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But For the Fear of What You Might Find Out

Description

This case highlights potential dilemmas encountered by postdoctoral fellows in a research setting. Are participants in a breast cancer imaging modality entitled to their test results when none of the modalities have been validated as medical screening tools? This case also explores the potential problems researchers face with clinical trials.

Body

Part 1

Part 2

Part 1

A university-based research team is developing four new breast cancer imaging modalities based on tissue property reconstruction. The methods image tissue properties such as light attenuation, mechanical stiffness, microwave energy absorption and electrical impedance. Currently, the researchers are conducting very early examinations of volunteers, working to sort out issues of data collection, patient comfort, initial experience with biological tissue, etc. These tests are not intended to generate scientific data for detailed study but merely to establish a basic level of preparation for each method in anticipation of the large-scale clinical trials they will face in the future. It is important to note that at this point, none of the

modalities is a validated medical screening tool since the clinical studies required for validation have not been performed.

Given that these experiments are not actual clinical exams, the interaction with these early volunteers is fairly informal. The women are asked if they would like to participate merely in an effort to help out with the development of the project. Women who volunteer to be imaged are told about the various techniques in basic terms, and the scientists working to develop the methods, primarily engineers, describe the resulting images to them.

Recently, two of the four modalities localized some type of heterogeneity in a volunteer's left breast, both showing almost identical size and location for the anomaly. The other two experimental imaging modalities indicated nothing unusual in either breast, and the woman's standard mammogram had come back perfectly clean. However, the researchers knew that a large malignant tumor, originally misdiagnosed as a false negative from a mammography exam, had previously been removed from the woman's right breast and that it had been discovered through palpation. Uncertain how to proceed but concerned that they had detected a potentially serious health problem, the experimenters, both radiologists and engineers, tried to decide on their next step.

Discussion Questions

1. Should the woman be notified of the results of the imaging exam?

2. Should anyone else be brought in for consultation?

3. Should some sort of protocol have been in place before the experiments were begun that would clarify what actions should be taken in situations such as this? What should such a protocol dictate?

4. Should women with high potential for undiscovered malignancies be allowed to volunteer for screening procedures that have not been validated?

5. What role should the woman's history with mammography exams play in the decision of what to do next?

6. How important is it that the woman was previously diagnosed with breast cancer?

Part 2

After extensive discussion, the researchers decided that the results were too inconclusive to risk informing the woman at this point, but that given the potential gravity of the situation, further tests should be conducted. The researchers consulted the woman's primary care physician, and a month after the first images were taken the woman was brought back for a second examination by the four modalities. When the results from these second tests came back nearly identical to the first, the research team informed the woman of the situation and initiated a dialogue between the woman and her primary care physician. Together, they decided to follow the standard protocol for a positive mammography result, including an ultrasound examination and a high resolution MRI. When both of these tests came back perfectly clean, the woman considered the case closed and no further tests were performed.

Discussion Questions

7. Is the case really closed?

8. Who gets to decide whether the case is closed or not?

9. Was it appropriate for the researchers to consult the primary care physician without the woman's consent?

10. Who should be financially responsible for the cost of the high resolution MRI (over $2000 in some cases)?

11. Was it appropriate for the research team and the primary care physician to wait a month before repeating the imaging process, or should they have taken action sooner?

Notes

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