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Developing an Atrial Fibrillation Guideline Support Tool (AFGuST) for Shared Decision Making

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Abstract

Objective—Patient values and preferences are an important component to decision making when tradeoffs exist that impact quality of life, such as tradeoffs between stroke prevention and hemorrhage in patients with atrial fibrillation (AF) contemplating anticoagulant therapy. Our objective is to describe the development of an **A**trial **F**ibrillation **Gu**ideline **S**upport **T**ool (AFGuST) to assist the process of integrating patients' preferences into this decision.

Materials and Methods—CHA_2DS_2VASc and HAS-BLED were used to calculate risks for stroke and hemorrhage. We developed a Markov decision analytic model as a computational "engine" to integrate patient-specific risk for stroke and hemorrhage and individual patient values for relevant outcomes in decisions about anticoagulant therapy.

Results—Individual patient preferences for health-related outcomes may have greater or lesser impact on the choice of optimal antithrombotic therapy, depending upon the balance of patient-specific risks for ischemic stroke and major bleeding. These factors have been incorporated into patient-tailored booklets which, along with an informational video were developed through an iterative process with clinicians and patient focus groups.

Key Limitations—Current risk prediction models for hemorrhage, such as the HAS-BLED, used in the AFGuST, do not incorporate all potentially significant risk factors. Novel oral anticoagulant agents recently approved for use in the United States, Canada, and Europe have not been included in the AFGuST. Rather, warfarin has been used as a conservative proxy for all oral anticoagulant therapy.

Conclusions—We present a proof of concept that a patient-tailored decision-support tool could bridge the gap between guidelines and practice by incorporating individual patient's stroke and bleeding risks and their values for major bleeding events and stroke to facilitate a shared decision making process. If effective, the AFGuST could be used as an adjunct to published guidelines to enhance patient-centered conversations about the anticoagulation management.

Keywords

Decision Support Tools; Decision Analysis; Shared Decision Making; Atrial Fibrillation

Background and Significance

Atrial fibrillation (AF) is the most common significant cardiac rhythm disorder and is also the most powerful common risk factor for stroke: about 15% of all strokes in the U.S. are attributable to AF. Its frequency increases strikingly with age, reaching a prevalence of 10% in those over age 80.[1] With the aging of the U.S. population, the prevalence of AF will increase substantially from over 2.2 million currently to more than 3 million Americans by the year 2020.[1] Over the past decade, numerous randomized trials have established that anticoagulation can reduce significantly the stroke risk posed by AF. However, studies in community settings have demonstrated that inappropriate treatment is common and that there is wide variation in adherence to practice guidelines.[2] Surveys exploring this gap have identified the pivotal physician-related factor to be an "insufficiently balanced evaluation of the risk versus benefit" of oral anticoagulant therapy.[34]

Patient values and preferences are an important component to decision-making when there are tradeoffs that impact quality of life, such as the tradeoffs between stroke prevention and major hemorrhage in patients with AF contemplating long-term anticoagulant therapy.[5] While clinical trial data may report major outcomes, such as deaths, non-fatal strokes, and non-fatal major hemorrhages, techniques are needed to help determine the tradeoffs patients are willing to make between these outcomes. Guidelines such as the 9th edition of the American College of Chest Physician's (ACCP) Antithrombotic and Thrombolytic Therapy Guidelines sought to incorporate patient values and preferences in a far more explicit manner than in the past.[6] However, we still lack convenient tools that can facilitate the incorporation of individual patient's values and preferences for health outcomes into the decision-making process and discussion. Decision analysis is a technique that can facilitate the formal incorporation of patient values (utilities) into the decision making process. Life spent in less-than-perfect states of health, such as life following a non-fatal stroke, can be valued through multi-attribute metrics, such as quality-adjusted life expectancy, to facilitate explicit tradeoffs between the risks and benefits of therapies.[7] Furthermore, patients differ in their underlying risk for ischemic stroke[8], and their risk of major bleeding from anticoagulants [9]. Thus, the decision to treat AF patients with antithrombotic therapy is ideally suited to a patient-centered decision analytic approach that incorporates both patient-to-patient variability in risk factor profiles and in values and preferences for health outcomes.[5]

Decision analysis has been suggested as an approach for involving patients in a shared decision-making process.[10] For several decades the Clinical Decision Making group at Tufts has supported a consultation service that has provided such personalized decision analyses.[11] Rather than providing generic information regarding a particular set of treatments for any given clinical problem, as is frequently the case with many decision aids, decision analysis can support an individualized treatment recommendation based on both patient-specific risks and individual patient values and preferences for health outcomes.[12–17] Indeed, several prior decision aids have been developed using decision analysis to guide patients in the choice of anti-thrombotic therapy for AF.[18–22]

Realizing that guidelines generated by expert panels are static documents, our goal was to develop tools to *enhance* guidelines so that the values and preferences of individual patients for treatments and health outcomes can be easily incorporated in discussions clinicians have with their patients. In a qualitative study examining this issue, Van der Weijden and colleagues have suggested several approaches, including the development of patient versions of clinical practice guidelines and wording in the guideline itself that stresses the importance of incorporating patient participation in the decision-making process.[2324] A nice example that complements a clinical practice guideline with a patient version is the recently published AF guideline by the UK National Institute for Health and Clinical Excellence (NICE) in which a patient decision aid has been published alongside the clinician guideline.[25] Thus, the *enhanced* guidelines can be used to facilitate a shared decision making process. To accomplish this, we developed the **A**trial **F**ibrillation **Gu**ideline **S**upport **T**ool (AFGuST).

Methods

Development of decision analytic model

In order to develop patient-specific recommendations that could be used as an adjunct to AF guidelines, we first developed decision analytical models that consider various antithrombotic therapies for patients with AF. We did not model treatment with any of the novel oral anticoagulants (NOACs) that have recently been approved for use in the United States, Canada, and Europe. Anticoagulant therapy with warfarin is used as a proxy for more generalized oral anticoagulant therapy. Since this makes the decision support tool's recommendation for anticoagulant therapy more conservative, use of any of the NOACs would be reasonable when oral anticoagulation with warfarin is recommended (as supported by the most recent ACCP guidelines). We used a standard computer program (Decision Maker, Boston, Massachusetts) to build the model, analyze results, and perform sensitivity analyses. During each monthly cycle, patients face a chance of stroke and hemorrhage, either of which may lead to death, significant neurological sequelae or symptom resolution. The simulation is run for the entire life expectancy of the hypothetical cohort of similar patients. Base case values for model parameters are summarized in Table 1 and the decision tree figure and modeling details are provided in appendix figure 1 and figure 2 and accompanying text. Patient-specific stroke risk was based upon the CHA_2DS_2VASc (Congestive heart failure, Hypertension,

Age ≥75 years [double weight], Diabetes, previous Stroke [double weight], Vascular disease, Age 65–74 years, female Sex category)[47] (Appendix Table 1), while patient-specific risk of major extracranial bleeding was based upon the HAS-BLED score (Hypertension, Abnormal renal or liver function, Stroke history, Bleeding History, Labile INR, elderly - Age ≥65 years, Drugs – non-steroidal anti-inflammatory drugs or alcohol) (Appendix Table 2).[48] Patient-specific annual rates of ICH were calculated separately using a multivariable regression model (see hazard ratios in Table 1).[30]

Development of patient-specific guideline support

Our goal was to develop tools that can be used to: 1) quickly and easily obtain patient utilities for health outcomes and treatments, and 2) facilitate shared decision making by showing patients and clinicians how those patient-specific values and preferences impact the optimal treatment decision. Using steps described to facilitate the development of web-based decision support tools[49], we first specified and developed consensus regarding the necessary clinical content. The synthesis of evidence was facilitated by the PI's (MHE) participation as a member of the American College of Chest Physician's 2012 guideline development for antithrombotic therapy in patients with AF [6] In the early design phase ("sandpit testing") we experimented with many alternative graphical approaches for presenting data to patients (e.g., numeric tables, graphs, pictograms). We tested prototypes of the AFGuST through individual meetings with clinicians (general internists, cardiologists, and neurologists) and a series of patient focus groups. The director of our primary care network along with 2 other general internists (ME, DS, NW), 3 cardiologists (GL, AC, FK), and 3 stroke neurologists (MF, DK, BK) are members of our project team. We conducted a series of 4 patient focus groups and iterated on patient pamphlet and video design after each focus group. Between 2

and 5 patients attended each focus group. Other focus group attendees included the PI (MHE), study coordinator (RW), qualitative researcher (LA), and 2 graphic designers (RW, KN). To avoid ethical issues regarding treatment recommendations that may have been at odds with current therapy, focus groups were comprised of patients who did not have AF. We sought patients between the ages of 60 and 85 years as the prevalence of AF increases substantially with increasing age. The average age of AF patients in clinical trials is 69 years.[8] We also sought patients who had at least one significant non-AF diagnosis. Study protocols for focus groups were approved by the University of Cincinnati Institutional Review board (IRB).

We developed a 25-minute video that patients can view prior to their office visit that provides some clinical background about the risk of stroke from AF, the efficacy of anticoagulation therapy and the tradeoffs between the risk of stroke and the risk of bleeding from anticoagulant therapy. The video also helps patients to understand the standard gamble [5051] technique that we use in the personalized patient pamphlet to assess their individual values for relevant health outcomes. We felt this was particularly important in light of difficulties described in other studies using a standard gamble utility assessment approach within a decision aid.[52] The patient pamphlet was reviewed and edited by our organization's PR department to make sure the language was understandable at a 5th grade level.

Using an iterative process[49], we presented the video and personalized pamphlet to focus groups and clinicians, determined what they had difficulty understanding and obtained their feedback about what we could improve or add. We then updated and improved both the pamphlet and the video and met again with focus groups.

Results

Obtaining patients' values and preferences for key health states

A particular challenge in this project was determining an efficient and understandable method to obtain patient values and preferences (i.e., utilities) for health outcomes in order to incorporate them into the decision-making process. The decision analytic model (see appendix) contains a number of different health states for which patient-specific utilities could be assigned. From a purely practical perspective, attempting to perform utility assessments for all health states would take a prohibitive amount of time. The major trade-off that patients need to consider is the risk of major bleeding events (increased by anticoagulant therapy) versus the risk of AF-related stroke (prevented to some degree by anticoagulant therapy). The vast majority of major hemorrhages are gastrointestinal bleeds. [4053] In addition, the quality adjustment factors used for stoke in our model, are based upon the degree of neurological deficit and not the cause of the stroke (i.e., ischemic vs. hemorrhagic). We performed comprehensive sensitivity analyses on the values (utilities) of all health outcomes within clinically plausible ranges to see which had the greatest impact on the decision. We found that the values assigned to major gastrointestinal hemorrhage and stroke (AF-related or hemorrhagic) with severe long-term neurological sequelae had the greatest impact on the result of the decision analysis. Thus, to simplify the process of

personalized utility assessment we focused only on patients' values for these two health outcomes.

Multiple techniques exist to assess utilities for hypothetical health states (i.e., those not yet experienced by patients). These include visual analog scales, standard gambles, and time tradeoffs.[505455] The standard gamble, which determines the risk of a bad outcome, such as death, that a patient would be willing to take to avoid the outcome for which the utility is being assessed (e.g., stroke with severe long-term neurological sequelae) and the time tradeoff, which involves giving up future years of life in a less than perfect state of health in exchange for a shorter life expectancy in a good state of health, are difficult to use for the assessment of temporary health states.[56–58] This is because few patients are willing to take a risk of death or tradeoff life expectancy to avoid a health outcome that is only transient. Visual analog scales, frequently called feeling thermometers are simple and easy to administer. Thus, we settled on using a visual analog scale to obtain quality of life for the temporary health state of a hypothetical gastrointestinal bleed, and a standard gamble for long-term sequelae following a hypothetical severe stroke.

The pamphlet provides a detailed scenario description of a major gastrointestinal bleed which we adapted from Devereaux et al.[59] This description includes physical symptoms, treatment and expected recovery (see figure 1 - left panel). We use a visual analog scale to obtain a rating of their quality of life in the immediate period following a hypothetical major gastrointestinal bleed (see figure 1 - right panel).

We next provide a detailed scenario description of stroke with long-term major neurological sequelae, again adapted from Devereaux et al. (see figure 2 – left panel).[59] For the standard gamble, we use an approach which to our knowledge has not been described in the literature. Using an illustration of a bottle containing 100 pills patients are told that they can take a single pill from this bottle and it will relieve them of their stroke symptoms. They also are told that a certain number of pills in this bottle will cause a painless but fatal reaction and they will not wake up from their sleep if they received such a "poison pill." We next ask them to draw a circle around the largest number of "poison pills" they would tolerate being in the bottle while still being willing to take a chance on the curative medicine (see figure 2 – right panel).

While the poison pill analogy has been used before[60], the standard gamble typically requires a time consuming iterative ping-pong approach to zero in on the patient's indifference point. By providing a demonstration of the standard gamble in the video, patients in the focus groups understood the concept well enough to be able to simply circle the number of poison pills in the bottle they would be willing to tolerate in the gamble.

Decision Analyses and Generation of Patient-Specific Templates –

While much of the patient pamphlet is generic, we insert a personalized template which we generate from the decision analytic model based upon each patient's individual risk of stroke and major bleeding, calculated using the CHA_2DS_2VASc [47] and HAS-BLED [48] scores, and their risk of intracerebral hemorrhage.[30]

We use this template to help clinicians discuss the anticoagulation decision with their patients while also incorporating their patient's values for health outcomes (obtained in the steps described above) including major extracranial bleeds and stroke with severe neurological sequelae. Patients are shown several examples and then asked to map out their own results. Figure 3 shows one of the examples.

In order to create these personalized templates, we analyzed the decision model for a large number of scenarios consisting of different combinations of demographic and clinical parameters. For many scenarios the best choice of treatment was insensitive to patient values and preferences for the two health states assessed. For instance, for a 64 year-old woman with a CHA_2DS_2VASc of 1 and a HAS-BLED of 1, 2, 3, or even 4 (but no history of prior ICH), aspirin is always the optimal choice, independent of a patient's preferences for the two health outcomes assessed. On the other hand for a 74 year-old woman with a CHA_2DS_2VASc of 2 and a HAS-BLED of 1, oral anticoagulation therapy is always best. However, there are numerous scenarios in which patient preferences may drive the optimal choice of treatment. Figure 4 and Figure 5 demonstrate examples of two such patient scenarios in which preferences are important - a 74 year-old woman with a history of a prior bleed and heavy alcohol use (CHA_2DS_2VASc of 2, HAS-BLED of 3) and 60 year-old man with a history of diabetes mellitus, hypertension, alcohol use, NSAID use, and abnormal liver function and renal function (CHA_2DS_2VASc of 2, HAS-BLED of 4).

Using the AFGuST in Clinical Practice

A decision aid such as the AFGuST could be used in a variety of clinical settings. One could provide decision support for patients with newly incident AF during their initial hospitalization. The guideline support tool could be used retrospectively as a quality assurance tool to flag patients who may not be receiving optimal antithrombotic therapy. Utilizing the AFGuST in the ambulatory care setting to provide decision support for patients with prevalent AF is particularly appealing, being both practical and clinically rational. First, it is important to recognize that treatment decisions about antithrombotic therapy are not static and must be continually revisited. Clinical events that alter the risk factor profile for either thromboembolism or major bleeding may follow the initial decision regarding antithrombotic therapy. Furthermore, numerous studies have demonstrated that both under use and inappropriate use of anticoagulant therapy for patients with AF is common.[61–63] Therefore, a strategy employing the integration of the AFGuST into an ambulatory care environment for patients with AF of undetermined duration makes sense.

In preparation for an ambulatory visit during which the anticoagulation decision would be discussed or revisited, we would envision giving patients a personalized pamphlet (based on their age, gender, CHA_2DS_2VASc and HAS-BLED score) and either a DVD or web-link to the video that they can review while they read their pamphlet at home prior to their next office visit. Thus, time will be saved and they can come to their office visit activated and prepared to have a shared decision making discussion with their clinician.

Discussion

The recognition of stroke risk from AF and its prevention have become high profile issues for a number of organizations. The American College of Chest Physicians Foundation and the American Heart Association have developed standardized patient educational tools and booklets.[64] The Alliance for Aging Research recently convened a roundtable and developed a consensus document "Assessing Stroke and Bleeding Risk in Atrial Fibrillation,"[65] while a United States congressional resolution introduced into the House of Representatives in 2011 focused on encouraging programs that increase public and clinician awareness of AF, including risk assessment, treatment, and appropriate clinical management.[66]

As such, decision aids have been developed to provide AF patients with general information about the underlying stroke risks of AF and the benefits of antithrombotic therapy.[646768] In some cases patient-specific risk projections for stroke have been presented. However, most have not also presented patient-specific risk projections for major bleeding. Decision aids that have presented individualized risks of stroke and major bleeding have left it to the patient and their physician to decide whether a given change in risk/benefit with versus without treatment is worth taking.[25] Using graphical techniques (e.g., pictograms) such an aid might report for a given patient: with no medication 13 people out of 100 like you will have a stroke over 5 years while 2 in 100 will have a bleed. With coumadin, 5 people in 100 will have a stroke over 5 years and 9 in 100 will have a bleed.[2569] This is a cognitively complex task that requires a high level of numeracy. Using a decision analytical approach and multi-attribute outcome metrics allows us to decompose the cognitive problem into several simpler tasks by first assessing patient's values and preferences for stroke and major hemorrhage, and then projecting a single outcome, in quality-adjusted life years, for each strategy. Thus, the comparison the patient and their clinician must make is simply which strategy provides the largest quality-adjusted life expectancy.

Other studies have explored using a decision analytic approach to augment decision aids for the antithrombotic therapy decision in patients with AF.[7071] The Decision Analysis in Routine Treatment Study (DARTS) team has examined the feasibility of a shared decision-making tool for patients in the United Kingdom (UK) with AF.[7273] Using stroke prediction models from the Framingham study[74] and a large series of look-up tables representing results of a decision model, they developed patient-specific guidelines for warfarin therapy in patients with AF.[72] Through focus groups with general practitioners in the United Kingdom, they described uncertainty about the appropriate usage of warfarin in patients with AF. Furthermore, they found that "readily accessible information on the evidence base would generally be welcomed."[73] The DARTS model differs from the AFGuST in a number of ways. There are profound differences in the calculation of patient risk for stroke and bleeding and in the probabilistic events considered in the decision models. DARTS uses a variant of the Framingham stroke risk equation which is not specific for patients with atrial fibrillation, or for cardioembolic stroke, whereas the AFGuST uses the CHA_2DS_2VASC score[47], developed specifically on patients with AF. Bleeding risk for the DARTS analysis only considers gastrointestinal bleeding, whereas the AFGuST also considers the far more devastating central nervous system bleeds. In a more recent clinical trial (DARTSII) examining the efficacy of this computerized decision aid compared with a paper-based

guideline tool, Thomson and colleagues found that use of the computerized decision aid significantly lowered decisional conflict and improved patients' sense of being well informed.[22] Of particular interest, they discontinued the arm of their study that used a standard gamble approach to assessing utilities for the personalized decision analysis.[52] This was done as a result of a qualitative analysis using videotaped transcripts of clinician-patient interactions that suggested the standard gamble values elicitation exercise was causing confusion. Indeed, this is one of the reasons we demonstrated a sample standard gamble exercise in the video that accompanies the AFGuST.

Finally, it should be realized that the decision regarding antithrombotic therapy for patients with an elevated risk of both stroke and major bleeding is preference sensitive; meaning there isn't a RIGHT decision for every patient. Thus, the true goal for these patients is that the decision making process be the best it can be. To achieve that, the delivery of patient-centered care requires an active role for the patient, and the communication of understandable and relevant, patient-specific information by healthcare professionals to patients.[7576] Therefore, the AFGuST has been designed to inform and activate patients and to prompt physicians to discuss the anticoagulation decision with their patients, hopefully resulting in "better" decisions, measured by increased patient knowledge, and improved confidence and satisfaction with the decision-making process.[7778]

The AFGuST has several limitations. In order to calculate stroke risk we have used the CHA_2DS_2VASC[47], which is similar to the $CHADS_2$ [79], but provides additional discrimination for age (65 to 75), female gender, and the presence of concomitant vascular disease. Studies have shown their receiver operator curve areas to be comparable.[47] While the European Society of Cardiology's guidelines uses both CHA_2DS_2VASc and HAS-BLED, the most recent version of the ACCP guidelines published in 2012 still used the $CHADS_2$. In addition, guidelines do not explicitly integrate a quantitative assessment of bleeding risk in their recommendations. Therefore, it is possible or even likely that for some patients the ACCP guideline will make a different recommendation (based on the $CHADS_2$ score) than the AFGuST. Finally, if evidence continues to accumulate that stroke risk is lower in non-clinical trial settings, [3380] this will expand the size of the population for whom anticoagulant therapy is a preference-sensitive decision, making a tool like the AFGuST helpful for an even larger group of patients facing this difficult decision.

Despite their continued development, current risk prediction models for major hemorrhage, such as $HEMORR_2HAGES$ and HAS-BLED, do not incorporate psychosocial and socio-demographic information or fall risk that may bear on the risk of bleeding with anticoagulant therapy.[4881] Therefore, the recommendation of the AFGuST cannot be interpreted as a mandate that replaces clinical judgment. Rather, it must be interpreted holistically within the broader clinical context of the whole patient. We must make sure to appropriately communicate these limitations to the clinicians using such decision **support** tools.

Over the past 2 years, several novel anticoagulants have come on the scene. Four, dabigatran, rivaroxaban, apixaban and edoxaban have received approval for use in patients with AF. At this time, knowledge regarding the efficacy and safety of these novel agents is

limited to a small number of studies. Uncommon but serious adverse events may emerge with larger-scale use of these agents. Thus, decisions among anticoagulant agents are complex and a bit premature, and the benefits and circumstances in which one agent may be better than another for an individual patient remain unclear. Furthermore, the most recent guidelines from the ACCP focus on the decision to use anticoagulant therapy rather than specifying a particular anticoagulant. Therefore, our guideline decision support tool does not address choices among competing anticoagulants. The guideline support tool is sufficiently flexible to incorporate new data at an appropriate future date to either substitute a newer agent in the place of warfarin, or possibly consider choices among anticoagulants.

Finally, shared decision making represents a significant opportunity to operationalize the goals of patient-centered care featured in the new Health Care Affordability Act. The final rule for Medicare accountable care organizations requires that delivery systems engage in shared decision making to qualify for participation in the Medicare Shared Savings Program.[8283] In order to operationalize this mandate, tools such as the AFGuST will need to be developed, refined, tested and used in clinical settings.

Conclusion

Using an iterative design process that included clinicians and patient focus groups, we developed patient-tailored booklets and an informational video that could be used to facilitate a shared decision making experience for patients and their clinicians considering alternate treatments to prevent stroke due to AF. The AFGuST could facilitate a patient-centered discussion that incorporates patient-specific information regarding stroke and bleeding risk as well as individual patient's values and preferences for relevant health outcomes.

Practice Implications

As suggested by the International Patient Decision Aids Standards (IPDAS) collaboration[84], having developed a stable prototype, we are currently pilot testing the AFGuST to evaluate its usability and understandability in a small clinical study of patients with AF. Our next goal is to perform a cluster-randomized clinical trial to evaluate the impact of the AFGuST on the decision-making process and various measures of decision quality. If effective, the AFGuST could be used as an adjunct to published guidelines to enhance patient-centered conversations about the anticoagulation management of patients with atrial fibrillation. Although we have developed an application for patients with AF, the conceptual model of patient-centered decision-making can be extended to other patient populations, and the general tools and paradigm developed to support these activities (e.g., patient-specific decision models, and decision analysis results reporting modules) can be used to address other clinical decisions. Mindful of the increasing use of electronic health records (EHR), we develop these tools with the eventual goal of integrating them into comprehensive health information systems (e.g., through patient portals and as point-of-care decision support for clinicians).

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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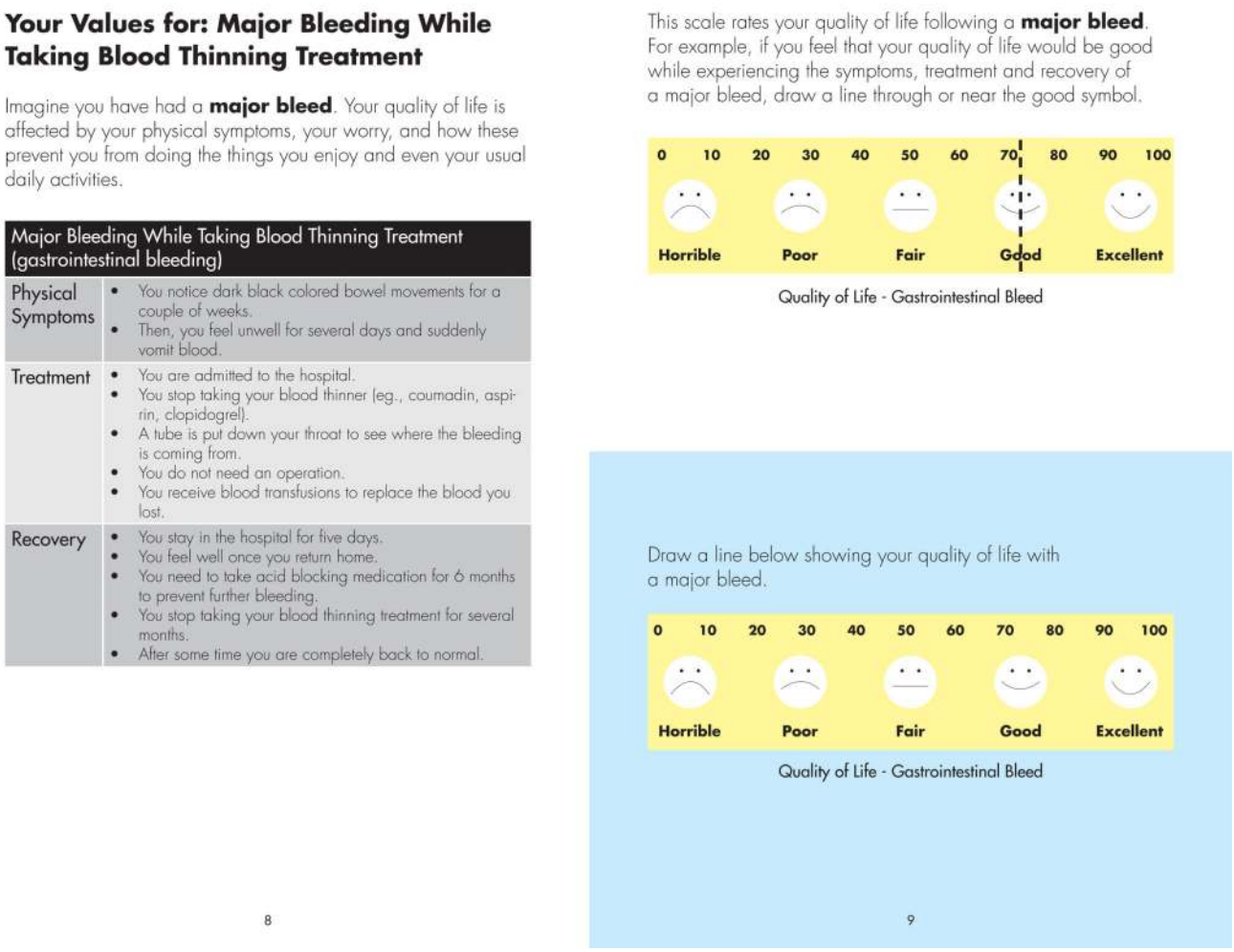


Your Values for: Major Bleeding While Taking Blood Thinning Treatment

Imagine you have had a **major bleed**. Your quality of life is affected by your physical symptoms, your worry, and how these prevent you from doing the things you enjoy and even your usual daily activities.

Major Bleeding While Taking Blood Thinning Treatment (gastrointestinal bleeding)	
Physical Symptoms	• You notice dark black colored bowel movements for a couple of weeks. • Then, you feel unwell for several days and suddenly vomit blood.
Treatment	• You are admitted to the hospital. • You stop taking your blood thinner (eg., coumadin, aspirin, clopidogrel). • A tube is put down your throat to see where the bleeding is coming from. • You do not need an operation. • You receive blood transfusions to replace the blood you lost.
Recovery	• You stay in the hospital for five days. • You feel well once you return home. • You need to take acid blocking medication for 6 months to prevent further bleeding. • You stop taking your blood thinning treatment for several months. • After some time you are completely back to normal.

8

This scale rates your quality of life following a **major bleed**. For example, if you feel that your quality of life would be good while experiencing the symptoms, treatment and recovery of a major bleed, draw a line through or near the good symbol.

Quality of Life - Gastrointestinal Bleed

Draw a line below showing your quality of life with a major bleed.

Quality of Life - Gastrointestinal Bleed

9

Figure 1. Your Values for: Major Bleeding While Taking Blood Thinning Treatment

The panel to the left describes Physical Symptoms, Treatment, and Recovery that can be expected following a major gastrointestinal bleed. The panel to the right shows a visual analog rating scale used to assess a patient's quality of life following a hypothetical major bleed. The top portion of the panel demonstrates an example, while the bottom portion of the panel is used to obtain a patient's personalized assessment for quality of life following a major bleed. In order to assist with numeracy, emoticons are also used to describe the zero to one hundred numerical scale.

Your Values for: Severe Stroke

Imagine you have had a **severe stroke**. Your quality of life is affected by your physical symptoms, your worry, and how these prevent you from doing the things you enjoy and even your usual daily activities.

Make-believe there is a new pill that will cure you of all your **severe stroke** symptoms.

You only need to take **one** pill from a bottle with 100. However, the bottle also has a certain number of pills which result in sudden but painless death in your sleep.

Given everything you know about how a **severe stroke** would affect your quality of life and your ability to do the things that are important to you, we want to know what you think about this pill.

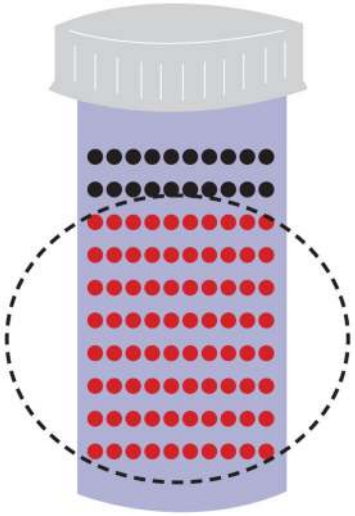
Severe Stroke	
Physical Symptoms	• You suddenly cannot move or feel your arm and leg on one side of your body. • You have difficulty eating and swallowing without choking. • You cannot talk.
Mental Symptoms	• You have trouble expressing yourself. • You can't understand what is being said.
Treatment	• You are admitted to the hospital. • The nurses feed you. • You cannot dress yourself. • You cannot walk.
Recovery	• You are transferred from the hospital to a rehabilitation facility. • After one month of physical therapy you are able to wiggle your toes and lift your arm off the bed. • You need help to do most of your daily activities, including eating, washing up, and going to the bathroom. • You remain this way for the rest of your life.

10

CHOOSE

Live with symptoms and disability following a **severe stroke**.

or, take **one** pill from this bottle that will cure you and relieve your stroke symptoms.



However, a certain number of pills in this bottle of 100 pills will cause a fatal reaction.

How much of a risk would you be willing to take?

- For instance, if there were 80 "poison pills" (the circled red pills) in the bottle, would you be willing to take an 80% chance on getting a pill that would kill you and a 20% chance of getting a pill that would cure you?

11

Figure 2. Your Values for: Severe Stroke

The panel to the left describes Physical Symptoms, Mental Symptoms, Treatment, and Recovery that can be expected following a severe stroke. The panel to the right uses a pill bottle motif to perform a standard gamble, assessing how large a risk of painless death a patient would be willing to take to avoid living with the long-term sequelae of a severe stroke. The next page in the pamphlet (not shown) is used to obtain the patient's own value of quality of life for this health outcome.

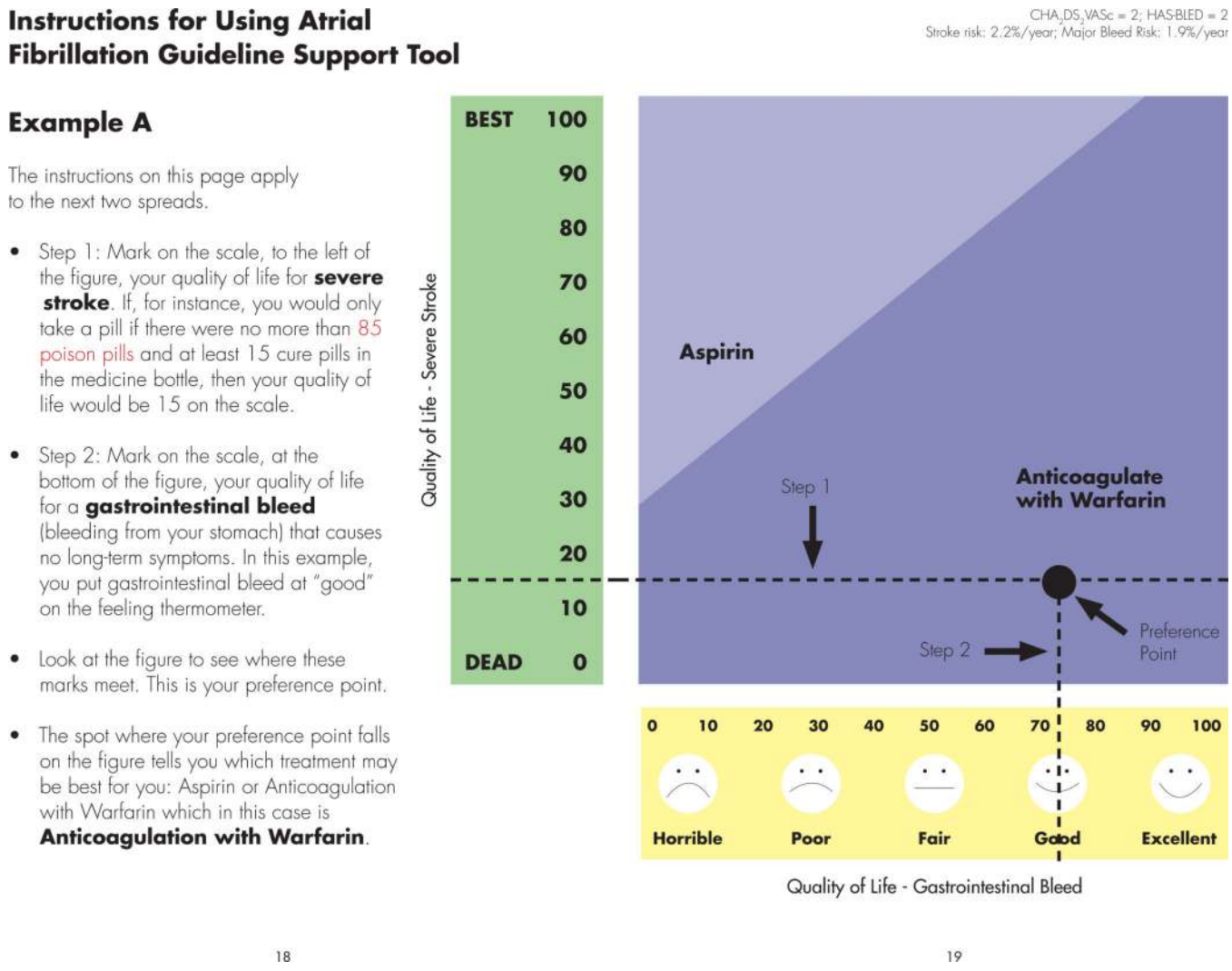
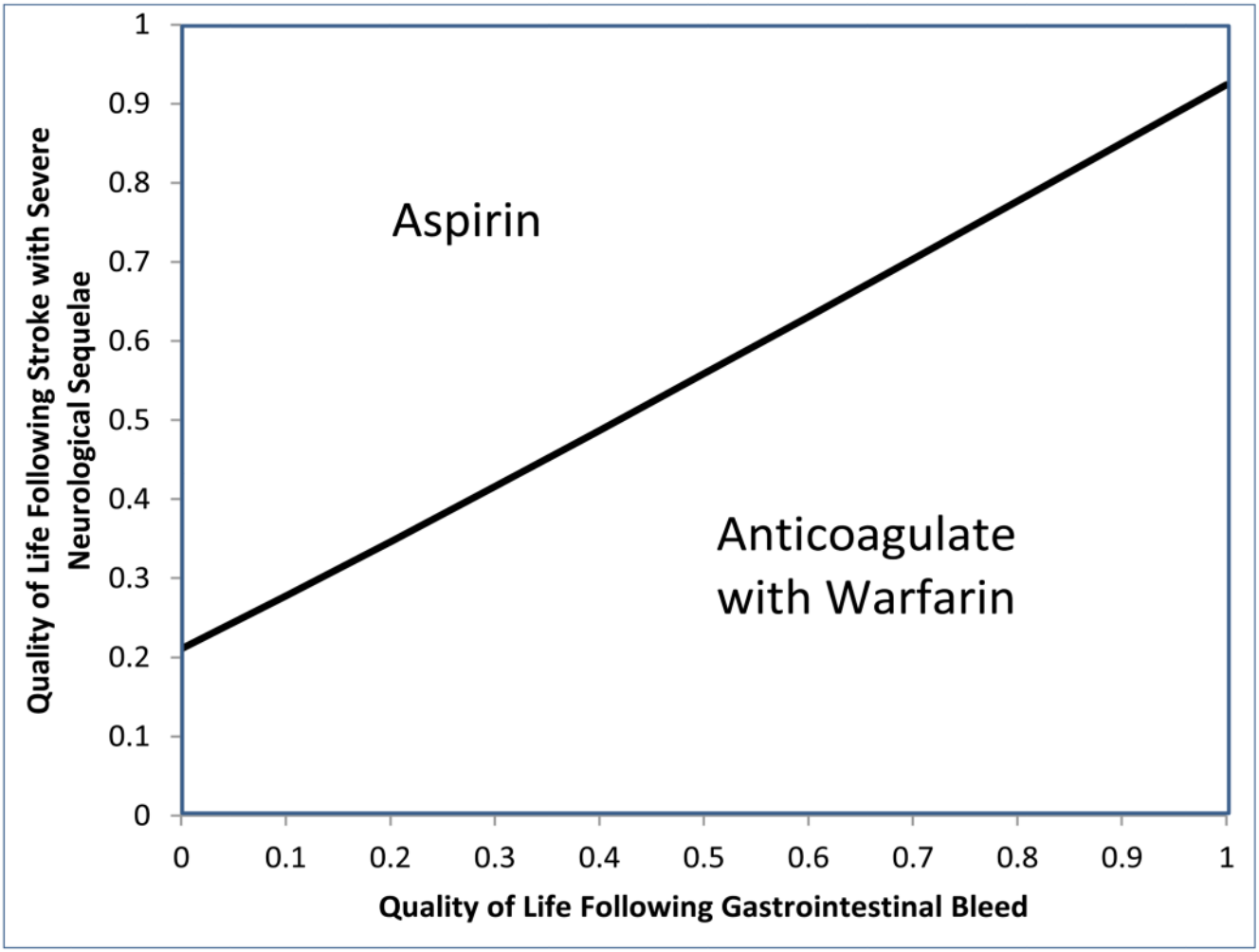


Figure 3. Instructions for Using Atrial Fibrillation Guideline Support Tool

This figure demonstrates an example for patients of how they can use the AFGuST to find their "optimal" choice of antithrombotic therapy, based upon their personalized risk of stroke, major bleeding while receiving aspirin or oral anticoagulant therapy and their values for the health outcomes of major gastrointestinal bleed and severe stroke. Instructions are provided to the left of the figure. The horizontal, x-axis represents an individual patient's values and preferences (quality of life) for a gastrointestinal bleed, while the vertical, y-axis represents a patient's quality of life following a stroke with severe neurological sequelae. There are two treatment regions in the figure representing the optimal strategy for a patient with this particular combination of stroke and bleeding risk. Patients mark the values (utilities) they provided previously for quality of life following a severe stroke (step 1) and quality of life in the early aftermath of a gastrointestinal bleed (step 2). They then draw a line from each of these points on the y- and x-axes and mark the point where these two lines intersect. This is called their "preference point." An example is shown for a patient with a CHA_2DS_2VASc of 2 (stroke risk – 2.9%/year) and a HAS-BLED of 2 (major bleeding risk – 1.9%/year), who believes their quality of life would be low following a stroke with severe

neurological consequences (~ 15, on a zero to one hundred scale), and higher following a significant gastrointestinal bleed (~73, on a zero to one hundred scale). The "preference point" for such a patient falls in the region to the lower right where anticoagulation with warfarin is best. Alternatively, for a patient who felt that their quality of life following a major bleed and following a stroke would be modestly decreased (not shown), aspirin would be the best treatment choice, since their decision point would fall above the threshold line dividing the two treatment regions. The patient is asked to find their own "preference point" using their personalized health values on a following page of the pamphlet.



Figures 4 and 5.

provide examples of different patient-specific templates that could be inserted into the AFGuST pamphlet for a 74 year-old woman (figure 4) with a history of a prior bleed and heavy alcohol use (CHA_2DS_2VASc of 2, HAS-BLED of 3) and 60 year-old man (figure 5) with a history of diabetes mellitus, hypertension, alcohol use, NSAID use, and abnormal liver function and renal function (CHA_2DS_2VASc of 2, HAS-BLED of 4). The region in which Anticoagulation with Warfarin is the best choice is larger in Figure 4 for the patient with a lower risk of major hemorrhage.

Table 1

Data Required in the Analysis: Probabilities, Rates, and Quality of Life.

Parameter	Value			
Annual Rate of Ischemic Stroke (untreated)	Based upon CHA_2DS_2VASc score [see Appendix Table 2] [26]			
Efficacy of treatment with warfarin -	0.68 [8]			
aspirin – at age 50	0.60 [27]			
aspirin – at age 77	0.00 [27]			
Probable outcome of Ischemic Stroke:				
Death -	0.16 [28]			
Permanent sequelae :	0.44 [8 29]			
with severe disability -	0.69 [8 29]			
with mild disability -	0.31 [8 29]			
Good recovery -	0.40 [8 29]			
Annual Rate of extracranial bleeding event: (warfarin) -	Based upon HAS-BLED score [see Table 3] [30]			
(untreated) –	(HAS-BLED bleeding rate)/2.4 [31]			
(aspirin) -	(Bleeding rate in untreated) * 1.08 [31]			
Annual rate ICH low risk referent group (untreated)	0.0004 [30]			
Multivariate Hazard Ratios for ICH (untreated)	[30]			
Age < 65	1.0			
Age 65 – 74	1.97			
Age ≥75	2.43			
Female	0.7			
Prior Ischemic Stroke	1.21			
Hx of ICH	8.92			
Hx of Severe Bleed	3.1			
Hx of Myocardial Infarction	0.82			
Hx of Ischemic Heart Disease	0.81			
Hx of Poorly Controlled HTN †	1.32			
Annual rate Subdural Hematoma (untreated)	0.00027 [8 32 33]			
Location of hemorrhage	Lobar ICH	Deep ICH	Subdural hematoma	Extracranial
Relative hazard of bleeding (vs. no treatment)				

Parameter	Value			
warfarin -	4.1 [3334]	4.1 [3334]	5.5 [333839]	2.4 [41]
aspirin -	1.84 [35–37]	1.84 [35–37]	2.0 [40]	1.08 [41]
Probable outcome from bleed (without warfarin/with warfarin)*	[42]	[42]		
Death –	0.19 / 0.38	0.21 / 0.41	0.267[37 43]	0.024/0.051
Severe long-term disability -	0.43 / 0.43	0.44 / 0.42	0.07/0.09 [44]	[3743]
Mild long-term disability -	0.20 / 0.11	0.19 / 0.10	0.40/0.50 [44]	
Good recovery -	0.19 / 0.08	0.17 / 0.07	0.263/0.143	
Long-term symptoms	Base-Case Value of Quality of Life			
Well	1.0			
Well while receiving anticoagulant therapy	0.99 [45]			
Severe long-term disability	0.11 [45]			
Mild long-term disability	0.76 [45]			
Death	0.0			
Short-term symptoms				
ICH‡	0.79			
Ischemic stroke‡	0.79			
Extracranial bleed ξ	0.84			
	Base-Case Value of Age-Adjusted Annual Excess Mortality			
Stroke with long-term disability	0.08 [46]			

†Poorly controlled hypertension – systolic BP ≥160 mmHG.

*Assume outcomes of bleeding events for aspirin-treated patients are the same as for untreated patients.

‡Assume quality of life is 0 for duration of hospitalization. Length of stay for specific cerebrovascular disorders except transient ischemic attack (diagnosis-related group, 14) is 6.4 days.

ξLength of stay for gastrointestinal hemorrhage (diagnosis-related group, 174) is 4.9 days. Duration of short-term utility loss for major extracranial bleed is 12 months.