



Balancing the Harm and Benefit of Disclosure: A Laboratory Physician's Perspective

Chantale Pambrun*

IWK, Children's & Women's Health Centre, Dalhousie University, Canada

*Corresponding author: Chantale Pambrun, MD, FRCPC, Head, Division of Hematopathology, Assistant Professor of Pathology and Laboratory Medicine, IWK, Children's & Women's Health Centre, Dalhousie University, 5850 University Avenue, P.O. Box 9700, HalifaxNova Scotia B3K 6R8, Canada, Tel: (902) 470-2797, Fax: (902) 470-6974, E-mail: chantale.pambrun@iwk.nshealth.ca

Commentary

The four principles of medical ethics that so often appear in the literature encourage physicians to uphold them whenever possible. We are to respect the autonomy of our patients, try to bring them clinical benefit, refrain from harming them, and to be just and fair [1]. The following real life scenario illustrates how using the principles to consider a complex issue can shed light on how best to proceed.

A Caucasian female laboratory technologist of child bearing age, volunteered to provide a blood sample for the Canadian clinical laboratory that she works. Her sample, and the ones from other volunteers, is used as a normal control in order to validate tests, reagents and instrumentations. The volunteers sign a document acknowledging their participation in order to receive financial reimbursement for his/her blood donation. At the time of this event, there was no policy or signed documentation stating how the blood would be used or what would be done with the results. In this particular case, the laboratory technologist's blood was used to valid a new reagent for a clot-based Factor V Leiden mutation screening test; the activated protein C resistant assay. Her sample was found to be positive. What should she be told about the positive test? Should she be told at all?

To answer these questions, let's consider the implications of applying the principles to this situation.

The principles of beneficence and non-maleficence demand that we act in a way that maximizes benefit and minimizes harm for our patients. The literature supports the fact that female patients with a Factor V Leiden mutation should not be oral contraceptives, and if they have a previous history of a clot, they should be on anticoagulation while pregnant. Whether patients with the mutation would benefit from more intense or prolonged anticoagulation is unknown. Factor V Leiden mutation is a genetic mutation inherited in an autosomal dominant fashion, and therefore the results may impact the technologist's children and family members. The benefit of having this knowledge can possibly prevent the occurrence of deep vein thrombosis or potentially deadly pulmonary embolism.

Disclosure of this information appears to be the obvious decision; however there is also harm which can come with the disclosure. Life insurance premiums could increase or be denied if insurance has not

already been established. Because the testing was done as part of a Canadian clinical laboratory validation process, the results of the test will not appear in her health record; however once the positive test result is disclosed to the individual is required to disclose that information on an insurance application. At present, she can apply for life insurance without this test result ever being discovered by a third party.

The actual benefit to the patient is not definitively known, as confirmatory testing as well as personal and family history would need to be obtained. If she is in fact heterozygous for the mutation without a history of previous clot, the benefit is negligible, as her risk of a clot in the future would be similar to the general population. Being heterozygous for Factor V Leiden increased a person's chance of having a clot by three- to six folds. When the incidence of having a idiopathic thromboembolism in a Caucasian population is 230 in 1,000,000 a three- to six fold increase in that risk is negligible; 0.02% versus 0.14% [2].

The literature supports the fact that the best predictor of having a thromboembolic event is a personal and family history of having had a clot; as such history increases the risk of having another clot by seventy fold. If in fact, she has a previous personal history of a clot then her risk of a recurrence is 21.5% [3]. It could be argued that regardless of her genetic thrombophilic state, the fact that she has had a previous clot should be indication enough for her treating physician to avoid oral contraceptives and possibly anticoagulate her during pregnant [4]. The benefit of knowing the test result in this case, is again negligible. Her past medical history and whether she already has life insurance is unknown in this case and therefore this brings about much uncertainty.

The principle of respect for autonomy compels us to give our patient the opportunity to make an informed decision without coercion, however this often conflicts with the other principle of beneficence; our duty to first do no harm. In this case, in order for the technologist to even have a chance to exercise her autonomy, she would have to know about the situation. While disclosure respects autonomy, the potential harm of giving this knowledge is real. The prime motivation for non-disclosure is the negligible risk to a patient who has a heterozygous Factor V Leiden mutation.

Then there is the question of the golden rule. What would I want

if I was the “victim”? The negligible increase in a thromboembolic risk is not worth the insurance implication and the possible anxiety it would cause myself and my family. How would I feel about colleagues knowing this information about me, while I am in the dark? If another person had this information about my health that I was not aware of, that would be unjust.

In public health, the concept of autonomous decision making is related to informed consent. Virtually all medical and research codes of ethics now hold that physicians and researchers must obtain the informed consent of patients and research subjects before undertaking procedures. These consent measures have been designed to enable autonomous choice by patients and subjects, but they serve other purposes as well, including the protection of patients and subjects against harm and the encouragement of medical professionals to act responsibly in their interaction with patients and subjects [5]. There is however no such code of ethics related to laboratory physician for the validation process requiring normal controls. And in light of this case, I believe laboratory policies should be in place to protect individuals’ autonomy.

A possible solution is that blood sample volunteers should be signing a consent form. They can choose to waive their rights to the test results or agree to face the consequences, such as possible insurance implication and further testing requirement. If such consent form had been obtained in this case, the decision to disclosure would have been made autonomously by the individual and would not have been left in the hand of her colleagues who are faced with balancing the harm and benefit of disclosure.

Our laboratory colleagues’ autonomy needs to be respected and the use of his/her blood samples as controls for method validation needs to have clear policies in place to protect all those involved. Both the Canadian Access to Information Act and Privacy Act and the United States HIPPA privacy rules can be applied in the laboratory setting and used for development of such policies. As laboratory physicians we are faced with different ethical dilemmas than our clinical colleagues; however the four principles that we swore to uphold in our Hippocratic Oath are still applicable and we should strive to uphold these principles in all aspects of our work.

References

1. Gillon R (1994) Medical ethics: four principles plus attention to scope. *BMJ* 309: 184-188.
2. White RH, Zhou H, Romano PS (1998) Incidence of idiopathic deep venous thrombosis and secondary thromboembolism among ethnic groups in California. *Ann Intern Med* 128: 737-740.
3. Hansson PO, Sörbo J, Eriksson H (2000) Recurrent venous thromboembolism after deep vein thrombosis: incidence and risk factors. *Arch Intern Med* 160: 769-774.
4. Price DT, Ridker PM (1997) Factor V Leiden mutation and the risks for thromboembolic disease: a clinical perspective. *Ann Intern Med* 127: 895-903.
5. Beauchamp TL and Childress JF (1989) *Principles of Biomedical Ethics*. (3rd edition) New York: Oxford University Press.