

The Ethical Implications of Discontinuing Warfarin Therapy in the
Cognitively Impaired Patient

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Summary of the Case Study

Kathryn Mead is a 65-year-old African American female from Dallas who has been a patient in the Anticoagulation Monitoring Clinic (AMC) for 5 years. She was referred by her primary care provider for management of her warfarin therapy, which she receives due to a history of recurrent deep venous thrombosis (DVT). She is seen by the author on a monthly basis to adjust her warfarin dose, based on the results of her international normalized ratio (INR). Her other diagnoses include bipolar disorder, hypertension, bilateral degenerative joint disease of the knees, history of tubulovillous adenoma, and syphilis. She was diagnosed with Alzheimer's disease in August 2009. She also has a history of falls despite use of a walker but has had no serious injuries to date. Her medications include Detrol, amlodipine, imipramine, sertraline, topiramate, depakote, warfarin, aspirin, and hydrocodone. Mrs. Mead lives alone. Her son travels frequently but is involved in her care. A visiting nurse assists her with medications.

At her last clinic visit, Mrs. Mead was confused and agitated (see Appendix A). As this was a worrisome change from her baseline functioning, the author contacted patient's geriatric provider to discuss her observations. She also expressed concern for the patient's increasing cognitive dysfunction coupled with fall risk, precluding safe warfarin use. The geriatric provider answered with a question: What if the patient wants to stay on warfarin?

General Ethical Dilemma

The patient and her health care providers are faced with difficult medical and ethical choices. The patient wants to continue warfarin treatment, but her Alzheimer's disease with its attendant cognition dysfunction may prevent her from being able to take the drug safely. The

duty of the provider is to do no harm; however, continuing warfarin treatment places the patient in harm's way. Conversely, not continuing warfarin carries serious risks of thromboembolism. There are no studies that identify the safest option. Do the dual dangers of maleficence and impaired ability to give informed consent dictate that her autonomous desires be overridden? What course of treatment will provide the most benefits and the least risk to the patient? In addition, the issue of justice simmers in the background. Her socioeconomic status as an elderly African American female places her at risk for disparate treatment. This paper will attempt to dissect these issues and formulate a safe, effective, and ethically sound treatment plan.

Stakeholders in the Issue

The primary stakeholders are the patient and her family. A decision in any direction can lead to profound disability or death. Patients with similar medical predicaments are also stakeholders, as individual cases have the potential to become standardized practice. Also affected are her primary care provider and nurse, as they care for this patient regardless of the outcome. This author is affected, as she will need to deal with the ramifications of negative outcomes based on her recommendations. Secondary stakeholders are Medicare and society as a whole; an adverse outcome in any direction will be costly to the system.

Background Information

Rationale for Treatment with Warfarin

Deep vein thrombosis (DVT) usually arises in the calf veins. Untreated, 20% of calf vein thrombi extend into the proximal venous system. Of these, 10% will cause fatal pulmonary embolism, and another 50% will cause pulmonary embolism or recurrent venous thrombosis (Pineo & Hull, 2005). Warfarin is highly effective for preventing recurrent venous thromboembolism (VTE) (Kearon, Kahn, Agnelli, Goldhaber, Raskob, & Comerota, 2008). This

patient has had three episodes of DVT, with her last episode recurring two months after discontinuing therapy. In this scenario, patients require lifelong treatment with warfarin (Anderson, 2005).

Risks Associated With Warfarin

Managing warfarin therapy has been described a “high-wire balancing act”, with success partially determined by avoidance of two equally serious clinical failures: over-anticoagulation and under-anticoagulation (McCormick, 2005, p. 14.1). The most common anticoagulation-related bleeding sites associated with warfarin with significant morbidity are gastrointestinal, genitourinary tract, and soft tissue injuries (Byeth, 2005). The most serious complication of warfarin therapy is intracranial hemorrhage (ICH), which causes 90% of the deaths and most of the permanent disability from warfarin – associated bleeding (Hart, 2009). Rates of anticoagulation-related ICH range from 0.3 to 2.0% each year. Adding aspirin therapy to warfarin doubles the risk of ICH. Patients on warfarin need to be able to take warfarin correctly and consistently, adhere to dietary recommendations, avoid certain medications, keep appointments for INR monitoring, and recognize and respond to symptoms of excessive bleeding. Alzheimer's disease consists of progressive impairment of memory, orientation, language, judgment, problem solving, and perception. The concern is that Mrs. Mead’s declining cognitive function interferes with her ability to fulfill these criteria, while her history of falls puts her at risk for serious bleeding and hemorrhage.

Ethics Section

The ethical duties of this author in this case study are to avoid harming the patient, provide benefits, maintain patient autonomy, and promote justice. Conflict immediately arises when attempting to reconcile the competing demands to fulfill the ethical imperatives of

autonomy and nonmaleficence. This dilemma has been described by Miller, who stated, “In clinical bioethics, the right to autonomy of individuals is in tension with healthcare professionals’ obligations to benefit patients” (1995, p. 246). The preeminence of autonomy is described by Grace (2009 p. 19) as being “one of the powerful moral principles framing Western social and political system.” As such, it will be addressed first.

Autonomy

The word “autonomy” is derived from the Greek word for “self-law” or “self rule” and means the moral right to choose and follow one’s own plan of life and actions or the moral ability to identify and pursue our goals (Merriam-Webster online, 2009). The moral philosopher Kant (1785/1967, p. 317) asserted, “Because human beings have the ability to reason, decide and act, they should be free to make their own personal decisions without interference.” This right is reinforced within the patient- provider relationship by the provider’s duty of fidelity. Miller (1995,p 246) describes three elements of the psychological capacity of autonomy: (a) agency, recognizing that one’s self has desires and intentions and acting on them; (b) independence, the absence of influences that control a person to the degree that it cannot be said he or she wants to do it; and (c) rational decision-making, which requires that one’s beliefs are subject to truth and evidence, the ability to recognize commitments and act on them, change their decisions based on their beliefs, and make commitments based on their beliefs and values. When these criteria are met, the patient is able to give true, informed consent. Lo (2009, p. 77) described an assessment of informed consent by asking three questions: (a) Can the patient make decisions and communicate choices? (b) Does the patient understand the medical issues and prognosis? (c)

Does the patient understand the plan of care, the alternatives to this plan of care, and the risks and benefits resulting from this plan of care?

In Mrs. Mead's case, impending dementia may decrease her ability to give true informed consent. Swonger and Burbank (2005) observed that mental capacity may be diminished in the elderly due to the nature of disease processes as well as changes in capabilities that accompany aging. They recommend that the patient's mental competency be evaluated if this is suspected. If her ability is diminished, a proxy should be designated to assist her with decision-making. If the patient is considered competent and wants to continue warfarin, her desires need to be respected.

Nonmaleficence

As much as the right to autonomy is seen as a foundation in our culture, societal expectations necessitate that physicians keep the vows of *Primum non nocere*: "Above all, do no harm" (Soskolne & Sieswerda, 2002). There is a considerable potential for adverse outcomes when continuing warfarin in the setting of cognitive dysfunction and fall risk. A fall could result in an inter-cerebral hemorrhage or other internal bleeding. The patient may inadvertently underdose herself, which would lead to another thrombosis, while an overdose could lead to hemorrhage. She may be unable to maintain the dietary restrictions necessary to keep her INR within therapeutic range. She may not be able to recognize and respond to symptoms of excessive anticoagulation. Conversely, as discussed previously, not continuing warfarin carries a great risk of morbidity and mortality from pulmonary embolism. There are no definitive studies to help guide treatment options. Jacob, Billet, Freeman, Dinglas, and Jumquio (2009) completed a retrospective observational study of closely monitored nursing home patients with a history of falls and dementia. The indication for treatment was atrial fibrillation and the mean age was 82. Jacob et al. concluded that these patients had low rates of stroke, hemorrhage, and death. The

results of these findings cannot be applied in this case, as Mrs. Mead lives alone without the benefit of 24-hour per day observation and assessment.

Beneficence

Beneficence, like nonmaleficence, is central to the Hippocratic Oath. It is the obligation to provide benefits or seek the welfare of another. (Churchill, 1995). The medical benefits of continuing warfarin are the reduced probabilities of recurrence of DVT and its associated risks of thromboembolism and post-phlebitis syndrome. The patient may also experience the emotional benefit of knowing that the risk of recurrent DVT is substantially diminished. The benefits of stopping warfarin include the termination of the risk of bleeding and injuries associated with therapy, as well as the freedom from the emotional, physical, and fiscal burden of monthly appointments, dietary and medication restriction, and surveillance for signs of excess anticoagulation.

Beneficence, Maleficence and Ethical Theories

Deontology is the study or science of duty. (Encyclopedia Britannica Online, 2009). Deontological theory claims that actions are either good or evil, while the result or product of the action is not considered ethically important. An act has moral worth if it fulfills and obligation. As such, deontic theory does not serve to inform us in this case. While principled motivations are necessary, the needs of this patient extend beyond virtuous intentions. Failure to determine the most medically sound solution could result in a serious negative outcome. It would be doubtful that the patient and her family would find comfort from the principled intentions of her provider if she were to suffer an intracranial hemorrhage. Conversely, the provider could have malevolent intentions but inadvertently have a good patient outcome. The theory of utilitarianism also does not help enlighten the decision. Naverson and Wellman (1970)

describe utilitarianism as being a theory that ranks outcomes from an impersonal standpoint. Utilitarians consider that the best outcomes are those that contain the greatest amount of collective individual welfare. How can one treatment decision affect the health, happiness and freedom of the majority? In a society where health care rationing was in effect, a utilitarian might argue that continuing therapy is a waste of resources in a patient with these diagnoses, as it diverted resources from the majority.

The ethics of risk versus benefit analysis was evaluated to help provide ethical clarification. Hansson (2007, para.1) defines risk as being the probability of an unwanted event which may or may not occur. He notes that this theory has been not been widely discussed, as it has been left to the arena of decision theory. He does explain that moral philosophy assesses human behavior in well-determined situations. Decision theory takes these assessments, adds the probabilities and derives assessment for behavior . This theory is not able to be utilized as there is no information about statistical probabilities in these circumstances.

Justice

The ethics of justice consist of “an ethical perspective in terms of which ethical decisions are made on the basis of universal principles and rules, and in an impartial and verifiable manner with a view to ensuring the fair and equitable treatment of all people” (Botes, 2000, p. 1072). Rawls (1971) asserted that justice is the most important asset of social institutions. Beauchamp and Childress (2009) maintain that there is racial, ethnic, and gender discrimination in health care. Smedley, Stith, and Nelson (2003) discussed how, despite steady improvement in the overall health of Americans, racial and ethnic minorities still experience higher rates of morbidity and mortality than non-minorities. African- Americans have the highest rates of mortality for cancer, heart disease, cerebrovascular disease, and HIV/AIDS than any other group.

Smedley et al. admitted that the reasons for the differences are complex but maintained that at least one of the factors is the direct and indirect consequences of discrimination. Mrs. Mead, as an elderly, cognitively impaired African American female, is at high risk for inequitable treatment. There are no data telling us exactly what therapy a middle class male Caucasian with the same risk factors would receive. Presence of family members to advocate for the patient and healthcare providers cognizant of this issue can help ensure Mrs. Mead receives thoughtful and equitable care.

An Alternate Way of Reasoning

The American Nurses Association (ANA, 2009) code of ethics states that nurses must practice with compassion and respect for the inherent dignity, worth, and uniqueness of every human being. In addition, nurses must promote, advocate for, and strive to protect the health, safety, and rights of each patient (ANA). In Jean Watson's caring theory, nurses provide a supportive, protective, and/or corrective physical, socio-cultural, and spiritual environment (Cara, 2003). The ethical provision for these directives is fulfilled in this case analysis. The individual risk versus benefit analysis acknowledges the inherent uniqueness of Mrs. Mead. The role of the author in conferring with patient and healthcare providers fulfills the need of the patient for an advocate to protect her health, safety and rights. Finally, the author creates a protective environment by developing a patient safety net to minimize harm and maximize benefits of therapy.

Legal Issues

The FDA's Adverse Event Reporting System determined that warfarin is one of the top 10 drugs that reported the largest number of severe unfavorable events from 1990 to 2005. Wysowski, Nourjah, and Swartz (2007) found the following:

From U.S. death certificates, anticoagulants ranked first in 2003 and 2004 in the number of total mentions of deaths for drugs causing adverse effects in therapeutic use. Data from hospital emergency departments for 1999 through 2003 indicated that warfarin was associated with about 29,000 visits for bleeding complications per year, and it was among the drugs with the most visits. (p. 1414)

McCormick (2005) stated the negative information about warfarin has given lawyers ammunition to initiate litigation for medical malpractice and professional negligence. The Internet abounds with advertisements for “warfarin lawyers” willing to assist clients who perceive they have been injured while on this therapy. In 2008, there were 18 cases regarding either complications, failure to monitor properly, or inappropriate indications related to the use of warfarin (McCormick). Bungard, Ghalie, Teo, McAlister, and Tsuyuki (2000) found the plaintiffs won the majority of the cases, with some of the settlements for more than 1 million dollars. Concern about litigation influences physicians’ prescribing patterns. Bungard et al. describes fear of litigation as a reason for physicians to under-prescribe warfarin in patients who could benefit from this therapy. Lo (2009) believes that healthcare providers are held more accountable for their actions than their omissions, causing them to be reluctant to prescribe the more risky therapies. The following case from the Journal of Family practice identifies part of the solution. Susman (2009) discussed the case of a 37-year-old man with a history of stroke due to a hypercoaguable state who was placed on warfarin. Therapy was discontinued several years later when his hypercoaguable state had resolved. He then had another large stroke, for which he received a 3.1 million dollar settlement. Susman’s comment was “by documenting a careful discussion of benefits and harms and consulting with experts, a date in court can sometimes be avoided” (p. 385). In this case, fulfilling ethical duty to provide fully informed

consent also provides the best legal prevention. Wysowski et al. suggested other ways for healthcare providers to prevent legal liability. He recommends establishing, maintaining, and documenting communication with family and other healthcare providers. He also advises monitoring patients to ensure they keep appointments in clinics and that the results of blood tests are in therapeutic range.

Personal Decision

This author supports the continued use of warfarin, but with qualifications. The reason for her support is that thrombosis is almost certain to reoccur without treatment. In contrast, the available literature suggests that the risk of death from internal bleeding is less of a threat. Mrs. Mead has indicated she wants to continue therapy. She has been able to keep appointments. Her INR results have been within range for 13 of 16 visits (see Appendix B). She has a home health nurse to set up and monitor her medication use. The qualifications would be that Ms. Meads receive neuropsychiatric testing to determine the stage of her Alzheimer's disease and start drug therapy if indicated. This author also recommends surgical consultation to determine if the patient is a candidate for placement of an inferior vena cava (IVC) filter. This author recommends that aspirin therapy be discontinued. A proxy decision maker (presumably her son) should be identified now due to the progressive nature of Alzheimer's disease, and advance directives should be completed. The patient needs to continue receiving home health nursing services. Her ability to safely continue warfarin should be reassessed every 6 months or whenever there is a change in her condition.

Summary

Warfarin therapy has the power to both extend life and to shorten it and requires careful monitoring to realize its benefits and curtail negative outcomes. This ability creates medical and

ethical dilemmas in situations where warfarin is strongly indicated, but the risks of adverse events are also great. The risks and benefits of warfarin therapy were examined through the ethical lenses of nonmaleficence, beneficence, autonomy, and in consideration of the principle of equitable care. A plan was developed to address safety concerns. With this in place, this author believes that the most medically and ethically sound decision at this time is to continue warfarin therapy.

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Appendix A

Patient Clinic Data

Anticoagulation Management Clinic**Progress Note**

9/04/2009

Pt expressing irritation and is agitated today: "Those Medicaid people told me you gave me the wrong medicine. And they kept asking me the same thing over and over again! They told me to have you fill this form out for me." Form is a two-page document that apparently originated from pharmacy. Discusses risks of addiction when using Lortab, and requires patient's signature. She is unable to tell me purpose of form or which medication was thought to have been prescribed incorrectly. Meds not with her. Pt is ambulating slowly with walker.

INR today - therapeutic @ 2.3 suggests she is taking the correct strength of warfarin, will not change dose. Pt knows location of geriatric clinic on the second floor. Arranged for her to see geriatric social worker now for assistance with form, Medicaid issues. RTC 1 month. Emailed PCP with concerns about patient's confusion, mental status seems worse, question if warfarin is still a safe option for her.

Elizabeth Gardner, RN, FNP

Appendix B

Patient Flow Sheet

Anticoagulation Management Clinic

Patient Flow Sheet

Patient: Kathryn Mead

Indication: Recurrent DVT

Goal INR: 2-3

Date	Current dose	Mg/ week	INR	New dose	Comments	RTC
9/3/08 ⁹	2.5 Wed, 5mg others	32.5	2.8	same		10/10/08
10/10/08	2.5 Wed, 5mg others	32.5	2.1	same		11/06/08
11/6/08	2.5 Wed, 5mg others	32.5	2.0	same		12/11/08
12/11/08	2.5 Wed, 5mg others	32.5	2.2	same		1/22/09
1/22/09	2.5 Wed, 5mg others	32.5	1.6	Extra 2.5 mg once same dose		2/05/09
2/05/09	2.5 Wed, 5mg others	32.5	2.7	same		2/26/09
2/26/09	2.5 Wed, 5mg others	32.5	2.3	same		4/3/09
4/3/09	2.5 Wed, 5mg others	32.5	2.2	same		5/01/09
5/01/09	2.5 Wed, 5mg others	32.5	2.5	same	Swelling R leg 2 weeks, rec. ER	5/22/09
5/22/09	2.5 Wed, 5mg others	32.5	2.8	same		6/19/09
6/19/09	2.5 Wed, 5mg others	32.5	2.7	same	"Just feel sick" leg swollen 2 weeks, started Etodolac	7/7/09
7/7/09	2.5 Wed, 5mg others	32.5	2.1	same	Had EMG(non- needle)	8/6/09
8/6/09	2.5 Wed, 5mg others	32.5	1.7	Extra 2.5 mg once, same dose	Dx'ed by neurology with Alzheimer's	8/28/09

Anticoagulation Management Clinic

Patient Flow Sheet

8/28/09	Patient cancelled	Appt rescheduled				9/4/09
9/4/09	2.5 Wed, 5mg others	32.5	2.3	same	agitated emailed PCP	10/09/09
10/09/09	2.5 Wed, 5mg others	32.5	1.5	Extra 5 mg, same dose		10/30/09

Appendix C

Case Consultation- Worksheet A

Case Consultation

Worksheet A

Step 1: Personal Responses

This patient seems to have declining cognitive function. She is on warfarin. Is she becoming too cognitively impaired to safely be on warfarin?

Step 2: Facts of the Case

Deep vein thrombosis has the potential to kill.

Warfarin is effective in preventing deep vein thrombosis.

Warfarin also has the potential to cause internal bleeding and with it, serious injury or death.

Warfarin therapy requires careful monitoring to prevent side effects.

This patient has risk factors that preclude her from taking this medication safely. She is cognitively impaired due to Alzheimer's disease. Her psychiatric medications may be contributing to the dysfunction. She is at risk to fall and hemorrhage.

Step 3a: Clinical/Psychosocial Issues Influencing Decision

Desires of patient and family member.

Level of confusion and dementia.

Ability to give informed consent.

Gait instability/fall risk.

Stability of INRs.

Presence of support systems.

Desire of primary care provider.

Availability of alternative regimen.

Step 3b: Initial Plan Step 2: Facts of the Case

Assess capacity to give informed consent.

Discuss risks versus benefits of treatment with patient, son, and PCP.

Determine patient and son's desires and concerns.

Assess and confirm support systems.

Determine frequency and intensity of falls.

Step 4: Policies & Ethical Code Directive

Nonmaleficence – do no harm- avoid interventions that may bring harm to patient.

Beneficence – provide benefits and promote welfare of patient.

Maintain autonomy.

Follow anticoagulation clinic policy and procedures: Consult with supervising MD in complicated cases.

Step 5: Ethical Principles Analysis

The absolute risk versus benefit status is not known.

Ethical justifications to continue warfarin:

Nonmaleficence: Stopping warfarin will most likely precipitate a recurrence of thromboembolism with its attendant risks of pulmonary embolism and death.

Beneficence: Continuing warfarin therapy will prevent recurrent thromboembolism and post phlebitis syndrome.

Autonomy: Patient may want to continue warfarin. To discontinue warfarin would be a violation of patient's autonomy. Her decision-making capacity, a function of her autonomy, may be impaired because of cognitive dysfunction.

Ethical justifications to stop therapy:

Nonmaleficence: Will prevent adverse bleeding events.

Beneficence: Patient no longer has to fear falling, have blood tests, close monitoring, or follow dietary restraints.

Justice: Patient is at risk for disparity of care due to socioeconomic status regardless of decision.

Step 6: Possible Legal Issues

The patient and family need to be clearly informed of the risks versus benefits of this therapy. If not, the clinic could be considered liable for adverse outcome.

Appendix D

Case Consultation: Worksheet B

Case Consultation: Worksheet B

Plan & Implementation Strategy

Refer for formal neuropsychiatric testing to assess level of dementia.

Discuss with PCP: Is patient a candidate for Alzheimer's drug?

Assess and verify support systems (i.e., RN for medication assistance).

Monitor level of compliance: Is patient able to keep appointments, and are her INRs stable?

Stop aspirin due to increased bleed risk.

Consider alternate therapies:

Low dose/low intensity warfarin - does not prevent DVT.

Low molecule weight heparin (enoxparin): Very expensive, patient needs to be able to inject herself twice daily , which she is unable to do.

Placement of Inferior Vena Cava filter (surgery consult).

Formally reassess plan every 6 months or if change in condition.

Write down how your plan:

Advances Clinical/Psychosocial Interests:

This plan

- (a) informs family and other healthcare providers of the clinical issues, identifies the need for increased patient assistance, and evaluates which option will be safest for patient.
- (b) identifies other treatment options.
- (c) addresses major patient safety issues:

The core purpose of this assessment is to reduce adverse patient outcomes. This is done by analyzing the risk versus benefits of therapy and formulating interventions to minimize harm and maximize benefit.

- (d) adheres to agency policies and professional ethics codes:

No specific agency policy exists for cases like this. The general agency policy of consulting with the patient's primary care provider and the Anticoagulation Management Clinic supervising physician in the event of complicated cases has been fulfilled.

Completion of a risk versus benefit analysis fulfills the ANA code of ethics that requires nurses to protect the health, safety, and rights of the patient.

- (e) minimizes harm and maximizes other ethical principles to the extent possible for the client and relevant others:

It minimizes harm by creating a safety net of ongoing support and assessment while allowing the patient to realize the benefits of therapy.

- (f) allows you to operate within the law:

Risks and benefits are thoroughly discussed with primary stakeholders, and results are well documented, reducing the possibility of successful litigation in the event of an adverse outcome.