	Agree	Strongly agree
<i>11. I will usually know if I have high blood pressure because I will feel bad or have symptoms.</i>	1	2	3	4	5
<i>12. High blood pressure can lead to heart attacks.</i>	1	2	3	4	5
<i>13. High blood pressure can lead to strokes.</i>	1	2	3	4	5
<i>14. High blood pressure can lead to heart failure.</i>	1	2	3	4	5
<i>15. High blood pressure can lead to kidney failure.</i>	1	2	3	4	5
<i>16. Too much salt can lead to high blood pressure.</i>	1	2	3	4	5
<i>17. Exercise can help lower high blood pressure.</i>	1	2	3	4	5
<i>18. High blood pressure can lead to cancer.</i>	1	2	3	4	5
<i>19. Not smoking can help lower high blood pressure.</i>	1	2	3	4	5
<i>20. Losing weight can help lower high blood pressure.</i>	1	2	3	4	5

Is there anything else you would like to tell us?

Thank you for completing this questionnaire!

Appendix 11

Fifth-graders Initiating Family Talk about Hypertension

A Health Collaborative
with _____ School

Date _____

Dear Parent/Guardian:

Recently, your child _____, participated in a school health project to learn about high blood pressure. As part of that project, he / she had two blood pressure measurements performed at school. Based on these measurements, his / her **blood pressure may be higher than it should be.**

The automatic machines used in the school project may not be as accurate as measurements taken in a health professional's office. Therefore, it is recommended that _____ **be evaluated by a health care professional such as your family doctor or pediatrician.**

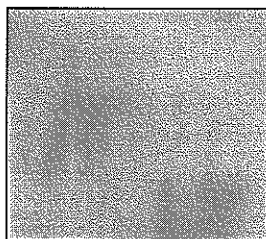
Sincerely,

Anthony Viera, MD

Appendix 12

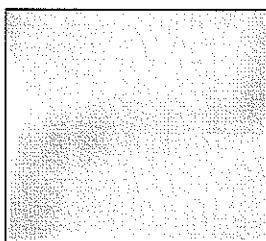
BLOOD PRESSURE ZONES FOR ADULTS

GREEN



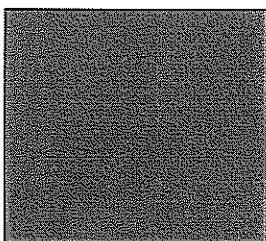
Top number is less than 140 AND bottom number is less than 90. This zone is usually okay, but ideal blood pressure is a top number less than 120 AND a bottom number less than 80.

YELLOW



Top number between 140 - 160 OR bottom number between 90 - 100. If you are in this zone, and it is confirmed by your doctor, you have high blood pressure.

RED



Top number higher than 160 OR bottom number higher than 100. If you are in this zone, and it is confirmed by your doctor, you have high blood pressure.

The measurements provided by the automatic machines may or may not be accurate. If you are in the yellow or red zone, it is recommended you see your health care professional for a blood pressure check. Even if you are in the green zone, you should adapt lifestyle changes that help keep blood pressure under control. These include maintaining a healthy weight, decreasing sodium (salt) intake, eating more fruits and vegetables, getting regular aerobic exercise, and limiting alcohol consumption.

None of the information presented here is meant to replace consultation with a health care professional.

Appendix 13

Fifth-graders Initiating Family Talk about Hypertension

A Health Collaborative with _____ School

Date _____

Dear Parent/Guardian:

Recently, your child participated in a school health project to learn about high blood pressure. As part of that project, he/she had a homework assignment to measure and record your blood pressure using an automatic machine. Based on these measurements, **your blood pressure is higher than it should be.**

However, the automatic machines used in the school project may not be as accurate as a measurement taken in a health professional's office. Therefore, it is recommended that you **be evaluated by a health care professional within one to two weeks to follow-up on your potentially elevated blood pressure readings.**

Sincerely,

Anthony J. Viera, MD
Robert Wood Johnson Clinical Scholars Program
University of North Carolina at Chapel Hill

Appendix 14

University of North Carolina-Chapel Hill Assent to Participate in a Research Study Minor Subjects (7-14 yrs)

IRB Study # 05-2696

Consent Form Version Date: 11-2-05

Title of Study: **Feasibility of a School Program to Improve Knowledge about Hypertension by Students and Their Parents**

Person in charge of study: Anthony J. Viera, MD

Where they work at UNC-Chapel Hill: **Robert Wood Johnson Clinical Scholars Program, CB 7105, 5034 Old Clinic Bldg, UNC Chapel Hill, Chapel Hill, NC 27599**

Other people who work on the study: Joanne Garrett, PhD; Halle Amick, Research Assistant; Kristen Rake, Research Assistant

Study contact phone number: (919) 966-3712

The people named above are doing a research study.

These are some things we want you to know about research studies:

Your parent needs to give permission for you to be in this study. You do not have to be in this study if you don't want to, even if your parent has already given permission.

You may stop being in the study at any time. If you decide to stop, no one will be angry or upset with you. Your grade in this class will not be affected.

Sometimes good things happen to people who take part in studies, and sometimes things we may not like happen. We will tell you more about these things below.

Why are they doing this research study?

You will be asked to fill in a form with your name, age, race/ethnicity. You will be asked six true/false questions about a health issue called high blood pressure. **It is not a test, and you will not be graded.** The reason for doing this research is to see if a new classroom lesson can help you learn about high blood pressure.

Why are you being asked to be in this research study?

All students in this class are being invited to be in this study.

How many people will take part in this study?

If you decide to be in this study, you will be one of about 75 children in this research study.

What will happen during this study?

This study will take place in your classroom. During class, you will get to write down your blood pressure after another student measures it with an automatic machine. In about three months, you will receive another form asking six true/false questions about high blood pressure. Again, it is **not a test, and you will not be graded**. Three months after that you will receive another form asking six true/false questions about high blood pressure. Again, it is **not a test, and you will not be graded**.

Who will be told the things we learn about you in this study?

Only Dr. Viera or his research assistant will have access to your answers to the questions or to your blood pressure information. Your parents will be sent information if we need to tell them about your blood pressure.

What are the good things that might happen?

People may have good things happen to them because they are in research studies. These are called “benefits.” The benefits to you of being in this study may be you will learn about high blood pressure.

What are the bad things that might happen?

Sometimes things happen to people in research studies that may make them feel bad. These are called “risks.” These are the risks of this study: if your blood pressure is high, you may have to see a doctor. Sometimes, seeing doctors makes people scared or worried.

Not all of these things may happen to you. None of them may happen or things may happen that the researchers don’t know about. You should report any problems to the researcher

What if you or your parents don’t want you to be in this study?

You will still get to learn about high blood pressure.

Will you get any money or gifts for being in this research study?

You will not receive any money or gifts for being in this research study.

Who should you ask if you have any questions?

If you sign your name below, it means that you agree to take part in this research study.

Sign your name here if you want to be in the study

Date

Print your name here if you want to be in the study