



Best Practices in Hypertension

Getting to Goal: Patient-Directed Blood Pressure Control

Fletcher Allen Health Care / University of Vermont
Burlington, VT



MEDICAL GROUP PROFILE

- **Fletcher Allen Health Care (FAHC) is the main tertiary care health center in the Burlington, Vermont region.** FAHC serves a population of 500,000 residents in portions of Vermont and northern New York State.
- **FAHC is made up of 30 patient care sites and 120 clinics.** FAHC employs more than 6,700 employees including 483 physicians and 6,267 non-physician employees.
- **Renal Services is an eight-person academic nephrology/hypertension health care practice** with three clinics and 4,400 annual outpatient visits. The renal clinic at FAHC serves as the subspecialty referral center for a suburban and rural population of about 500,000.

FUNDING/BUDGET

No additional budget was created for this project. All services and staff time were provided as in-kind contributions from Fletcher Allen Health Care.

EXECUTIVE SUMMARY

This demonstration project was undertaken to determine whether involving patients in the care of their own blood pressure (BP) management would improve BP control in patients attending the renal clinic. Target patients had high BP and were at high risk for adverse cardiovascular outcomes, including known

- 1 **chronic kidney disease (CKD);**
- 2 **diabetes;**
- 3 **hyperlipidemia;** and/or
- 4 **cardiovascular disease (CVD).**

FAHC identified a cohort of 163 patients who met the outlined criteria. Of the 163 patients identified for the study, 118 patients were identified as “not at goal.” Seventy-seven patients continued with usual care while 41 participated in the patient-directed care project. The project focused on increasing patients’ capacity to monitor, analyze, and direct BP treatment by educating each patient about the importance of BP control, teaching proper home BP measurement techniques, and setting individual BP goals. “Patient-directed” changes in treatment were made by patients contacting clinic staff when BP was not at goal or with the list of their BP measurements every two weeks. Clinic staff then contacted the physician and the patient with appropriate changes in management within 24-72 hours.

Over a six-month period, 90% of the cohort knew their BP goal. The proportion of the group at goal increased from 28% to 33%. Of those not at goal at the beginning of the project, 31% in the patient participation group achieved goal compared to 13% in the usual care group. Of the 30 patients who actively participated for at least six months, 53% achieved goal.

This feasibility project showed that patient participation in the control of BP is feasible and effective, and requires few extra clinic resources.

The project developed a patient BP tracking tool that is currently being used in the clinic. Also, the knowledge that BP was not at goal in the majority of clinic patients resulted in an increased awareness among the physicians that BP is an issue that needs more attention.

As a result of these findings, all clinic patients with CKD were encouraged to participate in a modified protocol. The proportion of patients with high BP and CKD who are at goal has increased from 33% to 59% in the 12 months since the feasibility project finished. These results were presented to the physicians.

Currently, mechanisms are being refined to ensure more patients are involved in their care, and to monitor overall BP control in the clinic population to establish a sustainable quality improvement program.

THE ISSUE

Despite the ready availability of evidence-based guidelines and effective anti-hypertensive strategies, only 34% of patients in the United States with known hypertension have their blood pressure under control (NHANES 1999-2000). The statistics are little better for those at high risk for adverse cardiovascular and renal outcomes, who are most likely to benefit from better BP control. In January 2000, the Department of Health and Human Services launched Healthy People 2010, a comprehensive, nationwide health promotion and disease prevention agenda. Healthy People 2010 contains 467 objectives designed to serve as a road map for improving the health of all people in the United States during the first decade of the 21st century. The Healthy People 2010 goal for patients in the United States with known hypertension to have their blood pressure under control is 50%.

In a preliminary study of CVD risk-factor control in “teaching physicians” offices in the FAHC region, only 40% of patients with hypertension, 40% of those with coronary artery disease, and 33% of those with diabetes had blood pressures at goal. In FAHC practice, where care is provided for people with difficult-to-control hypertension, including those with renal dysfunction from a variety of causes and those with organ transplants, 33% of 500 patients with hypertension seen in the three-month period prior to conceiving this project were at goal.

Studies examining the use of clinic-directed BP management with nurse providers, pharmacist consultants, clinical reminder systems, computer-assisted BP control automated telephone patient monitoring, and patient education, have generally shown positive results. However, most of these strategies require health-care resources that may not be readily available to most clinics or physician practices. Treatment guided by patient self-monitoring of BP has also been shown to be successful as part of management in several trials, but not all.

These issues prompted the Renal Services division of FAHC to explore the feasibility of improving BP control by building patient capacity to direct care while identifying factors involved in this approach. The hypothesis was that providing each patient with an individual BP goal, the ability to measure BP, and an

effective mechanism for changing treatment to achieve the goal would substantially increase the proportion of patients in the clinic who achieve and maintain BP control at minimal cost to the practice group.

GOAL AND OBJECTIVES

The overall goal of this project was to develop a strategy that would allow clinics or practices to increase the proportion of their patients who have BP at goal. The hypothesis was that building patient capacity to monitor, analyze, and direct BP treatment would improve BP control for individuals and groups.

The specific objectives were to:

- **Increase the percent of patients attending renal clinic,** including those patients at high risk for adverse cardiovascular or renal outcomes, who have BP at goal (<130/80 mmHg);
- **Increase patient awareness of his or her BP goal and capacity to achieve it;** and
- **Improve physician awareness of patient-perceived barriers to getting BP to goal.**

Identifying Target Populations

During April and May 2004, BP measurements for the majority of patients attending renal clinic were taken using an automated device. BP was measured three times for each patient, including:

- ① **At rest after 5 minutes;**
- ② **At rest after subsequent 2-5 minutes;** and
- ③ **Again, at rest, after subsequent 2-5 minutes.**

A cohort of 163 (60% M) patients with hypertension and one or more additional adverse cardiovascular risk factors, such as renal disease, diabetes, and/or existing cardiovascular disease, was identified. Those whose average BP was not at goal (<130/80 mmHg as designated by JNC 7 for this group), were asked by their physician if they would like to participate in a program to improve BP control.

Patients who were nursing home residents, who came to clinic very infrequently, or who were not thought suitable by their physician were excluded.

Those who agreed to participate in the study gave informed consent (see Appendices 1 and 2) and became part of the study

group. Follow-up BPs were measured and a questionnaire evaluating patient knowledge and behaviors about BP (see Appendix 3a) was administered to the entire cohort at a clinic visit as close as possible to six months after the initial measurements. Throughout the study, each patient had his or her anti-hypertensive care regulated by his or her nephrologist with consultation with other health care providers if necessary.

Tracking Information

Outcomes were assessed at baseline and six months.

1 Main outcome measures included:

- Percentage of patients with clinic systolic BP at goal in the cohort and the subgroups
- Percentage of patients who knew their BP goal
- Percentage of patients with capacity to influence their care

2 Secondary outcome measures included:

- Time to BP control (weeks)
- Time required by nurse to provide feedback to the patient regarding changes in management (in minutes/month/patient measured by nurse time logs). Although this was initially a goal, meaningful measurement of the time taken for interaction with patients was not possible.
- Patient attitude towards lifestyle change
- List of barriers to achieving goal (patient, physician, and system factors)
- Relationship between home and clinic BP readings

3 Analyses

Change in BP from baseline to six months for the percentage of patients at goal who knew their goal (from the questionnaire results) was evaluated by tests of proportions, and the relationship between home and clinic BP was evaluated by correlation barriers to control were tabulated as percentage of group responding.

INTERVENTIONS

Project Team

The project team included the MD team leader, RN project manager, RN clinic nurse, and medical assistant, who also helped with data entry. Project funds paid for the extra time needed for data entry. All worked in the same geographic location and interacted with each other daily. Other clinic members who participated were two receptionists who triaged all the calls and BP records, and six physicians who continued to manage their own patients' care.

Patient Involvement

For patients to be engaged in their own care, it was established that each patient must be able to:

- **understand** the importance of maintaining a healthy blood pressure;
- **set their own target goals** with the assistance of their physician;
- **monitor and track their own progress**;
- **understand** information about what they can do to attain their target goals; and
- **understand** how to get help from the healthcare system to reach their goals.

To assist patients, FAHC developed the following tools to assist patients in becoming engaged in their own care:

- 1 **Questionnaires** to assess patient knowledge about BP goals and barriers to achieving those goals (see Appendix 3a), and physicians' perception of patient barriers to BP control, were developed and modified with feedback from the physicians (see Appendix 3b).
- 2 **BP tracking sheets**, which included a table to determine if BP was or was not at goal, were provided to patients participating in the patient-directed group. The BP tracking tool became very useful in replacing the odd pieces of paper used to record BPs and the phoned-in lists of BPs that were common practice. The chart to enable patients to determine if they were or were not at goal proved unhelpful and was discarded. It was replaced by notation on the tracking sheets (see Appendix 4).
- 3 **Educational materials** to help patients understand BP goals and treatments including lifestyle changes were provided. FAHC chose to use information from the Department of Health and Human Services National Heart, Lung and Blood Institute, which was well-received. More information about these educational materials can be found at www.nhlbi.nih.gov.

Physician Involvement

As the goal of this project was to develop a strategy allowing clinics to increase the proportion of their patients with BP at goal by engaging these patients in their own care, one challenge was to get physicians to agree to this approach. Getting the Unit Director interested in and supportive of the project, presenting the project to all the physicians at a unit meeting, and persuading the whole group to agree to participate made it possible for FAHC to address the physician buy-in challenge. The preliminary survey of BP in the clinic population was very important in

helping the FAHC physicians recognize that the percentage of patients not at BP goal was not acceptable.

Measuring BP

Measuring BP according to JNC 7 guidelines requires “2 readings 5 minutes apart sitting in a chair.” Because FAHC was interested in whether single BP readings in the clinic setting were representative of a person’s resting BP, three readings were taken. It was initially a challenge to make sure this protocol did not disrupt clinic operations. Some clinics were too busy and BP could not be taken three times, limiting the number of participants in the initial cohort. However, during the follow-up, the clinic staff worked out how to get the extra BP taken while doing other tasks in between. Nevertheless, by taking the extra BP, the clinic visit was extended a little longer than usual. As described later, the first BP reading was on average 3 mm Hg higher than the second or third readings. Hence, in current practice, a second BP reading is only taken if BP is not at goal on the first reading.

LEADERSHIP

The Director of Medical Subspecialty Services and the Medical Director of Renal Services (two major leaders at FAHC) were instrumental in enabling the project to be undertaken. Leadership by the Renal Services director was very helpful in encouraging the physicians to take an interest in the project and tolerate small delays in the flow of clinic patients during the feasibility study. Both individuals provided critical in-kind support, e.g., clinic space and personnel time required for the additional BP measurements, patient education, and feedback while the project was being developed. They and the Chair of the Department of Medicine supported the efforts of the physician team leader. The leadership of the FAHC nurse manager was pivotal for problem solving and helping staff cope with relatively small increases in workload, which seemed large if the clinic was very busy. Also the FAHC nurse manager’s efforts were essential in helping clinic staff work out how to get in touch with the participants and their physicians, and coordinate changes in treatment in a timely and efficient manner.

PROJECT PLAN

Patient-directed care plan

Each person who agreed to participate in the study was given:

- **A BP goal;**
- **A 30-60 minute educational session** about the importance of BP control;

- **Information about treatment options** including potentially beneficial lifestyle changes; and
- **A sphygmomanometer.**

Because home BP measurements tend to be lower than those taken at the clinic, the home goal was set at <125/80 mmHg in the hope of achieving clinic BP of <130/80 mmHg. Emphasis was placed on achieving the systolic BP goal because of increasing recognition of its importance as a risk factor for adverse CVD outcomes, especially in persons >50 years of age.

Each person was directed to:

- 1 **Measure and record BP and pulse** (after rising in the morning, before taking any medications, and after dinner in the evening) every day until BP was at goal, or after changes were made in their treatment (active periods) and then twice a week during a maintenance period.
- 2 **Phone, fax, e-mail or mail readings** to clinic nurse after every two weeks during active periods, every two months during maintenance periods, and at any other time BP was not considered to be at goal.
- 3 **Evaluate if BP was at goal** every two weeks during active periods or every two months during maintenance periods. This was to be done by viewing the BP chart and determining if there was more than one BP reading above the goal for every two BP readings at or below the goal for systolic blood pressure for the period being assessed.
- 4 **Contact clinic nurse** by phone, fax or e-mail if, by this definition, BP was not at goal, to get instructions about how to improve BP control.

The clinic nurse then showed the information and clinic record to the patient’s physician, who made treatment changes. The clinic nurse informed the patient of the changes and the need to continue to take BP readings twice a day for the next two weeks and again contact the clinic if BP was not at goal. This pattern was repeated until BP reached goal and the maintenance phase began. Patients were instructed to keep all their BP charts so that they could be viewed at the next office visit for correct interpretation.

OUTCOMES

The first objective was to increase the percentage of renal clinic patients at high risk for CVD with a desirable BP <130/80

mmHg. Among the whole cohort of 163, 33% were at goal at six months compared to 28% at baseline, a smaller increase than expected. However, of the 118 not at goal at baseline, 31% of the patient-directed group were at goal at six months compared with 13% of the usual care group ($1c<0.05$). Of the 30 (73% of the 41 enrolled in the patient-directed group) who participated actively, 52% achieved goal (40% $<130/80$ mmHg and 12% told by their physician they were at goal). Ninety-two percent who achieved goal did so within four months.

The second objective was to increase patients' awareness of the BP goal and their capacity to achieve it. By six months, 90% of the cohort was aware that their BP were goal should be less than 130/80 mmHg; however, only 50% knew whether they were or were not at goal.

The major patient-perceived barriers to getting to goal were:

- **Not knowing if they were at goal;**
- **Not knowing what to do if not at goal;**
- **Not having the time or liking to exercise;** and
- **Not knowing what diet to follow** or not being able to follow a prescribed diet.

The third objective was to assess physician awareness of patient-perceived barriers to getting BP to goal. Physicians and patients were in concordance about the barriers described above, but physicians considered cost of medication to be a greater barrier than did the patients.

Other outcomes included evaluating the relationship between home and clinic BP measurements. Average home systolic BPs were 2-5 mmHg lower and diastolic BP 0-2 mmHg lower than clinic BP measured within a two-week period. There was a strong correlation between average home and average clinic BP for both systolic BP ($r = 0.5$) and diastolic BP ($r = 0.9$).

FAHC also noted that the first clinic BP reading was higher than the second and third clinic BP readings by an average of 3 mmHg ($p<0.001$) at both baseline and six-month follow-up.

KEYS TO SUCCESS

Following are the main factors that contributed to the success of this project:

- **Patients actively participating in the study were excited** about being involved in their own care and grateful that

their BP was being managed better. This encouraged all involved.

- **Small amounts of financial support for extra staff time required for data entry engaged the staff** and increased their interest in and enthusiasm for the project.
- **Presenting the results to all involved staff** confirmed that FAHC has an ongoing need to improve BP control in high-risk patients.
- **The realization that the tracking tools developed and minimal increase in clinic effort could improve BP control** in a significant proportion of high-risk patients has made it possible to continue with this project

CHALLENGES

- **The biggest operational challenge was to introduce the project without disrupting the clinic flow.** The main disrupter was the plan to take BP readings three times over a 10-minute period. However, this enabled FAHC to understand the relationship between first and subsequent BP readings.
- **Although the majority of patients in the active group were measuring their BP at home, some were not sending FAHC the readings.** One method that helped increase compliance was giving the patients an envelope addressed to the clinic.
- **How does one get patients to recognize when they are at goal or not at goal?** FAHC has not yet completely resolved this, but a patient gave us the answer by saying he looked to see if he had more in the red than in the green. We are now trying this approach.
- **Getting physicians to believe that this approach would not take more time.** As it turned out, the patient involvement and their use of the BP monitoring tool made communication with physicians and clinic staff more efficient and allowed some patients to get to goal before their next clinic visits.

LESSONS LEARNED

- **FAHC should have engaged the staff earlier** and enlisted their overall support more completely so they felt ownership in the project right from the beginning.
- **Patient's participation in the control of their BP is feasible and effective.**
- **Patient's knowledge of their BP goal is not enough to allow them to achieve it.** They need to have ways of identifying if they are *at goal* or *not at goal* and what to do next.
- **BP in FAHC clinic patients is not controlled as well as the staff originally thought** it was. In order to know

how FAHC is doing and make changes FAHC needs to track BP control on an ongoing basis.

- **BP control programs with patients measuring BP at home** and contacting the clinic or health care provider for changes in treatment can be run without extra clinic visits and thus could be useful for patients in other (especially rural and underserved) settings.
- **The BP tracking sheet required several modifications** before working well for patients and being effective and efficient for staff. It is certainly better than phoned-in lists or records on scraps of paper. FAHC is experimenting with adding personalized goals to allow a stepwise approach to getting to goal.
- **Patients in the FAHC service area used mail rather than e-mail to send BP records to clinic.** Providing envelopes addressed to the clinic seems helpful.
- **Having patients meet in groups to learn about BP goals, treatments and measurement methods was not feasible for FAHC because many people lived long distances from the clinic.** However, shorter one-to-one sessions with a patient and clinic nurse around the time of a regular clinic visit worked well.
- **Staff participation in the project increased understanding of BP measurement, goals and treatment and the value of studies as part of patient care.**
- **FAHC confirmed that the first clinic BP taken is likely to be artificially elevated,** and if high, may need to be repeated. In addition, it was confirmed that home BP tends to be a few mmHg lower but is a useful measure for tracking and making changes to treatment regimens.
- **One can always learn from patients.**

ADVICE TO OTHERS

- **Establish baseline data for the target population.** Present this prior to initiating an intervention to establish the need for the intervention and importance of the issue.
- **Think about how the success or failure of the intervention** can be used in the future prior to starting the project.
- **For feasibility projects or the feasibility phase of larger projects, take every opportunity to find the problems and make changes as early as possible in the process.** Looks at all tools, information sheets, clinic practices, etc., and try to make sure they are reliable, practical, and understandable, and use time efficiently. There are always unforeseen issues in the best-planned projects, and the solution is to look for them, recognize them, and make changes promptly.
- **Inform anyone likely to be affected by the project**

(no matter how slightly) about what you want to do before starting, and deal with issues they might see as real or

perceived problems for them. This stops obstacles from being erected and encourages support from sources that one may not have thought were needed.

- **Engage clinic staff in the project and provide them with information about it at the beginning and throughout the project.** Allowing clinic staff to take on extra reimbursable activities for the project, such as data entry, can provide a sense of ownership and promote involvement and enthusiasm.

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FOR ADDITIONAL INFORMATION

Contact

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Appendix 1

IRB APPROVAL – INFORMED CONSENT TO BE SIGNED BY ALL PATIENTS PARTICIPATING IN THE GETTING TO GOAL STUDY

TITLE OF RESEARCH PROJECT: Getting to Goal: Patient Directed Blood Pressure Control

PRINCIPAL INVESTIGATOR: Virginia Hood, MD
Fletcher Allen Health Care
Department of Renal Services
1 South Prospect Street
Burlington, VT 05401

SPONSOR: American Medical Group Association (AMGA) and Pfizer, Inc.

You are being invited to take part in this research study because your doctor has identified you as someone with high blood pressure that is not adequately controlled. This study is being conducted by/at Fletcher Allen Health Care, Inc., the hospital affiliated with the University of Vermont College of Medicine.

We encourage you to ask questions and take the opportunity to discuss the study with anybody you think can help you make this decision.

Why Is This Research Study Being Conducted?

Hypertension (high blood pressure) damages the kidneys, heart and other organs. It has been found that if blood pressure (BP) is controlled, the damage caused by high blood pressure can be reduced. The goal in this study is to see if better blood pressure control can be achieved with patients are involved in their own care.

How Many People Will Take Part In This Study?

One hundred (100) people from the Department of Renal Services medical practice will take part in this study. Your participation will last for up to 12 months.

During the 12-month period, you will be asked to come to your kidney doctor's office at Fletcher Allen Health Care 6 times.

What Is Involved In this Study?

If you decide you would like to participate in this research study, you will be asked to attend a one-hour educational session in the renal clinic. At this meeting, you will be taught about BP and the importance of controlling your BP. You will be given a BP goal. Different treatment options and potentially beneficial lifestyle changes will be discussed. You will be given a sphygmomanometer (blood pressure cuff) and trained to use it. You will be asked to measure and record your BP and pulse twice a day. You will measure your blood pressure in the morning before taking any medications and after supper in the evening. You will be asked to do this every day for the first two weeks of the study. You will be given a chart on which to record the measurements. After this 2-week period, you will be asked to inform the

Appendix 1 (con't)

IRB APPROVAL

clinic nurse if your BP is at goal and send the readings to the clinic. This can be done by phone, fax or e-mail. The nurse will show your information to your kidney doctor, and he or she will make changes to your medication based upon the numbers you have provided. The nurse will inform you of any changes made.

If your BP medications are changed at any time during the course of the study by your kidney doctor or other doctor you see, you will be asked to measure your BP 2 times a day for 2 weeks, just as you did at the start of your participation. This is called the active phase of the study.

Once your BP is at goal and there have been no recent changes in your BP treatment, you will measure your BP 2 times a day, 1 day a week. This is the maintenance phase.

Every 2 months, you will be required to come to the clinic and have your blood pressure measured by a clinic nurse. You will be asked to bring your chart, and the results will be reviewed. If it is determined that your blood pressure is controlled, you will continue in the maintenance phase measuring BP one day a week and return to the clinic in 2 months. If any changes are made with your blood pressure medication, you will return to the active phase where you measure your BP each day.

You will be asked to complete a questionnaire 3 times during this study. This will take approximately 15 minutes. The purpose of this questionnaire is to see how much knowledge you have about BP control and what you see as barriers to your BP control.

What Are the Risks and Discomforts of the Study?

There are no risks associated with measuring blood pressure.

What Are the Benefits of Participating in this Study?

The benefits of participating in this study include careful monitoring and treatment of your condition. You will gain knowledge about controlling your blood pressure and will be actively involved in your treatment.

You will be given a sphygmomanometer (blood pressure cuff) and will be trained to use it.

It is possible that you will receive no benefit from participating in this study.

What Other Options Are There?

You do not have to enter this study to be treated for your condition. There are many treatment options available, including drugs, diet, and lifestyle changes. Please feel free to discuss these options with your doctor. Your treatment will be determined by your doctor, not the study team.

Appendix 1 (con't)

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Are There Any Costs?

There are no costs directly associated with your participation in this study. You or your insurance will be charged for office visits and you will be required to purchase drugs for your hypertension. This is considered routine care.

What Is the Compensation?

There is no monetary compensation for participating in this study.

Can I Be Withdrawn from this Study?

You may decide to withdraw your participation at any time without penalty.

What about Confidentiality?

A record of your progress will be kept in a confidential form at the Department of Renal Services. The security of your record will be maintained by Dr. Hood. The results of this study may eventually be published and information may be exchanged between medical investigators, but patient confidentiality will be maintained.

The sponsors of this study, the American Medical Group Association, Pfizer Inc., or their appointed designees as well as the Institutional Review Board, will be granted direct access to your original medical and research records for verification of clinical trial procedures and/or data.

If your record is used or disseminated for government purposes, it will be done under conditions that will protect your privacy to the fullest extent possible consistent with laws relating to public disclosure of information and the law enforcement responsibilities of the agency.

Please refer to the separate Authorization Form that explains more specifically how your personal health information will be used.

What Happens if I Am Injured?

If you are injured or become ill as a direct result of participating in this research project, Fletcher Allen Health Care, the hospital affiliated with the University of Vermont, will provide reasonable and customary medical care for that injury or illness at no cost to you providing certain conditions are met.

These conditions are:

- 1 The costs of the care are not covered by your insurance or other third part coverage, or you have no such coverage or insurance;
- 2 It is the opinion of the investigator and/or sponsoring agency that the injury or illness is a result of the research;

Appendix 1 (con't)

IRB APPROVAL

- ③ For studies which provide treatment of a specific condition or disease, it is the opinion of the investigator and/or sponsoring agency that the injury is not associated with your disease/condition or with the expected complications of the usual therapies for the disease/condition;
- ④ You have followed all of the directions of the investigator;
- ⑤ You have notified the investigator of the injury or illness in a timely manner after the onset; and
- ⑥ You have followed medical advice regarding the injury or illness.

It is not the policy of the University or Fletcher Allen Health Care to provide any further financial compensation in the event of an injury or illness. You should understand, however, that by acknowledging this you are not waiving or releasing any of your legal rights.

You may contact Dr. Virginia Hood, the investigator in charge of this study, at 802-847-3572 for more information about this study. If you have any questions about your rights as a participant in a research project or for more information on how to proceed should you believe that you have been injured as a result of your participation in this study, you should contact Nancy Stalnaker, the Institutional Review Board Administrator at the University of Vermont at 802-656-4067.

Statement of Consent

You have been given and have read or have had read to you a summary of this research study. Should you have further questions about the research, you may contact the person conducting the study at the address and telephone number given below. Your participation is voluntary and you may refuse to participate or withdraw at any time without penalty or prejudice to your present and/or future care.

You agree to participate in this study and you understand that you will receive a signed copy of this form.

Signature of Subject

Date

Name of Subject Printed

Signature of Principal Investigator or Designee

Date

Name of Principal Investigator or Designee Printed

Virginia Hood, MD
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Appendix 2

IRB APPROVAL - AUTHORIZATION FORM TO PERMIT THE USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION FOR RESEARCH PURPOSES

TITLE OF STUDY: Getting to Goal: Patient Directed Blood Pressure (BP) Control

PRINCIPAL INVESTIGATOR: Virginia Hood, MD

Department of Renal Services
Fletcher Allen Health Care/UHC Campus
1 South Prospect Street
Burlington, VT 05401

CHRMS NUMBER: 04-265

PURPOSE AND SCOPE OF AUTHORIZATION

You have agreed to participate in the study identified above, and have signed a separate consent form that explains the study procedures and provides representations regarding the confidentiality of your personal health information.

This Authorization is required by privacy regulations that are a part of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), and other applicable laws. Any health care provider who is subject to the HIPAA Privacy Regulations is referred to in those regulations as a "Covered Entity" (meaning, it is governed by those regulations).

This Authorization applies to each Covered Entity who maintains personal health information about you that is relevant to this research study. Fletcher Allen Health Care, Inc. ("FAHC") is one such Covered Entity. As of the date that you sign this Authorization, other include

[This blank must be filled in by the researcher before you sign this authorization.]

This Authorization legally permits FAHC and other Covered Entities, even if they are not identified by name in this document to use and disclose your personal health information for this research study, but only in accordance with the restrictions set forth below. A Covered Entity might not be identified by name above because at the time you signed this Authorization, we may not have known that the Covered Entity maintained personal health information about you that was relevant to the research study.

The HIPAA Privacy Regulations use a special term to identify your personal health information – they call it "protected health information", or "PHI", for short. We refer to "PHI" below to mean your personal health information.

Appendix 2 (cont)

IRB APPROVAL - AUTHORIZATION FORM TO PERMIT THE USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION FOR RESEARCH PURPOSES

This Authorization gives you detailed information about how your PHI will be used, disclosed and protected in the context of this study, and answers the following questions:

- ① What PHI about you will be used or disclosed by a Covered Entity?
- ② Who within each Covered Entity may use or disclose your PHI?
- ③ To whom may a Covered Entity disclose you PHI?
- ④ How long will a Covered Entity be able to use or disclose your PHI?
- ⑤ Will you be able to access your PHI associated with this study?
- ⑥ What happens if you decide not to sign this Authorization?
- ⑦ Can you change your mind and revoke this Authorization?
- ⑧ What happens once your PHI has been disclosed by a Covered Entity?
- ⑨ Will the results of the study be presented in publications?
- ⑩ Who should you contact with any questions or concerns regarding your privacy rights?

1. What PHI about you will be used or disclosed by a Covered Entity?

The following PHI may be used by a Covered Entity, or disclosed to authorized persons by a Covered Entity, in connection with your involvement with this research study.

Basic personal demographic information, including name, address, Social Security number, date of birth, occupation, marital and family status, and similar information. Pre-existing health information pertaining to you that the researchers will need to use in connection with the performance of the study, such as, inpatient medical records, outpatient medical records, primary care physician's notes (such as internists, family practitioners, obstetrician-gynecologists), specialist's notes (such as surgeons, oncologists, cardiologists, and others as needed). We will review your records as few years back as necessary to gather the pertinent information to perform this study. We will not access mental health records as they are not relevant to this study.

All of the health information you will receive in the course of this research study. These tests, procedures, medications and treatments are set forth in the consent form that you signed, and can be found under the "What Is Involved In The Study" section of the consent form. More specifically, the types of tests, procedures, medications and other treatments include: attending an educational session, measurement of blood pressure at home and in the clinic, completing of logs to monitor your progress, and completing of a questionnaire 3 times a year.

2. Who within each Covered Entity may use or disclose your PHI?

The following persons or classes of persons within each Covered Entity are authorized to use or disclose your PHI for this research study:

The Principal Investigator (the individual with primary responsibility for the research project) and the Principal Investigator's study team, to the extent such persons are employees of a Covered Entity, for the purposes of conducting the study; Employees of a Covered Entity's Health Information Management Department (or other holders of

Appendix 2 (con't)

IRB APPROVAL - AUTHORIZATION FORM TO PERMIT THE USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION FOR RESEARCH PURPOSES

health records), for the purpose of managing the proper release of your PHI to this research study; health care providers employed by a Covered Entity, for the purpose of (1) fulfilling orders made by the investigators for health care services (e.g., laboratory tests and diagnostic procedures) associated with the research study; (2) addressing correct payment for tests and procedures ordered by the investigators; and (3) for internal operations (e.g., quality assurance); Other employees of a Covered Entity who may reasonably need to access your PHI, for the purposes of performing their jobs (e.g., to ensure the integrity of the research, to ensure proper billing for treatment associated with the research, to ensure appropriate grant accounting, for billing and auditing, to maintain records resulting from the research, and for other similar and related matters); Other employees of a Covered Entity who may need to access your PHI, for the purposes of treatment, payment and health care operations, as such terms are explained in a Notice of Privacy Practices previously provided by each Covered Entity to you;

3. To whom may a Covered Entity disclose your PHI?

As part of the study, a Covered Entity may disclose your PHI (including the results of study tests and procedures), to the following persons or classes or persons:

- The Principal Investigator and the Investigator's study team, to the extent such persons are not employees of a Covered Entity, for the purposes of conducting the study;
- The University of Vermont ("UVM") Institutional Review Boards (or other institutional review boards), for the purpose of overseeing the protection of human subjects;
- Health care providers who are not employed by a Covered Entity, for the purpose of (1) fulfilling orders made by the investigators for health care services (e.g., laboratory tests and diagnostic procedures) associated with the research study; (2) addressing correct payment for tests and procedures ordered by the investigators; and (3) for internal operations (e.g., quality assurance);
- Authorized representatives of the sponsor of this research study, the American Medical Group Association and Pfizer, Inc., for the purposes of monitoring the accuracy and completeness of the research data, monitoring and reporting on patient safety matters, and performing required scientific analysis of the research data, and authorized representatives of regulatory agencies, for the purpose of monitoring the research.
- UVM employees who may reasonable need to access your PHI, for the purpose of performing their jobs (e.g., to ensure the integrity of the research, to ensure proper billing for treatment associated with the research, to ensure appropriate grant accounting, for billing and auditing, to maintain records resulting from the research, and for other similar and related matters);
- Authorized representatives of other medical centers or institutions participating in the research study, including members of any data safety monitoring board established for this study, for the purpose of enabling their full and active involvement in the research study;

4. How long will a Covered Entity be able to use or disclose your PHI?

This Authorization for this specific study does not expire. Your PHI may be maintained in a research repository (i.e., a database) by a Covered Entity for this specific study. However, a Covered Entity may not re-use or re-disclose your PHI collected in this study for another purpose other than the research described in this document unless you have given written permission for the Covered Entity to do so or the Covered Entity has obtained permission to do so from an

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Institutional Review Board in accordance with applicable laws. An Institutional Review Board is a committee whose job it is to protect the safety and privacy of research subjects.

5. Will you be able to access your PHI associated with this study?

You will be able to have access to your PHI that is created or obtained by a Covered Entity in the course of this research study, to the extent such access is otherwise permitted by applicable laws, but only after this study has concluded. You will not be able to access the PHI during your participation in the study, to prevent the knowledge of study results from affecting the reliability of the study. Nevertheless, your PHI will be available to your treating doctors should an emergency arise that would require those doctors to know this information to best treat you.

6. What happens if you decide not to sign this Authorization?

You are not obligated to sign the Authorization. However if you decided not to sign the Authorization, you will not be allowed to participate or continue to participate in the research study, which means you will not be entitled to receive any treatment related to the research. A decision to not sign this Authorization will otherwise have no effect on your current or future medical care from a Covered Entity or payment for the medical care, nor will it cause any penalty or loss of benefits to which you are otherwise entitled or eligible.

7. Can you change your mind and revoke this Authorization?

You may withdraw your permission for the use and disclosure of your PHI for this research study, but you must do so in writing to the Principal Investigator at the address set forth above. If you withdraw your permission, the Principal Investigator for the research study may still use and disclose your PHI that was collected, to the extent necessary to preserve the integrity of the study. If you so withdraw, you may no longer participate in the research study.

8. What happens once your PHI has been disclosed by a Covered Entity?

We believe that most institutions involved with research understand the importance of preserving the confidentiality of participant health information. However, once a Covered Entity discloses your PHI, in a manner permitted by this Authorization, a re-disclosure of your PHI by the recipient will not be covered by this Authorization, and may not be subject to the HIPAA Privacy Regulations or other privacy laws. Of course, each Covered Entity and UVM agree to protect your PHI by using and disclosing it only as permitted in this Authorization and as directed by state and federal law.

9. Will the results of the study be presented in publications?

The results of the research study may be presented in publication; however, names and other personally identifying information about you and other research participants will not be revealed in such publications.

Appendix 2 (con't)

IRB APPROVAL - AUTHORIZATION FORM TO PERMIT THE USE AND DISCLOSURE OF PERSONAL HEALTH INFORMATION FOR RESEARCH PURPOSES

10. Who should you contact with any questions or concerns regarding your privacy rights?

If you have any questions or concerns about your privacy rights, you should contact the Principal Investigator at 802-847-3572 or the Privacy Officer at the appropriate Covered Entity. For FAHC, the Privacy Officer is Michael Hawkins and he can be reached at 802- 847-3532.

All of the above has been explained to me and all of my current questions have been answered. I understand that, throughout my participation in the research study, I am encouraged to ask any additional questions I may have about the research use and disclosure of my PHI. Such future questions may be answered by the Principal Investigator or the Investigator's study team.

I have read this Authorization, and acknowledge that I am the research subject or authorized to act on behalf of the research subject. By signing this Authorization, I agree to allow the use and disclosure of my PHI for the purposes described above, and I agree to the other terms identified above. A copy of this Authorization (as signed below) will be given to me.

Subject Name [print]

[Signature]

Date

Person obtaining authorization [print]

[Signature]

Date

For subjects unable to give authorization, the authorization is given by the following legally authorized subject representative

Subject Representative [print]

[Signature]

Date

If a representative signs the authorization, a description of such representative's authority to act for the subject must be provided below:

Committee on Human Research
Date 02/25/04

Virginia Hood, MD
Department of Renal Services

Appendix 3a

QUESTIONNAIRE EVALUATING PATIENT KNOWLEDGE AND BEHAVIORS ABOUT BLOOD PRESSURE

BP AT GOAL PATIENT QUESTIONNAIRE

Please circle one answer for each question

1. Do you consider your BP to be under control?

yes no don't know

2. At what value would you consider your BP to be under control?

120/70 130/80 140/90 150/100 don't know

3. What problems do you see that stops your BP being controlled?

Circle all that apply

- a. I do not know my BP goal
- b. I do not know what my BP is or how to measure it
- c. I do not know how to decide if my BP is well-controlled
- d. I do not know what to do when my BP is not at goal
- e. I do not know how to talk to my doctor about BP control
- f. My blood pressure medications make me feel bad
- g. My blood pressure medications are too expensive
- h. I do not have time or do not like to exercise
- i. I do not know what diet to follow
- j. I have difficulty following the diet prescribed by my doctor
- k. I have too many other things to worry about

Date _____

Appendix 3b

QUESTIONNAIRE EVALUATING PHYSICIAN'S ASSESSMENT OF THE PATIENT'S KNOWLEDGE AND BEHAVIORS ABOUT BLOOD PRESSURE

BP AT GOAL PATIENT QUESTIONNAIRE

Mark on the corresponding scale of 0-10 with 0 being least important and 10 being most important your assessment of your patients' perception of the following barriers to their BP being at goal.

- a. I do not know my BP goal
0 _____ 10

- b. I do not know what my BP is or how to measure it
0 _____ 10

- c. I do not know how to decide if my BP is well-controlled
0 _____ 10

- d. I do not know what to do when my BP is not at goal
0 _____ 10

- e. I do not know how to talk to my doctor about BP control
0 _____ 10

- f. My blood pressure medications make me feel bad
0 _____ 10

- g. My blood pressure medications are too expensive
0 _____ 10

- h. I do not have time or do not like to exercise
0 _____ 10

- i. I do not know what diet to follow
0 _____ 10

- j. I have difficulty following the diet prescribed by my doctor
0 _____ 10

- k. I have too many other things to worry about
0 _____ 10

Date _____

Appendix 4

BP TRACKING SHEETS AND TABLE FOR ASSESSING IF BP WAS AT GOAL FOR PATIENTS PARTICIPATING IN THE PATIENT DIRECTED ARM

IS MY BLOOD PRESSURE AT GOAL

RECORD YOUR BLOOD PRESSURE

Write a "1" in column 1 (green) if your SBP is 130 or lower
 Write a "1" in column 2 (red) if your SBP is higher than 130

Column 1

Column 2

Date	Time	SBP Systolic (Top)	DBP: Diastolic (Bottom)	Pulse	SBP 130 or lower	SBP higher than 130
	Am					
	Pm					
	Am					
	Pm					
	Am					
	Pm					
	Am					
	Pm					
	Am					
	Pm					
	Am					
	Pm					
	Am					
	Pm					
	Am					
	Pm					
	Am					
	Pm					
	Am					
	Pm					
Your Name				Totals		

If your BP is not at goal, contact Renal Services at 802-847-3572 or mail this sheet to us.

Please bring this sheet to your next doctor's visit if you have not mailed it.

ADD UP EACH COLUMN
 If this total is HIGHER You are at YOUR BP GOAL

ADD UP EACH COLUMN
 If this total is HIGHER You are at NOT at your BP GOAL



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