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Older Adults' Understanding of Cardiovascular Risk And Preventive Medication Benefit

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Older Adults' Understanding of Cardiovascular Risk
And Preventive Medication Benefit

A Thesis Submitted to the
Yale University School of Medicine
in Partial Fulfillment of the Requirements for the
Degree of Doctor of Medicine

by

Elizabeth R. Wahl

2008

OLDER ADULTS' UNDERSTANDING OF CARDIOVASCULAR RISK AND PREVENTIVE MEDICATION BENEFIT

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Medication decision making in older adults with multiple chronic conditions is complicated; communication between patients and physicians to establish concordant treatment goals can enhance this process. While patients' ability to make informed decisions about treatment priorities depends on their ability to understand the risks and benefits of medications and the likelihood of disease outcomes, patients' knowledge of medication-related benefits is unexplored. We examined older adults' estimation of their 10-year risk of myocardial infarction (MI) and stroke, and the degree to which they thought common medications were able to prevent these outcomes. 150 male veterans age 65 or older and taking five or more medications (including an aspirin, a statin, or an antihypertensive drug) were interviewed at VA Connecticut. Using a bar graph with bars representing 0, 10, 25, 50, 75, and 100%, participants were asked to estimate their 10-year risk of stroke and MI when: a) taking no medications, and b) when taking preventive medications (aspirin to prevent MI and stroke; statins to prevent MI; and anti-hypertensives to prevent stroke).

Participants had a mean age of 76 ± 6 years and were on 10 ± 3 medications: 90% had hypertension, 76% had diabetes, 15% had prior MI, and 12% had prior stroke. Framingham data suggest the 10-year risk of MI in this population is close to 25%, which decreases to about 15% on aspirin or statins. 130/147 (87%) participants overestimated their risk of MI (48% estimated it at 75 or 100% over 10 years), 37 (24%) participants felt that aspirin provided at least a 50% absolute risk reduction in MI, and 33% of participants felt that statins could reduce MI risk by the same degree. However, 18% of participants felt that daily aspirin did not change their MI risk at all, and 20% felt a daily

statin did not change their MI risk. For stroke, Framingham data suggest that 10-year risk in this population is close to 25%, which decreases to 15% on aspirin and anti-hypertensives. 128/149 (86%) participants overestimated their stroke risk, with 90 (60%) estimating that risk to be 75 or 100%. 46/147 (31%) participants estimated that aspirin could reduce provide a 50% absolute risk reduction in 10 year stroke risk, and 39% estimated that anti-hypertensives could provide at least a 50% absolute risk reduction. 18 (12%) participants felt that taking a daily aspirin, and 18% felt that taking a daily anti-hypertensive did not change their ten-year stroke risk.

A large proportion of older males overestimated both their 10 year risk of MI and stroke. They also over- and under-estimated the magnitude of benefit conferred by aspirin, statins, and anti-hypertensive drugs in preventing these adverse clinical outcomes. Both findings have important implications for medication decision making, since under-estimation of benefits may play a role in non-adherence, while over-estimation of benefits may result in tolerance of medication side effects with the expectation that they provide a greater degree of benefit. This study suggests the need for increased patient-physician communication regarding the risks and benefits of commonly prescribed preventive medications.

Acknowledgements

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Introduction

Medication prescribing and decision making, particularly in an older population with multiple morbidities taking multiple medications, presents challenges for patients and physicians alike. Patients taking multiple medications should have some understanding of the risks and benefits conferred by their medications in order to make informed decisions about treatment priorities, particularly for those drugs requiring lifelong preventive therapy.

Medication Use in Older Adults: the Current Prescribing Milieu

Current Medication Prescribing Practices in the Elderly

With the population in the United States older than 65 growing rapidly, the number of people affected by and treated for multiple chronic conditions will continue to grow. Reports from nearly a decade ago using 1999 Medicare claims data found that 32 percent of Medicare beneficiaries have four or more chronic conditions; moreover, these patients are responsible for 79 percent of Medicare program spending (1). Studies of medication use in the ambulatory adult population show that 50 percent of adults who are 65 years and older take five or more medications weekly, and 12 percent take ten or more medications weekly (2, 3).

Current evidence supports multiple medication prescribing for the prevention of negative sequelae for many of the most common chronic diseases—hypertension, diabetes and ischemic heart disease. Disease-specific guidelines for these conditions recommend that patients take two, three, or more medications per condition for optimal management. For example, the 7th report of the Joint National Committee guidelines for management of hypertension were released in 2003, promoting the use of 2 or more antihypertensive medications in most patients to achieve goal blood pressure (4).

Similarly, revisions in 2003 to the American Diabetes Association guidelines recommend that patients take multiple classes of medications to maintain adequate glycemic control, in addition to aspirin, statins, and ACE-inhibitors for prevention of cardiovascular and renal complications (5). Recent American Heart Association recommendations for management of ischemic heart disease and heart failure support multiple medication prescribing to optimize treatment for these conditions as well. Thus, with the development of novel therapies to treat disease, and growing evidence that preventive medications can limit disease burden, both the number and complexity of drugs prescribed to the elderly has increased.

Other factors which contribute to multiple medication prescribing may include the number of available prescribed and over-the-counter pharmacotherapies, as well as physicians' ability to treat conditions or symptoms that may have been less treated in the past (e.g., reflux disease). Additionally, direct-to-consumer advertising for management of conditions that predominantly affect the elderly, such as hyperlipidemia, osteoarthritis, osteoporosis, and dementia, may impact medication prescribing practices (6, 7).

Evidence for Medication Benefit in the Elderly

There is a lack of high-quality evidence to guide prescribing practices in older patients (6, 8), largely because older persons have been historically excluded from participating in clinical trials because of their multiple morbidity and possible cognitive impairment (9-11). Gurwitz et al. report that between 1960 and 1991, 60% of trials excluded persons over 75 years old (9). Less is therefore known about optimal prescribing in these patients, as well as the extent to which these medications provide benefit relative to harm in this population. Additionally, no study has explored (or could easily explore) whether the multiple medications recommended for separate medical conditions cumulatively have the same effect as they do individually (8). While there may

be clear evidence documented by randomized controlled trials that a certain medication prevents a health outcome by a certain amount, few trials exist to test whether multiple medication regimens taken by older persons collectively provide the same level of preventive or therapeutic benefit as that demonstrated for each medication alone.

Medication Use and Risk for Adverse Medication Outcomes

Medications used to treat chronic disease provide benefit to patients by preventing hospitalization and disease progression, improving or relieving symptoms, and even extending life. However, multiple medication use places older patients at increased risk of several important outcomes, including adverse drug events (12), drug interactions, increased medication costs (13, 14), and decreased medication adherence (15). A 2004 study of cost-related medication non-adherence among Medicare beneficiaries conducted prior to implementation of the Medicare drug benefit showed that patients with multiple morbidities were nearly three times as likely to have problems with adherence related to medication cost (13). Chronic disease management (and thus multiple medication prescribing) in the elderly is complicated by a need to provide adequate management of disease while minimizing drug-related problems.

Adverse drug events in the elderly are common and often preventable (12, 16). Multiple studies have explored adverse drug events in the elderly in both the inpatient and the ambulatory setting. Specific classes of medications, such as psychoactive medications, opioids, anti-histamines, and anti-cholinergics have been implicated in adverse drug events (17-19). Previous investigations have shown that simply being on four or more medications places patients at increased risk of adverse drug events (17, 18). In a study of community-dwelling older adults, participants taking five or more medications were three times as likely to have unintended weight loss, and nearly twice as likely to have impaired balance after controlling for comorbidity (19). Gandhi et al.

reported that 25 percent of patients age 65 and older in the ambulatory setting had a medication-related adverse effect over the course of one month, many of which were a result of physicians' failure to respond to symptoms or patients' failure to communicate these symptoms (6, 20). Other studies exploring ambulatory patient medication knowledge also suggest that patients do not always disclose adverse effects (21, 22).

In addition to adverse medication effects, older patients are subject to inappropriate medication prescribing, particularly when they are followed by multiple health care providers (23). In 2006, a study of ambulatory older veterans taking five or more medications found that 65% of participants took a medication that was contraindicated, and 57% were taking a medication that was ineffective, not indicated, or duplicative (24). Medication review strategies have been proposed as one means to address the risk for these drug-related prescribing problems.

Patient Medication Preferences and a Role for Shared Decision Making

Medication decision making for older adults may be especially difficult because of the increased likelihood of adverse events and less certain likelihood of benefit (25). Improved communication strategies between physicians and patients may help elicit patient preferences, beliefs, and health priorities. Shared decision making and patient-centered decision making models exist to address these challenges (25-27). In these models, the physician provides the patient with information about a choice, and the patient considers individual preferences and health priorities in order to reach a decision that is reasonable for the individual patient, and that reflects an understanding of the possible ramifications of the decision (26). In regard to making decisions about pharmacotherapies, one core component of the shared decision making model is that patients have some understanding of drug risks and benefits, and the risks that may be involved with not taking the medication.

Studies of treatment preferences for preventive medications among older adults suggest that not all patients are interested in a participatory decision making model (25). However, older patients are capable of expressing preferences about treatment trade-offs and can express a range of thresholds for which they would be willing to accept a medication, for example for a preventive treatment (28). One study of 675 older adults in the ambulatory setting found that 15% of seniors did not think highly effective, inexpensive medications to prevent heart attacks were “worthwhile”, while 22% of seniors felt low-yield, costly medications to prevent heart attacks were worthwhile (28). This study underscores the capability of seniors to express preferences regarding medication benefits and trade-offs.

Medication Knowledge in Older Adults

Older patients' understanding of medication roles (health knowledge and health literacy)

Taking multiple medications is particularly problematic in the context of an older population that may experience age-related changes in cognition. Patients taking five or more prescription medications surveyed in ambulatory settings were three times more likely to misunderstand medication dosage instructions compared to those taking fewer medications (29). Furthermore, poor medication knowledge has been shown to impact adherence (30-32). Studies examining medication knowledge usually focus on the extent to which adults can state medication indications, dosing schedules, and side effects. In a study of 122 British patients over the age of 65, patients were unaware of 25% of both their illnesses and their medications (33).

In the United States, the Iowa 65+ Rural Health Study surveyed medication knowledge in a rural elderly population and found that patients did not know the indication for 10% of their drugs (34). Another study of ambulatory patients of all ages in a more urban setting found that 13.5% of patients did not know the indication of at least

one of their medications, most commonly cardiovascular drugs, with lack of knowledge most likely for patients who were older, black, or had a high school education or less (35). Similarly, a survey of 344 ambulatory patients in New Zealand found that 15% of patients did not know or misidentified a drug name, 21% did not know its therapeutic action, 13% did not know why the doctor prescribed the medication, and 17% of patients did not know dosage (36). A related study conducted by Tarn et al. examined physician communication during new medication prescribing and found that physicians do not consistently educate their patients when they are prescribing new medications: physicians communicated a drug name for 74% of new prescriptions, explained the purpose for 87% of new drugs, addressed adverse effects for only 35% of new drugs, and discussed frequency and timing of dosage 55% of the time (37). These data suggest that health knowledge among older patients, particularly seniors who take multiple medications, is suboptimal.

Impaired Medication Literacy and Health Outcomes

In addition to studies looking at health *knowledge* among older adults, other studies have explored health and medication *literacy*, defined as the capability to obtain, interpret, and understand health information and the ability to use the information and services in ways which improve health. The National Health Education Standards, published in 1995, also define health literacy as the ability to read prescription drug labels, interpret dosages, and use medications appropriately (38). Although patients reading at or below the sixth grade level can correctly state medication dosing instructions, this correlates poorly with the ability to demonstrate the number of pills one should take daily (29). In patients with chronic diseases such as hypertension and diabetes, inadequate functional health literacy limits the effectiveness of traditional patient education strategies (39). Poor health literacy in the elderly results in poor self-

reported health, worse physical and mental health, and has been found to independently predict overall and cause-specific mortality (40, 41).

Patients' Beliefs about Medications

Patients' health beliefs also impact their health behaviors, particularly in terms of medication use and adherence (42-44). Patients reporting high levels of concern about taking medications have lower self-reported adherence (43). Additionally, patients do not always openly discuss medication beliefs and behaviors with their physicians, and many feel ambivalent about taking medication (42, 45-47). While physicians believe they understand patient preferences and priorities in taking medication, they may focus on disease-specific outcomes rather than quality-of-life issues (48). There is, however, significant variability in the extent to which patients want to be involved in making decisions about their medications (25). Thus, some researchers have emphasized the importance of concordance between patient and physician health goals rather than focusing specifically on medication adherence (49).

Risk Communication Strategies

Using Numbers to Understand Risk, or Health Numeracy

Making choices about medications and health priorities depends both on the way in which physicians communicate risk to patients and on patients' ability to use numbers to understand risk, or their health numeracy (50). Health numeracy is the degree to which individuals have the capacity to access, process, interpret, communicate, and act on numerical, quantitative, graphical, biostatistical, and probabilistic health information needed to make effective health decisions (51). Studies asking patients to make trade-offs between different disease states depend on quantitative methodologies that require participants to have a facility with numbers (52). Low-probability events are especially

difficult for patients to understand and for physicians to communicate (53). Yamagishi showed that patients have great difficulty interpreting numerical risk in a study in which patients estimated, for example, that death rates of 1286 per 10,000 were rated as more risky than death rates of 24.14 per 100 (54). Additionally, patients have difficulty extrapolating long-term risk from annual risk data. In a study by Fuller et al., older patients were told about two treatment options for stroke that each carried a specific annual risk. Participants were then asked to estimate their cumulative 10 year risk of stroke on each treatment. Answers varied widely, with the majority dramatically overestimating risk (55). Notably, previous studies assessing physicians' ability to estimate patients' cardiovascular disease risk suggest they too over- and under-estimate risk: Canadian physicians overestimate their patients' absolute risk of coronary disease (56), while British physicians tended to underestimate cardiovascular risk in elderly hypertensive patients (57).

Challenges of Risk Communication

Both language and methods used to communicate risk can vary, thus influencing the way in which patients make decisions. Concepts such as 'rare' or 'likely' have different implications for medical decisions in different settings and may be understood differently by different patients (53, 58). Communicating disease risk and prevention benefit clearly is particularly difficult when multiple models—relative risk reduction, absolute risk reduction, number needed to treat—are used (58-60). Relative risk reduction models are most sensitive to framing effects by physicians and can profoundly alter patients' perceptions of medication benefit (61). A survey of ambulatory patients by Misselbrook and Armstrong highlights the difficulties in interpreting patient preferences: of 300 ambulatory patients asked to rank whether or not they would want treatment for hypertension based on relative risk reduction, absolute risk reduction, number needed to

treat, and personal probability of benefit, the percentage of patients wanting treatment ranged from 44 to 92%, depending on the model used (62).

Visual tools used in risk communication

Images provide an alternate means of communicating risk information and aiding patient decision-making. Several studies have examined the utility of graphical displays in communicating risk magnitude, relative risk, cumulative risk, uncertainty, and interactions among risk factors, although data have yielded conflicting results and suggest that individuals' performance is task-dependent (53, 58, 63, 64). Graphical displays evaluated include bar charts, risk ladders, facial displays, line graphs, pie charts, and histograms. In a pilot study, Fortin et al. conducted focus group interviews with middle age women and presented women with risk information in multiple graphical formats, metrics (absolute vs. relative risk reduction, and number needed to treat), and time scales; women preferred bar graphs over line graphs, representative faces, and survival curves (65). A larger-scale study of web-based patient information for diabetic patients found that patients preferred bar chart formats and found other graphs (line graphs and facial displays) as well as anchoring information unhelpful (66).

Patient preferences do not always correlate with accurate quantitative judgments; graphical features that improve accuracy of quantitative reasoning differ from those features most likely to alter behavior or intentions (63). Studies looking at accuracy of quantitative risk judgments in older adults suggest that risk information is best presented and processed using vertical bars with a scale (64). In a study of 216 community-dwelling adults over 50, people were asked to compare two graphically depicted percentages and choose the larger chance of survival or the smaller chance of side effects. Vertical bars with scales were the fastest and most accurately processed, and errors occurred most frequently with pie charts and facial displays blocked in at random.

Gaps in Current Knowledge

Older patients' understanding of medication benefit is largely unexplored in the literature. Although there are studies that describe impaired medication knowledge in older patients, as well as studies that ask patients to make choices about medications based on side effect profiles, studies have not explored the extent to which patients understand the benefit they get from commonly used drugs, such as daily preventive medications. Improving medication prescribing and shared decision making between physicians and patients, particularly older adults with a high chronic disease burden, depends on patients' ability to make informed decisions regarding medication benefits and risks. It is therefore critical that patients have some understanding of the magnitude of benefit conferred by their preventive medications, as well as of their underlying risk of important endpoints such as cardiovascular outcomes. Further research is needed to understand patients' perceptions of their long-term risk of outcomes such as myocardial infarction and stroke, and to better characterize their perceptions of how well common preventive medications, such as aspirin, statins, and anti-hypertensives work to prevent these clinical outcomes.

Purpose

The purpose of this study is to examine older patients' perceptions of their long term risk of cardiovascular outcomes, their perceptions of long-term benefit from common preventive medications (e.g., aspirin, statins, and anti-hypertensives) and to explore their medication adherence in relation to their general beliefs about medications and estimates of preventive medications' benefit.

Hypotheses

We hypothesize

1. Older patients on multiple medications have a poor understanding of their long-term risk of cardiovascular outcomes such as myocardial infarction and stroke.
2. Older patients have a poor understanding of the long-term benefit of commonly used preventive medications such as aspirin, statins, and anti-hypertensives, specifically that they have a poor understanding of the magnitude of the ability of the medication to prevent myocardial infarction or stroke.

Specific Aims

The aims of this study are

1. To determine the extent to which older patients quantitatively understand their 10-year risk of myocardial infarction and stroke.
2. To determine the extent to which older patients quantitatively understand their 10-year risk of myocardial infarction while on aspirin or statins, and their 10-year risk of stroke while on aspirin or anti-hypertensives, and thus to describe the magnitude of benefit patients believe is conferred by common preventive medications.

Methods

Study Design

We performed a cross-sectional survey examining older adults' ability to estimate medication benefit, followed by a chart review of enrolled participants to identify clinical characteristics, medication history, and adherence. A new instrument was developed for use in this study. The study protocol was approved by the Human Studies Subcommittee at VA Connecticut Healthcare System and the Yale University School of Medicine Institutional Review Board.

The survey was developed by Elizabeth Wahl, with input from Joseph Agostini, MD, and Terri Fried, MD. Elizabeth Wahl wrote and submitted the protocol for IRB approval, recruited participants at the VA Connecticut Primary Care Center, administered the survey, created the Microsoft Access database, conducted chart reviews for all participants, and entered data. Data was analyzed by Elizabeth Wahl.

Setting

We conducted the study and enrolled patients at the West Haven Veterans Affairs (VA) Primary Care Center from May to October 2007. The West Haven VA is part of the Veterans Affairs Connecticut Healthcare System, and includes a 191-bed inpatient facility and an ambulatory care center that registers more than 512,000 outpatient visits in West Haven and its clinics in New London, Stamford, Waterbury, Windham, Winsted and Danbury. The Primary Care Center consists of two medical firms; patients are randomly assigned to one firm for their medical care.

Participants

We enrolled a convenience sample of adults attending previously scheduled primary care or pharmacy education visits in each of the two medical firms. Participants were eligible for the study if they met the following inclusion criteria: age 65 years or older, community-dwelling, English-speaking, and taking 5 or more medications on a daily basis, including at least one of the drugs of interest (aspirin, a statin, or an anti-hypertensive drug). A statin was defined as any HMG-coA reductase inhibitor drug (e.g., atorvastatin, simvastatin); an antihypertensive was defined as any of the five commonly prescribed classes of medications used for hypertension management, including ACE-inhibitors, beta-blockers, calcium-channel blockers, diuretics, or centrally-acting agents. Over-the-counter vitamins, saline eye drops or nasal spray, and as needed (prn) medications were not counted as medications for the purposes of this study. Exclusion criteria included a diagnosis of dementia in the medical record, participants documented as not competent to make their own medical decisions, and patients not receiving the majority of their medications through the VA system.

Recruitment

Participants were recruited from May to October 2007. Eligible patients were identified on a daily to weekly basis from primary care provider and pharmacist schedules through the VA computerized medical records and appointments systems. Pharmacist visits emphasized diabetes education, anti-hypertensive medication regimen education, or medication review. Birth-date and active medication lists were used to confirm eligibility. The provider was notified of potential patients each day at the start of clinic and then invited patients to participate at the close of each visit. Patients who agreed to learn more about the study were then taken to a private room where the study was explained. If the patient agreed to the study, informed consent was obtained and the

survey completed. The survey instrument consisted of 43 items and took approximately 15-20 minutes per participant to complete. The interviewer read each question aloud to the participant and responses were recorded on a paper copy of the survey before being entered into a database created on Microsoft Access. Once the survey was complete, a medical record review consisting of clinical and medication-related data was conducted, recorded on paper, and entered into the database.

Measures

A survey instrument was developed for this study that included both novel and validated tools to assess three main outcomes: estimates of cardiovascular disease risk and medication benefit (Appendix 1), medication-related behaviors, including self-reported adherence and experience with medication side effects, and attitudes and beliefs about medications. Data collection also included a medical record review of all interviewed patients to obtain clinical and medication-related data.

Five demographics questions were recorded, including living situation (alone or with another person), current marital status, years of school completed, and ability to complete seven instrumental activities of daily living (IADL) (67), such as housework and handling finances.

Self-reported medication adherence was recorded using 4 questions from the Medication Adherence Scale developed by Morisky et al (68). Participants were asked: “Do you ever forget to take your medications?”; “Are you careless at times about taking your medications?”; “When you feel better, do you sometimes stop taking your medications?”; “Sometimes, if you feel worse when you take your medication, do you stop taking it?” Those who answered no to all four questions were considered adherent; those who answered yes to at least one question were considered non-adherent. This is the accepted definition of non-adherence used with the Morisky scale. Participants were

also asked to report how many doses of medication they had missed in the past 2 days, if any. Potential adverse effects related to medication use were elicited using questions about the experience of medication side effects with use of aspirin, statins, and anti-hypertensives. Questions included: a) whether an adverse effect occurred (e.g., bleeding with aspirin); b) whether the drug was stopped; and c) whether the side effect was discussed with a doctor.

Attitudes and beliefs about medications were assessed using the Beliefs about Medicines Questionnaire (BMQ), developed and validated by Horne et al (69). The BMQ consists of ten questions examining the extent to which participants agree or disagree with such statements as “My life depends on my medications.” Responses were recorded on a 5 point Likert scale, ranging from 1 (strongly agree) to 5 (strongly disagree). Participants were also asked whether they felt that the number of medications they were taking was about right, too many, or too few.

Participants’ estimates of cardiovascular disease risk and medication benefit were assessed by 6 novel questions developed for this survey. We focused specifically on participants’ perceived risk of myocardial infarction and stroke, both at baseline (on no medications) and on preventive medications such as aspirin, statins, and anti-hypertensives. Perceived medication benefit was estimated by calculating the difference between participants’ risk estimates on and off medication. Because the magnitude of preventive benefit conferred by these medications for myocardial infarction and stroke in a one-year period is extremely small, we focused on the ten-year risk of these outcomes. A large scale visual aid—a bar graph with answer choices at 0, 10, 25, 50, 75, and 100—was developed and used with the questions, and a teaching module orienting participants to the visual aid preceded the questions.

To assess perceived disease risk and medication benefit, participants were asked, “For 100 people your age, who are just like you, with your exact same health

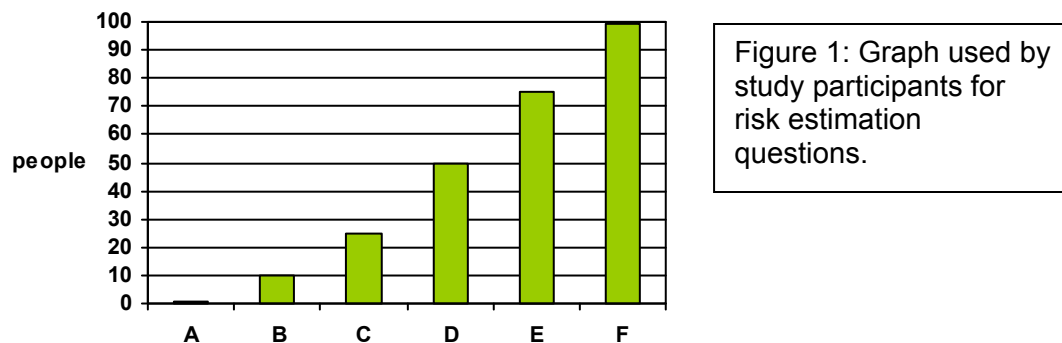
problems, a certain number of them will have a heart attack in the next ten years. Of those 100 people, who are your age with your exact same health problems, who *aren't* taking any medication to prevent having a heart attack (like an aspirin or a statin), how many of them do you think will have a heart attack in the next ten years?" Participants were asked to point to their answer choice on the bar graph. Next, participants were asked, "Now, what if we put these [same] people on a daily aspirin [or statin, in the next question], now how many will have a myocardial infarction in the next 10 years?" Participants were again asked to select one of the six choices corresponding to their closest estimation. The questions were repeated if participants required further thought. Participants were encouraged to answer even if they were not certain of the "exact" answer. If a patient was unable to answer after prompting, then this was recorded. Participants were queried about each of the following scenarios: baseline MI risk without medication; MI risk on aspirin or on statin medications; baseline stroke risk without medication; and stroke risk on aspirin or anti-hypertensive medications.

In order to develop a visual aid that reflected an appropriate range of answer choices, Framingham data was used to calculate the 10-year risk for an "average" 75 year-old male with type 2 diabetes, total cholesterol of 200, HDL of 45, blood pressure of 130/80, and taking anti-hypertensives. Data from primary prevention meta-analyses were used to calculate the benefits when patients take aspirin, statin, and anti-hypertensives. Based on Framingham data the ten-year risk of myocardial infarction for this "average" person (resembling the typical older male at VA Connecticut) falls within the range of 25-35% (70, 71), and the ten-year risk of stroke is between 20-35% (72, 73). These values are consistent even when varying certain characteristics. When mean blood pressure is 170/80, the cardiovascular and cerebrovascular risk falls at the high end of the range; when diabetes is removed, the risk falls at the low end of the range. For example, the 10-year risk of stroke is 17% for patients without diabetes and

23% for those with diabetes, for African American patients the risk is 22-28%, and for patients with atrial fibrillation or cardiovascular disease to the risk is 35%. In the worst case scenario, LVH increases ten-year stroke risk to about 40%.

Clinical trial and meta-analysis data were used to derive the “average” 75-year old person’s 10-year risk of myocardial infarction on aspirin or statins, which both reduce the ten-year risk of myocardial infarction by about one-third to 15% (74-76). For participants with diabetes, their 10-year risk of MI on medication may be closer to 20% since their starting risk is higher; however some data suggests that diabetic patients may derive greater benefit from aspirin for primary prevention of cardiovascular events. For strokes, aspirin reduces the 10-year risk in high-risk patients by about one-quarter to 15% (77). Trials of anti-hypertensives in the elderly show that treatment of systolic hypertension in these participants (with any anti-hypertensive) resulted in a 37% reduction in stroke risk (78), so participants’ 10-year risk of MI on these medications is approximately 13%.

Given this range of “correct” answer choices, a bar graph was developed as a visual aid to depict a range of answer choices that captured the idea of “small risk,” “medium risk,” and “large risk,” from which people could choose. Based on current literature regarding chart literacy and numeracy, we chose to use a bar graph format with a 100-point scale to represent the number of people that could have a myocardial infarction or stroke in the next 10 years (64, 65). In our graph, answer options were placed at 0, 10, 25, 50, 75, and 100. These numbers were chosen because they span the range of small, medium, and large risk, but also reflect close “correct” answers to our questions (e.g., the ten-year risk of myocardial infarction/stroke is best correctly answered as “C” on the graph, corresponding to about 25; and the ten-year risk on any of the preventive medications is best answered as “B”, or about 10). All participants were given the same full-page enlargement of the bar graph with clear lettering in large (28



point) font to minimize problems due to visual impairment (see figure1 and full-size version in Appendix 1).

Because of concerns about numeracy and ability to read graphs, a teaching module was developed to familiarize participants with the numerical values on the bar graph prior to asking the questions about cardiovascular risk and medication benefit. Participants were shown the graph and told that it would be used to answer questions about chances of having a myocardial infarction and chances of having a stroke. They were oriented to the graph axes and then asked, “Can you show me the bar that best represents all 100 people? Can you show me the bar that best represents [x] people?” for all bar values on the graph. The questions were repeated until the participant could correctly identify all bar values. Answers to the teaching module were not recorded (but no participants failed the teaching exercise).

Ascertaining participants’ risk estimates can be challenging because participants’ responses may be related to the sequence in which the questions were asked. Prior investigators have demonstrated that the way in which questions are asked can drive choosing one answer over another (58, 59, 62). To address this issue, we sequenced the questions so that baseline risk preceded risk on either medication, and questions were asked about myocardial infarction and then about stroke. We varied whether participants were first asked about aspirin or the other medications to prevent either myocardial infarction or stroke for the first 20 surveys conducted; no patterns emerged,

and the ordering was not altered, although we cannot be certain that there were no framing effects.

Chart review

Electronic medical records were also reviewed. Domains included: twelve chronic medical conditions from a pre-selected list, number of medications the participant was taking at the time of interview, number of primary care and specific subspecialty (cardiology, endocrinology, nephrology, neurology) visits to an outpatient clinic in the year prior to the interview, and adherence to medications. Adherence was defined using refill data (the percentage of actual versus expected refills for aspirin, statin, and anti-hypertensive medications during the year prior to the interview).

Data Plan

Raw data from the survey and the chart review were collected using codes to protect participants' confidentiality. Data were collected on paper, stored in a locked cabinet, and then entered into a secure Microsoft ACCESS database.

Data Analysis

Data were analyzed with univariate statistics to describe patient characteristics, demographics, and comorbidities, as well as the frequency with which patients estimated selected clinical outcomes when taking or not taking common preventive medications.

Results

Study population

One hundred and fifty participants were recruited from the Primary Care Clinics at the VA Connecticut Healthcare System in West Haven between May and October 2007. Participants were drawn from regular primary care visits and pharmacy education visits for diabetic or hypertensive patients or patients on a complicated medication regimen. Of 160 participants approached, 10 refused, and the final study sample and data analysis consisted of 150 participants.

Overall, the mean age of participants was 75.8 ± 6.0 years, all were male, and 19 (12.7%) were non-white. Participants had a mean of 12.5 ± 3.1 years of education. Participants' baseline characteristics are summarized in Table 1. Forty participants (27%) reported "fair" or "poor" health, and 31 (21%) participants reported difficulty with 1 or more instrumental activities of daily living (IADLs). Participants had a mean of 3.7 ± 1.2 of 12 pre-specified chronic medical conditions; 134 (89.9%) had hypertension, 83 (55.7%) had ischemic heart disease, 113 (75.8%) had type 2 diabetes, 18 (12.1%) had a history of stroke, and 23 (15.4%) had a history of myocardial infarction. Participants had a mean of 2.9 ± 1.6 visits to their VA primary care provider in the past year, and a mean of 0.70 ± 1.4 visits to pertinent Internal Medicine subspecialties (Cardiology, Endocrinology, Nephrology, and Neurology).

Table 1: Baseline Characteristics of Study Participants (n=150)

Characteristic	Value
Age, mean \pm SD, years	75.8 \pm 6.0
Non-white, No. (%)	19 (12.7)
Education, mean \pm SD, years	12.5 \pm 3.1
Living alone, No. (%)	37 (24.7)
Difficulty with \geq 1 IADL*	31 (20.6)
Self-rated health, No. (%)	
Excellent	10 (6.7)
Very Good	35 (23.3)
Good	65 (43.3)
Fair	34 (22.7)
Poor	6 (4.0)
Chronic medical conditions, No. (%)	
Hypertension	134 (89.9)
Stroke	18 (12.1)
MI	23 (15.4)
Ischemic Heart Disease	83 (55.7)
Chronic Lung Disease (asthma/emphysema/COPD)	24 (16.1)
Diabetes	113 (75.8)
Arthritis	42 (28.2)
CHF	14 (9.4)
Cancer	38 (25.5)
Depression	35 (23.5)
Chronic Kidney Disease	29 (19.5)
Chronic Liver Disease	3 (2.0)
Chronic medical conditions reported from list above, mean \pm SD	3.7 \pm 1.2
Primary care visits in last year, mean \pm SD	2.9 \pm 1.6
Internal Medicine subspecialty visits in last year**, mean \pm SD	0.70 \pm 1.4

*IADLs are defined as Instrumental Activities of Daily Living as described in the text

**Internal Medicine subspecialties here include Cardiology, Nephrology, Endocrinology, and Neurology

Medication characteristics and adherence

Participants were taking a mean of 9.8 ± 3.3 medications; 122 participants (81.3%) reported taking aspirin, 129 (86.6%) were taking a statin, and 145 (96.7%) patients were taking an anti-hypertensive medication. Two thirds of participants were taking all three medications. 13 (10.6%) of participants taking aspirin reported side effects, 6.2% of participants taking statins reported side effects, and 14.5% of participants taking anti-hypertensives reported side effects. Both self-reported adherence data and actual refill data for statins and anti-hypertensives obtained by chart review were collected. Of all participants interviewed, 25 (19.5%) reported missing at least one dose of medication in the past two days, and 22 (17.3%) had a score of greater than one on the Medication Adherence scale, corresponding with poor self-reported adherence (68). Based on refill data, 22 of 129 (17.3%) participants on statins and 17 of 145 (11.9%) participants on anti-hypertensives had <80% of expected refills in the past year. Refill data were unable to be calculated for aspirin because most participants bought over-the-counter aspirin and therefore had no corresponding VA refill history.

Table 2: Medication Characteristics of Study Participants

Characteristic	Value
Active medications, mean \pm SD	9.8 \pm 3.3
Use of common preventive medications	
Aspirin, No. (%)	122 (81.3)
Statin, No. (%)	129 (86.6)
Anti-hypertensive, No (%)	145 (96.7)
Aspirin, statins, and anti-hypertensives, No. (%)	100 (66.7)
Patients reporting side effects experienced on	
Aspirin, (n=122), No. (%)	13 (10.6)
Statin, (n=129), No. (%)	8 (6.2)
Anti-hypertensive (n=145), No. (%)	21 (14.5)
Self-reported general medication adherence	
Missed \geq 1 dose in last 2 days, No. (%)	25 (19.5)
Medication Adherence Score >1 (poor), No. (%)	22 (14.7)
Refill data from VA medication database, past year	
<80% expected statin refills (n=129), No. (%)	22 (17.3)
<80% expected anti-hypertensive refills (n=145)*	17 (11.9)

* An average refill rate was calculated for patients taking >1 anti-hypertensive drug

Medication beliefs

When asked about their perception of the number of medications they were taking, 111 (74%) of participants felt they were on ‘about the right number,’ while the remainder (25%) felt they were on ‘too many’ (see Table 3). Only one participant felt he needed to be on more medications. In addition, participants answered questions from the Beliefs about Medications Questionnaire (69) to explore attitudes towards medication necessity and medication harm. Medication was felt to be important for preserving health and maintaining well-being, with participants’ mean responses ranging from 1.7 to 2.3 on a 5 point Likert scale (1=strongly agree, 5= strongly disagree) for ‘medication necessity’ domains. Patients were more ambivalent (expressed less agreement) towards statements exploring the extent to which medication is harmful, burdensome, or

addictive, with mean responses of 3.1 to 3.6 on the 5-point scale for 'medication concern' domains.

Table 3: Participants' Beliefs about Medications

Characteristic	Value
Perceived number of medications	
Too many, No. (%)	37 (24.7)
About right, No. (%)	111 (74.0)
Too few, No. (%)	1 (0.7)
Don't know, No. (%)	1 (0.7)
Beliefs about Medicines Questionnaire (69)	
<i>Necessity Domains, mean ± SD</i>	
<i>My health right now depends on my medicines</i>	1.7 ± 0.6
<i>My life would be impossible without my medicines</i>	2.3 ± 1.0
<i>Without my medicines, I would be very ill</i>	2.1 ± 0.9
<i>My health in the future depends on my medicines</i>	1.9 ± 0.7
<i>My medicines protect me from becoming worse</i>	1.9 ± 0.6
<i>Concern Domains, mean ± SD</i>	
<i>Having to take medicines worries me</i>	3.4 ± 1.0
<i>I sometimes worry about the long-term effects of my medicines</i>	3.1 ± 1.2
<i>My medicines are a mystery to me</i>	3.3 ± 1.2
<i>My medicines disrupt my life</i>	3.6 ± 1.0
<i>I sometimes worry about becoming too dependent on my medicines</i>	3.4 ± 1.1

* Participant responses based on a 5-point Likert scale (1=strongly agree and 5=strongly disagree)

Estimating Risk of Myocardial infarction and Stroke

Based on Framingham data, the 10-year risk of myocardial infarction for this population is approximately 25-30% (70, 71). Participants were asked to estimate their 10-year risk of myocardial infarction (MI risk) while on no medications, and were presented with a bar graph with answer choices at 0, 10, 25, 50, 75, and 100. Of 150 participants asked, 17 (11%) were able to accurately estimate their MI risk (Table 4).

Nearly all overestimated their risk; 130 (87%) participants guessed that their risk was 50% or more, and 72 (48%) participants guessed their MI risk was 75 or 100%. Two participants underestimated their risk, guessing it was 0 or 10%, and one subject declined to guess.

Table 4: Estimating 10-year risk of MI and CVA On and Off of Preventive Medications*

	Participants who estimated their 10-year risk at. . . No. (%)						<i>Total</i>
	0	10	25	50	75	100	
10 year risk of MI							
No medication	1 (1)	1 (1)	17 (11)	58 (39)	37 (25)	35 (23)	149
Aspirin	3 (2)	20 (14)	54 (36)	53 (36)	16 (11)	2 (1)	148
Statin	3 (2)	25 (17)	54 (37)	47 (32)	15 (10)	3 (2)	147
10 year risk of CVA							
No medication	0 (0)	2 (1)	19 (13)	38 (26)	57 (38)	33 (22)	149
Aspirin	0 (0)	22 (15)	54 (37)	52 (35)	18 (12)	1 (1)	147
Anti-hypertensive	4 (3)	38 (26)	48 (32)	39 (26)	18 (12)	1 (1)	148

* Data were missing from 3 patients who refused to guess in some or all scenarios. Shaded boxes indicate the most accurate answer for the population.

Framingham data project the 10-year risk of stroke at approximately 20-25% depending on presence or absence of diabetes (72). Nineteen participants (13%) were able to accurately estimate their CVA risk, while 128 (86%) guessed that their risk was 50% or more (Table 4). Overall, participants estimated a higher baseline risk of CVA than of MI, with 90 participants (60%) estimating their 10-year CVA risk was 75 or 100%. No subject thought CVA risk was zero, two underestimated risk at 10%, and one subject declined to guess.

Risk of Myocardial infarction on Preventive Medications

Data from trials looking at aspirin and primary prevention of myocardial infarctions show that daily aspirin should reduce the 10-year risk of MI by about a third, which corresponds to about 15% for this population, or a 'correct' answer of about 10% on the bar graph (74). When asked to estimate 10-year MI risk while taking daily aspirin, 20 participants (14%) chose the 'correct' answer, although this does not take into consideration the accuracy of their baseline risk estimate (Table 4). One hundred twenty-five (84%) participants overestimated their risk of MI on aspirin, guessing it to be 25% or higher. Eighteen (12%) participants guessed that their risk was as high as 75 or 100%; 3 (2%) participants underestimated MI risk on aspirin, and two participants declined to guess.

Statin prevention benefit is comparable to that of aspirin, with a reduction in the 10 year risk of MI by about one-third (75, 76), also corresponding to a 'correct' answer of 10% on our graph. Participants' estimates of MI risk while taking statins were similar to their estimates of MI risk while taking aspirin. Twenty-five (17%) participants 'correctly' estimated the 10-year risk of MI on statins (Table 4). One hundred eighteen (81%) participants overestimated their risk of MI on statins, with 17 (12%) of participants estimating it to be as high as 75 or 100%. Two participants (1%) felt that taking a statin eliminated the risk of MI entirely, while 3 participants declined to guess.

Risk of stroke on preventive medications

Daily aspirin should reduce the 10-year risk of CVA by about a third, corresponding to about 15% for this population and a 'correct' answer of 10% on our graph (77). Twenty-two (15%) participants 'correctly' estimated their risk of CVA on aspirin, while 125 (85%) participants overestimated their risk (Table 4). Nineteen (13%) participants guessed their risk was as high as 75 or 100%. No participants felt that

aspirin brought their risk of CVA to zero, and 3 participants declined to guess for this section.

Anti-hypertensives should reduce the 10-year risk of CVA by about 37% to about 15% in this population, or a 'correct' answer closest to the 10% choice on our graph (78). Thirty-eight participants (26%) chose the 'correct' estimate of CVA risk on anti-hypertensive medication (Table 4). One hundred six (71%) participants overestimated their CVA risk, with 19 (13%) participants estimating risk to be as high as 75 or 100%. Four participants (3%) felt that anti-hypertensives eliminated CVA risk altogether, and 2 participants declined to guess.

Preventive Medication Benefit

In addition to examining how accurately participants were able to estimate their risk of myocardial infarction and stroke both on and off of preventive medications, we also examined the number of participants who accurately estimated the magnitude by which aspirin and statins would reduce MI risk, and the magnitude by which aspirin and anti-hypertensives would reduce CVA risk. Results are summarized in TABLE 5(a-d).

Most participants estimated that medication reduced the risk of MI (TABLE 5a, 5b), although there was variability in terms of how *much* participants felt medication decreased risk. No participants thought aspirin decreased the risk of MI from 100 to zero, but two participants thought statins could decrease MI risk to this extent. One participant thought aspirin increased risk of MI and three thought the same of statins. Few participants estimated the 'correct' answer (that MI risk is around 25 and drops to around 10 on either medication)--overall, 15 (10%) participants made accurate guesses about aspirin and 10 (7%) participants made accurate guesses about statins.

TABLE 5a-d: Participants' Estimation of Risk on Preventive Medications, Taking Into Consideration their Initial Risk Estimation

Darkest boxes represent participants who felt that medication did not change their risk of outcome; each lighter shade represents those who felt that aspirin changed their risk by one (or two, three, or four) bars on the graph.

Table 5a. Participants' Estimate of MI Risk at Baseline and on Aspirin (N=148)

Participants' Estimate of Baseline MI Risk	Participants' Estimate of MI Risk on Aspirin, No. (%)						TOTAL
	100	75	50	25	10	0	
100	2 (1.4)	10 (6.8)	17 (11.5)	5 (3.4)	0	0	34
75	0	5 (3.4)	21 (14.2)	9 (6.1)	1 (0.7)	1 (0.7)	37
50	0	1 (0.7)	15 (10.1)	38 (25.7)	3 (2.0)	1 (0.7)	58
25	0	0	0	2 (1.4)	15 (10.1)	0	17
10	0	0	0	0	1 (0.7)	0	1
0	0	0	0	0	0	1 (0.7)	1
TOTAL	2	16	53	54	20	3	148

Table 5b. Participants' Estimate of MI Risk at Baseline and on Statins (N=147)

Participants' Estimate of Baseline MI Risk	Participants' Estimate of MI Risk on Statins, No. (%)						TOTAL
	100	75	50	25	10	0	
100	3 (2.0)	8 (5.4)	13 (8.8)	9 (6.1)	1 (0.7)	1 (0.7)	35
75	0	5 (3.4)	19 (12.9)	12 (8.2)	1 (0.7)	0	37
50	0	2 (1.4)	14 (9.5)	27 (18.4)	12 (8.2)	1 (0.7)	56
25	0	0	1 (0.7)	6 (4.1)	10 (6.8)	0	17
10	0	0	0	0	1 (0.7)	0	1
0	0	0	0	0	0	1 (0.7)	1
TOTAL	3	15	47	54	25	3	147

Table 5c. Participants' Estimate of CVA Risk at Baseline and on Aspirin (N=147)

Participants' Estimate of Baseline CVA Risk	Participants' Estimate of CVA Risk on Aspirin, No. (%)						TOTAL
	100	75	50	25	10	0	
100	1 (0.7)	9 (6.1)	17 (11.6)	6 (4.1)	0	0	33
75	0	8 (5.4)	31 (21.1)	16 (10.9)	2 (1.4)	0	57
50	0	1 (0.7)	4 (2.7)	28 (19.0)	5 (3.4)	0	38
25	0	0	0	4 (2.7)	14 (9.5)	0	18
10	0	0	0	0	1 (0.7)	0	1
0	0	0	0	0	0	0	0
TOTAL	1	18	52	54	22	0	147

Table 5d. Participants' Estimate of CVA Risk at Baseline and on Anti-hypertensives (N=148)

Participants' Estimate of Baseline CVA Risk	Participants' Estimate of CVA Risk on Anti-hypertensives, No. (%)						TOTAL
	100	75	50	25	10	0	
100	1 (0.7)	7 (4.7)	9 (6.1)	9 (6.1)	5 (3.4)	2 (1.4)	33
75	0	10 (6.8)	19 (12.8)	19 (12.8)	9 (6.1)	0	57
50	0	1 (0.7)	11 (7.4)	16 (10.8)	9 (6.1)	1 (0.7)	38
25	0	0	0	4 (2.7)	14 (9.5)	1 (0.7)	19
10	0	0	0	0	1 (0.7)	0	1
0	0	0	0	0	0	0	0
TOTAL	1	18	39	48	38	4	148

Most participants estimated that medication reduced the risk of CVA (TABLE 5c, 5c), although there was variability in terms of how *much* participants felt medication decreased risk. No participants thought aspirin decreased the risk of CVA from 100 to zero, but four participants thought anti-hypertensives could decrease CVA risk to this

extent, and one participant thought aspirin and anti-hypertensives would increase risk of CVA. Few participants estimated the ‘correct’ answer (that CVA risk is around 25 and drops to around 10 on either medication)--overall, 14 (10%) participants made accurate guesses about aspirin and anti-hypertensives.

Magnitude of benefit

Table 6 summarizes the extent to which people felt that aspirin, statins, and anti-hypertensives increased or decreased their risk of myocardial infarction and stroke, regardless of how accurate their estimates were. Because participants were forced into choosing specific values on a bar graph (0, 10, 25, etc.), moving up or down one bar was considered to represent one ‘level’ of change (whether that was from 100 to 75 or 25 to 10).

TABLE 6: Participants’ Perceptions of Medication Benefits from Preventive Medications by Level of Change

Medication and Outcome	Participants’ Estimate of Change in Risk on Medication, No. (%)						Total
	Did not change risk	↓ risk by 1 level	↓ risk by 2 levels	↓ risk by 3 levels	↓ risk by 4 levels	↓ risk by 5 levels	
Aspirin for MI prevention	26 (17.7)	84 (56.8)	29 (19.6)	7 (4.7)	1 (0.7)	0	148
Statins for MI prevention	30 (20.4)	64 (43.5)	37 (25.2)	11 (7.5)	1 (0.7)	1 (0.7)	147
Aspirin for CVA prevention	18 (12.2)	82 (55.8)	38 (25.9)	8 (5.4)	0	0	147
Anti-hypertensives for CVA prevention	27 (18.2)	56 (37.8)	38 (25.7)	19 (12.8)	5 (3.4)	2 (1.4)	148

*A small number of participants felt that taking the medication *increased* their risk of having an MI or a CVA – 1 in the ASA/MI group, 3 in the statins/MI group, 1 in the aspirin/CVA group, and 1 in the anti-hypertensives/CVA group.

Approximately half of participants thought that each medication decreased their risk by one level, or the correct amount: 84 (57%) participants thought aspirin lowered MI risk by one bar, 64 (43.5%) participants thought statins lowered MI risk one bar, 82 (56%) participants thought aspirin lowered CVA risk one bar, and 56 (38%) participants thought anti-hypertensives lowered CVA risk one bar. The remaining participants both over- and under-estimated the prevention benefit of each medication. 36 (25%) participants felt that aspirin decreased the risk of MI by two or more bars on the graph, while 50 (33%) participants felt that statins decreased the MI risk by at least that amount. Similarly, 46 (31%) participants felt that aspirin decreased CVA risk by at least two bars, while 64 (43%) felt that anti-hypertensives decreased CVA risk by two or more bars.

A substantial number of participants felt that preventive medications did not change their risk of MI or CVA. Twenty-six participants (18%) felt that taking a daily aspirin did not change their 10-year MI risk, and 30 participants (20%) felt that taking a daily statin did not change that risk. Eighteen participants (12%) guessed that taking a daily aspirin did not change their 10-year CVA risk, while 27 (18%) guessed that anti-hypertensives would not change that risk.

Discussion

Previous research with older adults in the ambulatory setting has suggested that patients have limited knowledge about the indications, dosing schedules, and side effects of their medications (35, 36). Because impaired medication knowledge has been shown to correlate with morbidity and mortality in the elderly (41), we sought to quantitatively assess the extent to which an older population understands their 10-year risk of myocardial infarction or stroke, and their perceptions of the ability of medications to modify this risk. We found that most patients have limited knowledge both about their 10-year risk of cardiovascular events such as myocardial infarction and stroke, as well as an inaccurate sense of how well common medications work to prevent these outcomes. Significant numbers of participants both over and underestimate their cardiovascular risk, as well as the ability of medications to provide benefit. Our data suggest that current efforts by clinicians to educate these patients have not adequately addressed participants' knowledge of cardiovascular risk and preventive medication efficacy, particularly since making informed decisions about medications requires that patients make accurate predictions about disease outcome and medication benefit and risk.

Medication Adherence and Medication Beliefs

Studies of statin adherence in the elderly from the previous decade suggested that adherence rates in the Medicare population drop as low as 42% after two years (79), although other studies suggest that rates may be somewhat higher (80). In our study, statin adherence rates were higher. About 80% of participants both had high self-reported adherence to medications and were found to be adherent to statins based on refill data, with only 8% reporting medication side effects. Of note, a recent study

examining factors that determine statin adherence for primary prevention of myocardial infarction among veterans found that low perceived risk was one factor associated with non-adherence (81). Our findings indirectly support this result, as our study population both perceived their risk of myocardial infarction to be high and had a higher adherence rate. Similarly, earlier studies of anti-hypertensive use also found low adherence rates in the elderly, although some studies have shown older age to be associated with improved adherence (82). Our study describes much higher rates of adherence (80%) to anti-hypertensives, both in terms of self-reported general medication adherence and specific refill data. Of note, we looked both at general medication adherence by self report (using the Morisky scale as well as self-reported medications missed in the past 2 days) and specific medication adherence by refill data. Refill data from VA Connecticut specify when medication is mailed to or picked up by the patient rather than whether the participant actually takes the medication. This may account for higher adherence levels in the population, although this technique has been used by other VA-based adherence studies.

Other studies that have used the Beliefs About Medicines Questionnaire (BMQ) have described a positive correlation between agreement with Medication Necessity domains and adherence, and a negative correlation between agreement with Medication Concern Domains and adherence (43). While our study did not specifically relate participants' BMQ responses to their adherence rates, our finding that participants agreed strongly with Medication Necessity domains correlates with our findings of high adherence rates observed in this population. In our study, the BMQ also served as a means of characterizing this populations' attitude towards medications. Most participants agreed strongly or very strongly with statements that medication in general could prevent them from becoming sicker, and that their well-being and life depended on their medications. It is possible that participants may have felt uncomfortable disagreeing

with questions about medication benefit, perceiving that the interviewer expected them to agree, although they did express ambivalence or disagree with the series of statements designed to elicit perceptions of medication harm. These findings may reflect a belief system of this particular generation or social group (veterans) that places great faith in their physicians, and support use of the BMQ to better understand attitudes toward medication held by patients of different ages.

Estimating Risk of Myocardial Infarction and Stroke

The finding that older adults do not accurately estimate their 10-year risk of myocardial infarction and stroke is not surprising, given that people have difficulty estimating events with small probabilities. Several studies suggest that when asked to estimate events with low probabilities, patients either dramatically over or underestimate these outcomes (53, 63, 83). In addition, several qualitative studies have described an 'optimistic bias' among participants estimating their cardiovascular risk, in that they perceive their risk level to be much lower than it actually is (84, 85). In contrast, our findings that participants largely overestimated their risk of MI and stroke are consistent with several studies that asked patients to estimate their cardiovascular disease risk (86, 87). In a study by Frijling et al., ambulatory patients with hypertension or diabetes in the Netherlands were asked to estimate their 10-year risk of MI and stroke using an analogue scale. The majority of patients overestimated their risk of these outcomes, with half of patients overestimating by more than 20%, and older patients especially estimating a higher risk.

There are several possible explanations for our findings that patients overestimate cardiovascular risk. First, participants may have had no idea of their actual risk of myocardial infarction or stroke, and may have selected the least extreme answer (50%), which is an overestimate by coincidence. Alternatively, for the small but

significant percentage of participants who had prior history of myocardial infarction (15.4%) or stroke (12.1%), their risk levels are truly higher than other patients, and their perception of risk may have been skewed to the high end of the choices. Third, many participants were recruited following education visits with pharmacists regarding their chronic conditions such as diabetes and hypertension. If participants received frequent counseling about the importance of taking diabetes and blood pressure medications, this frequent emphasis may have positively distorted their perceived risk of cardiovascular outcomes. Finally, many participants anecdotally referenced friends or family members who had experienced myocardial infarction or stroke as a reason why they believed their risk of these outcomes was quite high. Fear of loss of function may have contributed to an increased perceived risk of stroke, in particular.

Notably, some participants stated they had absolutely no idea of their risk, and felt it was their doctor's job to know their risk and decide about appropriate medications. We know from prior studies examining older patients' preferences about participation in medication-related decision-making that not all patients want to be included in the process (25). However, strategies to enhance patient knowledge may improve patient confidence and willingness to be involved in conversations about treatment decisions. Thus, improving education and knowledge about long term risk of myocardial infarction and stroke may be useful for patients taking multiple medications and allow them to think about treatment priorities. To that point, a recent study suggests that improving patients' knowledge of their coronary risk may even improve medication adherence and treatment efficacy (88).

We do not suggest that participants' overestimation of the baseline risk of myocardial infarction or stroke is purely problematic. In fact, there may be benefits to patients believing these risks to be higher than they actually are. A greater perceived risk of myocardial infarction and stroke may create incentive to take preventive medications,

which have lower adherence rates than medications which provide symptom relief (81), and can minimize the likelihood of costly disease sequelae.

Perceived Medication Benefit for Myocardial Infarction and Stroke Prevention

As hypothesized, a significant number of participants did a poor job of estimating the ability of aspirin and statins to reduce their 10-year risk of myocardial infarction, both under- and over-estimating the effectiveness of these medications. Prior studies have demonstrated variability in patients' expectations of preventive medication benefit (89, 90). A study by Llewellyn-Thomas and others found that 28-38% of ambulatory patients expected greater benefit than could be provided by their anti-hypertensives and lipid-lowering agents. Similarly, our study found that 33-43% of participants overestimated the benefit provided by these medications. This study supports our findings that people expect a higher level of benefit than can be provided by preventive medication. Of note, the mean age in our study was 20 years older than in the study by Llewellyn-Thomas, possibly suggesting that the expectation of benefit increases with age. In contrast, studies exploring reasons behind statin non-adherence have found that patients both expect lower levels of benefit from these medications and have lower levels of perceived cardiovascular risk (89). The reason for these discrepancies is unclear, but suggests that in general, patients do not have a good understanding of the benefit provided by their medications.

Many studies about medication benefit reported in the literature have focused on understanding risk-benefit trade-offs that patients are willing to make for a certain level of medication benefit (28), (90). These studies demonstrate that patients generally are willing to take daily preventive medication as the absolute risk reduction provided by those medication increases. Because so many participants in our study overestimated preventive medication benefit, it is possible that they may be more willing to tolerate

adverse medication effects and regular healthcare interactions given their high expectations.

On the other end of the spectrum, one in five participants in our study felt that medications did not reduce the risk of myocardial infarction or stroke. Poor perceived medication efficacy is a risk factor for non-adherence and also has important implications for shared decision-making regarding medication use. Patients who do not perceive any benefit from medications (that truly do have potential benefit) have limited ability to make informed decisions. The framework of shared decision-making between patient and physician is predicated on the fact that both parties take into account the best available evidence for risks and benefits of treatment. These findings—that participants both over- and under-estimate the potential benefit provided by their preventive medications—suggest that clinicians still have much work to do in educating patients about the role of medications.

Several qualitative studies have explored beliefs and common misconceptions that older patients have about their medications, such as the idea that missing a statin dose will result in a myocardial infarction the following day, or the more common notion that preventive medications are ineffective (42, 46). However, participants in this study exhibited less extreme, more nuanced thinking. Of the nearly 25% of participants who thought their 10 year risk of MI was 100%, none thought aspirin would drop that risk to zero, and only one thought a statin reduced the risk by that degree. Of similar numbers of participants who thought their 10 year risk of stroke was 100%, none thought aspirin could drop their risk to zero, and only two thought an anti-hypertensive could reduce it by that degree. The fact that patients are able to appreciate risk in these terms should inform and improve the way information is conveyed during a clinical encounter.

Several participants estimated that risk of myocardial infarction increased while on preventive medication. It is possible that these participants either did not understand

the initial question, or that they truly believe the medication does cause harm. While it is certainly possible that participants believe the medication to be harmful, the latter seems more likely, particularly since no person expressed this sentiment in the medication beliefs section of the survey. In addition, some participants commented (while answering the survey questions) that other factors, in addition to or instead of medication, modified their risk, particularly lifestyle factors such as diet, exercise, and smoking. Future studies could address the perceived benefit of preventive medication as compared to lifestyle interventions.

Participants' responses to the medication beliefs questionnaire suggests that the majority of felt that taking medication in general was beneficial for health and could prevent their health from getting worse. It was therefore unexpected that such significant numbers of participants felt that these medications had no beneficial effect. The discrepancy between the qualitative results from the medication beliefs questionnaire and the quantitative results of the risk estimation portion of the survey hint that medication beliefs and perceived benefits of medication are distinct concepts, and that to maximize patient understanding, each needs to be addressed in the clinical encounter.

Implications for Prescribing and Medication Decision-Making

While previous studies have addressed patients' estimates of their cardiovascular disease risk, to our knowledge, this is one of few studies to quantitatively assess patients' perceptions of preventive medication benefit. Our study confirms that older patients with multiple chronic conditions taking multiple medications both over- and under-estimated the ability of their preventive medications to prevent myocardial infarction and stroke. Patients who feel that medication provides no preventive benefit may be more likely to be non-adherent with medication. In addition, patients who

over-estimate the ability of medication to prevent outcomes may not be forthcoming about reporting medication side effects. These findings have important implications for patient education and the way in which doctors and physicians interact to arrive at decisions about medications.

It is particularly important for older patients who have a high medication burden, a high risk of adverse effects, and cost burden to be able to make choices about their medications. It is also important for these patients to be able to communicate priorities to their physicians to the extent that they are able and interested in doing so. In order to make informed choices about medications, however, patients need to understand the risk of common health outcomes (such as myocardial infarction or stroke), and how effectively medications prescribed to prevent these outcomes are expected to work. Since patients may prioritize health outcomes differently, prescribing medications with these outcomes in mind requires that clinicians understand patient preferences (25-27).

For patients taking medication to prevent cardiovascular outcomes such as myocardial infarction or stroke, patient education should focus on informing patients both about cardiovascular risk and about risk reduction provided by preventive medications over time. Decision aids or graphical representations may be helpful in communicating cardiovascular risk (91). Physicians can use graphs as one means of communicating the absolute risk reduction provided by common medications, which may be useful in helping patients better understand the potential benefit medications can provide.

Strengths and Limitations

Strengths of this study include the sample size, which provides a representative sample of older males with multiple chronic conditions who take multiple medications. Because the study setting is a Veterans Administration Hospital, the participants were veterans who had regular and frequent visits to general medicine and subspecialty care

physicians, in addition to low-cost (or free) prescription drug coverage. For these reasons, lack of healthcare access and medication coverage likely do not play a large role in why our participants' might answer health and medication questions incorrectly (compared to participants with little insurance or no primary care physician). This study is also the first study of which we are aware to look at older adults' understanding of medication benefit of commonly prescribed drugs. Earlier studies have focused on medication knowledge, medication literacy, and ability to understand risk. Our study therefore adds to this literature in these domains and provides relevant preliminary data to explore additional questions related to medication benefit in other diverse older patient populations. Although several previous studies have explored physicians' ability to estimate cardiovascular disease risk (56, 57), our study focused primarily on patients' understanding of these outcomes. Finally, this study explored the benefits of common preventive medications using a standardized method, developed a visual risk assessment tool based on previous health risk literature pertinent to older adults, and employed a clinically relevant context for older males by incorporating clinical conditions such as hypertension, myocardial infarction, and stroke that are common in this population.

The aim of our study was to describe patients' estimates of how well common medications work to prevent myocardial infarction and stroke. We did not expect patients to know their exact risk; rather, we wanted to understand whether they thought their risk was nearly zero, small, medium, high, or nearly 100%. For this reason, we selected values on a bar graph that do not correlate with any one patient's exact risk. Furthermore we did not calculate the exact risk for each individual; rather we calculated an average risk for the population surveyed. As a result, a small number of these participants likely had a higher risk than we estimated for the entire cohort (because 75% of the sample had diabetes, 15% had a history of prior MI, and 12% had a history of

prior stroke). However, this does not change the fact that significant numbers of participants believed medications had no benefit, nor does it discount the finding that many participants have a distorted sense of medications benefit.

All participants enrolled in the study were male veterans from the Korean War or World War II. This generation has a unique character and set of beliefs, namely that they generally prefer physicians to be responsible for their health-related decision making (25, 92). In addition, older persons may have less interaction with newer sources of healthcare information, such as the internet, compared to younger persons (93). And, although the majority of the aging population is women, women were not enrolled in this study. It is unclear if women would have similar risk estimates, or would respond differently to questions about medication beliefs. Finally, although this study had a robust sample size to characterize participants' perceived risk of myocardial infarction and stroke both on and off medications, the size was not large enough to look for an association between medication knowledge and adherence.

Summary

The majority of participants in this study significantly overestimated their risk of myocardial infarction and stroke, as well as the risk of these outcomes while on aspirin, statins, and anti-hypertensive medications. This suggests that patients do not have a good understanding of the long-term risk of these outcomes. A very small number of participants were able to accurately estimate their 10-year risk of myocardial infarction and stroke, and although by Framingham data these risks are similar, more participants thought their 10-year risk of stroke was higher than their risk of myocardial infarction. More than three quarters of participants felt that medications were able to reduce their risk to some degree, and almost no participants thought that medication could eliminate risk altogether; however, 25-44% of participants dramatically overestimated the ability of medications to reduce their risk. In addition, one in five participants felt that aspirin, statins, and anti-hypertensives did not modify their long-term risk of myocardial infarction or stroke. While overestimation of medication benefit may not be harmful to participants, the misperception may inappropriately influence patients' decisions about medications and treatment priorities. Because participants agreed strongly with statements that medications are important for maintaining health and were ambivalent towards statements that medications could be harmful, it was surprising that so many participants indicated that medication did not modify risk, suggesting a discrepancy between medication beliefs and medication knowledge. Our data suggest the need for improved communication between patients and physicians concerning long-term cardiovascular risk and medication benefit in patients with significant comorbidities who are taking multiple medications. Visual risk communication tools may be one means to improve the quality of these conversations.

APPENDIX 1: Survey Instrument

BELIEFS ABOUT MEDICINES QUESTIONNAIRE (BMQ)

Instruction: For the first part of the survey, I'm going to read you some statements that other people have made about their medicines, and I want to know how much you agree or disagree with them. Let's use this scale (where 1 means that you strongly agree with the statement, and 5 means that you strongly disagree with it). I want you to point to the answer that best shows how you feel. There aren't any right or wrong answers; I just want to know what you think.

1-strongly agree

2-agree

3-neither agree nor disagree

4-disagree

5-strongly disagree

7-ref

8-dk

9-na

1	My health right now depends on my medicines	1	2	3	4	5
2	<i>Having to take medicines worries me</i>	1	2	3	4	5
3	My life would be impossible without my medicines	1	2	3	4	5
4	Without my medicines I would be very ill	1	2	3	4	5
5	<i>I sometimes worry about the long-term effects of my medicines</i>	1	2	3	4	5
6	<i>My medicines are a mystery to me</i>	1	2	3	4	5
7	My health in the future depends on my medicines	1	2	3	4	5
8	<i>My medicines disrupt my life</i>	1	2	3	4	5
9	<i>I sometimes worry about becoming too dependent on my medicines.</i>	1	2	3	4	5
10	My medicines protect me from becoming worse	1	2	3	4	5

TEACHING EXERCISE [no recorded answers]

Instruction: Great. Now we are going to get oriented to this graph, and then we are going to use it to answer some questions about heart attacks and strokes. Along the left side of the graph, there are 100 people. Along the bottom, there are six bars that represent different numbers of people. Choice A shows almost no people at all. Choice B shows about 10 people. Choice C shows about 25 people. Choice D shows about 50 people. Choice E shows about 75 people, and choice F shows all 100 people.

Can you point to the bar that shows all 100 people?

Now can you point to the bar that shows 0 people?

Now point to the bar that shows 50 people.

And the bar that shows closest to 15 people?

And the 2 bars that show greater than 50 people?

Good job. Do you have any questions about this graph before we move on?

HEART ATTACK AND STROKE PREVENTION QUESTIONS (PQ)

Instructions: Now we are going to use the graph we just went over to talk about the chances of having a heart attack or a stroke, and to think about how much some of the medications you take change the chances of those events. It doesn't matter if you know the right answer! I just want you to think about the question and make a good guess. Please stop me at any time if you have questions.

7-ref

8-dk

9-na

- 11 First we're going to talk about heart attacks. Of 100 people who are your age with your same health problems, a certain number of these people will have a heart attack in the next 10 years. So for 100 people who are your age and your same health problems, but they are not taking any medications to prevent having a heart attack (like Aspirin or a cholesterol medication like Lipitor), how many of them do you think will have a heart attack in the next 10 years?
- 0 10 25 50 75 100

(Let me repeat that again [etc.] So you are saying that x people with your same health problems will have a heart attack in the next 10 years?)

- 12 The people we just talked about were not taking medicine to prevent heart attacks. Now, let's talk about people who are taking aspirin. Again, these are 100 people who are just like you in terms of your health, and they are taking a daily aspirin to prevent having a heart attack. Using the choices on the graph, how many of these 100 people do you think will have a heart attack in the next 10 years? (Choose the bar that is closest to what you think the answer is)
- 0 10 25 50 75 100

(Do you think that taking aspirin will change the number of people who will have a heart attack? Will the number go up or down? How much will it go up or down? Remember, you can choose any answer). You are saying (x) people taking aspirin will have a heart attack in the next 10 years?

- 13 Now instead of aspirin, the people are taking a cholesterol-lowering medication like Crestor, Lipitor, or Zocor to prevent having a heart attack. Using the choices on the graph, how many people would you say will have a heart attack in the next 10 years? (Do you think that taking the cholesterol medication will change the number of people who will have a heart attack? Will the number go up or down? How much will it go up or down? Remember, you can choose any answer). You are saying that (x) people taking cholesterol medication will have a heart attack in the next 10 years?
- 0 10 25 50 75 100

Now we are going to talk about strokes.

- 0 10 25 50 75 100
- 14 Let's again think about 100 people who are just like you. These people have the same health problems you do, but they are not taking any medicines to prevent stroke. Over the next 10 years, a certain number of these people will have a stroke. Using the choices on the graph, how many of these people do you think will have a stroke in the next 10 years? (Choose the bar that is closest to what you think the answer is). So you are saying that (x) people with your same health problems will have a stroke in the next 10 years?**
- 0 10 25 50 75 100
- 15 Now these 100 people who are just like you are taking a daily aspirin to prevent stroke. Using the choices on the graph, how many of these 100 people do you think will have a stroke in the next 10 years? (Choose the bar that is closest to what you think the answer is) (Do you think that taking aspirin will change the number of people who will have a heart stroke? Will the number go up or down? How much will it go up or down? Remember, you can choose any answer). You are saying (x) people taking aspirin will have a stroke in the next 10 years?**
- 0 10 25 50 75 100
- 16 Now instead of taking aspirin to prevent stroke, these 100 people who are just like you are taking a blood pressure pill (Diovan, Dyazide, Toprol, Lopressor) to prevent stroke. Using the choices on the graph, how many of these 100 people do you think will have a stroke in the next 10 years? (Choose the bar that is closest to what you think the answer is). You are saying (x) people taking blood pressure medication will have a stroke in the next 10 years?**

MEDICATION ADHERENCE (MA)

17 Would you say that your health is excellent, very good, good, fair, or poor?

- Ex - 1
- Vg - 2
- G - 3
- F - 4
- P - 5
- Ref - 7
- Dk - 8

18 Would you say that the number of medications you take on a daily basis is about right, too many, or too few?

- AR-1
- TM-2
- TF -3
- REF - 7
- DK - 8

19 How many doses of medication would you say you have missed in the past 2 days?

20 Do you ever forget to take your medicines?

- 1 Yes
- 2 No

Are you sometimes careless about taking your medicines?

- 1 Yes
- 2 No

When you feel better, do you sometimes stop taking your everyday medicines?

- 1 Yes
- 2 No

Sometimes, if taking your everyday medicines makes you feel worse, do you not take them?

- 1 Yes
- 2 No

Now I am going to ask you a few questions about medication(s) you take.

21 Do you take a daily aspirin?

- yes - 1
- no - 2
- ref - 7
- dk - 8
- na - 9

22 About how long have you been taking aspirin? Would you say. . .

- <1 yr - 1
- 1-5 yr - 2
- 6-10 yr - 3
- >10 yr - 4
- ref - 7
- dk - 8
- na - 9

23 Did you ever have a bad side effect from taking aspirin?

- yes - 1
- no - 2
- ref - 7
- dk - 8
- na - 9

24 What was it? _____

- GI bleed - 1
- upset GI - 2
- tinnitus - 3
- Other - 4
- false - 5
- ref - 7
- dk - 8
- na - 9

25 Did you stop taking the aspirin after that?

- yes - 1
- no - 2
- dose red - 3
- ref - 7
- dk - 8
- na - 9

26 Did you discuss the bad side effect with your doctor?

- yes - 1
- no - 2
- ref - 7
- dk - 8
- na - 9

27 Do you take a cholesterol medication?

- yes - 1
- no - 2
- ref - 7
- dk - 8
- na - 9

28 About how long have you been taking a statin? Would you say. . .

- <1 yr - 1
- 1-5 yr - 2
- 6-10 yr - 3
- >10 yr - 4
- ref - 7
- dk - 8
- na - 9

29 Did you ever have a bad side effect from taking the statin?

- yes - 1
- no - 2
- ref - 7
- dk - 8
- na - 9

30 What was it? _____

- lgcramp - 1
- Lft bump - 2
- Other - 4
- false - 5
- ref - 7
- dk - 8
- na - 9

31 Did you stop taking the statin after that?

- yes - 1
- no - 2
- dose red - 3
- ref - 7
- dk - 8
- na - 9

32 Did you discuss the bad side effect with your doctor?

- yes - 1
- no - 2
- ref - 7
- dk - 8
- na - 9

33 Do you take blood pressure medication?

- yes - 1
- no - 2
- ref - 7
- dk - 8
- na - 9

34 About how long have you been taking bp meds? Would you say. . .

- <1 yr - 1
- 1-5 yr - 2
- 6-10 yr - 3
- >10 yr - 4
- ref - 7
- dk - 8
- na - 9

35 Did you ever have a bad side effect from taking bp meds?

- yes - 1
- no - 2
- ref - 7
- dk - 8
- na - 9

36 What was it? _____

- weakness - 1
- fall - 2
- cough - 3
- Other - 4
- false - 5
- ref - 7
- dk - 8
- na - 9

37 Did you stop taking the bp med after that?

- yes - 1
- no - 2
- dose red - 3
- ref - 7
- dk - 8
- na - 9

38 Did you discuss the bad side effect with your doctor?

- yes - 1
- no - 2
- ref - 7
- dk - 8
- na - 9

GENERAL DESCRIPTIVE INFO (GDI)

39 Do you live alone?

yes – 1

No – 2

Ref – 7

Dk – 8

40 Who lives with you?	yes	no	ref	dk	na
a. spouse	1	2	7	8	9
b. child	1	2	7	8	9
c. other relative	1	2	7	8	9
d. friend	1	2	7	8	9
e. paid employee	1	2	7	8	9
f. other _____	1	2	7	8	9

41 Which of the following best describes your current marital status

single - 1

married – 2

divorced – 3

widowed – 4

ref - 7

dk - 8

42 How many years of school did you finish? _____

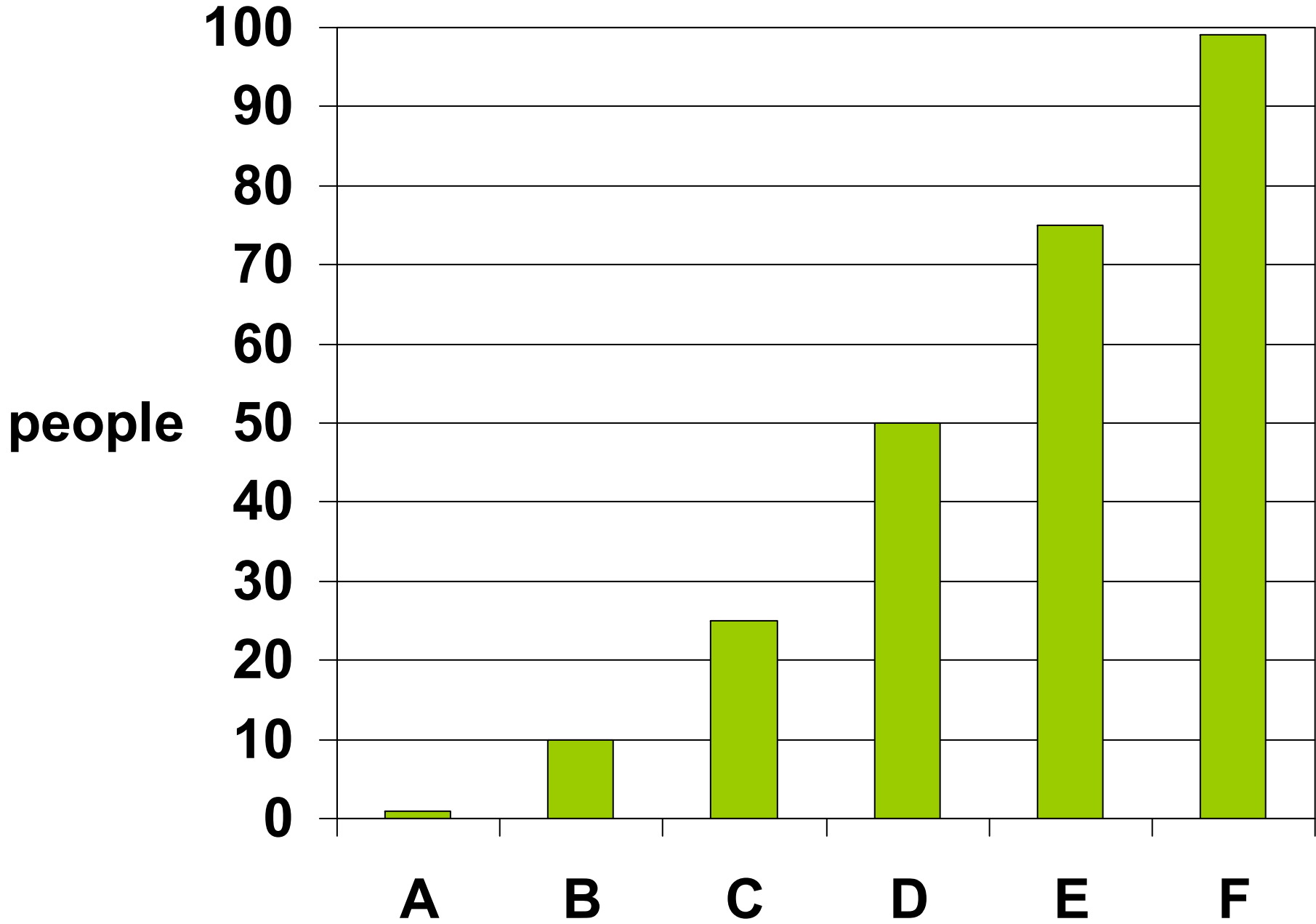
43 Do you need assistance with _____?	No assistance	Needs assistance
Telephone use	No – 0	Yes – 1
Shopping for groceries	No – 0	Yes – 1
Transportation	No – 0	Yes – 1
Meal preparation	No – 0	Yes – 1
Housework	No – 0	Yes – 1
Taking medications	No – 0	Yes – 1
Handling finances	No – 0	Yes – 1

TOTAL

44 DOES INTERVIEWER THINK PARTICIPANT UNDERSTOOD GIST OF SURVEY?

No - 0

Yes - 1



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