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FOR ENGINEERING AND SCIENCE

Blowing the Whistle on a Therapeutic Experiment

Year

1997

Description

This case discuss an actual incident of whistleblowing at a private psychiatric facility involving informed consent and human research subjects.

Body

Part 1

Part 2

Part 3

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Part 5

Part 6

Outcome

This case is based on a real incident of whistleblowing that occurred in the late 1970s and early '80s. For more details on the specific case, readers should refer to the reference list located at the end of the participant commentary. At various

phases of the case, readers are prompted to reflect upon what action they would take or recommend and provide a rationale for their response based on the ethical issues at stake at the time.

Part 1

Jan, an experienced nurse with a master's degree in psychiatric nursing, accepted a head nurse position in a private psychiatric facility. She was responsible for a unit where several experimental programs were in progress. One program was designed to test the potential benefits of orthomolecular therapy in psychiatric patients. The basic premise of the therapy was that psychiatric illness was due to cerebral allergies.

Within months, Jan began to suspect that the orthomolecular program abused patients. First, she found no informed consent documents for this experimental therapy in the patients' records. Psychiatric patients were admitted to the unit, taken off all medication, including psychotropic medications, and given bottled water for four to seven days, along with megadoses of vitamins, which they frequently vomited. After this fasting period, foods were introduced one by one to determine whether the patient was allergic to the particular food. Patients were confined to the unit to ensure adherence to the protocol.

Jan recalls that patients were emaciated, and they walked around like zombies, searching for food in garbage cans. More disturbed patients ate anything they could get their hands on, such as tissue and tampons. Several patients who were physically restrained chewed through their mattresses to eat the stuffing.

1. What action should Jan take?

A. Discuss her concerns with her immediate supervisor, the director of nursing (DON).

B. Discuss her concerns with the orthomolecular physician.

C. Contact the Institutional Review Board (IRB) to determine whether the IRB has reviewed the experimental programs.

D. Document her observations and forward them to the DON.

E. Do nothing.

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Part 2

Jan voiced her concerns to the director of nursing (DON) and also to the medical team during weekly grand rounds. The orthomolecular physician claimed that he had a 90-100 percent cure rate. To bolster his claims, he published an article on the success rates of his therapy. Admissions to the unit were growing rapidly, mostly from families desperate for a cure. Jan knew that something was very wrong, but found it difficult to challenge a "noted authority."

Over the course of the next six months, Jan witnessed numerous incidents of physical and psychological abuse of patients. For instance, one patient in an agitated state grabbed the orthomolecular physician's jacket. The physician struck the patient and pushed her into a hospital room. When she tried to come out of the room he slammed the door on her hand and quickly left the unit. When Jan reported the incident to the DON, she was told not to write up the incident because it was "too serious." In another case, Jan observed a physician eating in front of a fasting patient. Begging for food, the patient became enraged. The physician ordered Jan to put the patient in restraints and start intravenous vitamins. Jan refused and reported the incident to the DON and the medical director. The medical director voided the order and said that the physician was out of line. Jan had been documenting such occurrences on incident reports and in written memos at weekly grand rounds, yet nothing seemed to change.

2. What action should Jan take?

A. Resign and report the situation to state or federal authorities.

B. Meet with the hospital administrator and discuss her concerns.

C. Contact the state nurses' association for advice.

D. Continue to document misconduct

E. Contact external agencies for assistance (e.g., Health and Human Services (HHS), Joint Commission for the Accreditation of Hospitals (JCAH), etc.).

F. Go to the media with her documentation.

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Part 3

Jan scheduled a meeting with the hospital administrator. He told her that because this particular physician brought a lot of money into the hospital, essentially, his hands were tied. She learned that the experimental programs had not been reviewed by the hospital's Institutional Review Board (IRB). The hospital owner and administrator told the IRB that it was not necessary to review the experimental protocol, and the IRB was unwilling to override this decision. The hospital had no medical misconduct committee, but it did have an Internal Review Committee. Jan sent them all her documentation and requested that they address her concerns. Moreover, Jan contacted the hospital attorney and gave him her documentation. Subsequently, the attorney drafted a list of concerns and recommendations, which was sent to the medical committee. Some changes occurred. A protocol for the therapy was written, and a consent form for treatment was developed. Despite these formal changes, unethical and illegal conduct continued. Families were pressured to sign consent forms to admit their ill family members into the orthomolecular program. The physician was very charismatic in his approach to families, promising them a cure, and most families complied with his recommendations.

When the public health department (PHD), HHS and JCAH came for their annual inspections, orthomolecular patients and their medical records were moved off the unit. Jan was instructed by the hospital administrator not to discuss the program with the agencies. Jan felt she had no choice but to follow the gag order. The inspectors interviewed Jan in the presence of the DON, medical director and hospital owner. Jan was not permitted to have any private conversations with inspectors.

3. What action should Jan take?

A. Resign and report the situation to state or federal authorities.

B. Remain in her position; notify each inspecting agency of her concerns, and provide them with her documentation.

C. Go to the media/press with her documentation.

D. Wait to see whether the inspecting agencies cite the hospital for any violations.

E. Continue to document unethical, illegal or incompetent behavior.

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Part 4

Jan gave serious thought to quitting her job; however, the hospital administrator told her that he planned to open another facility and he wanted Jan to be the administrator. She would be given full authority to set the standards for the new facility. In the meantime, the PHD, HHS and JCAH reports came back citing no violations of mental health standards of care in the hospital. Serious violations of patients' rights continued to escalate on Jan's unit, and one prompted Jan to think seriously about blowing the whistle. A 36-year-old man who had been in the orthomolecular program for a week told the physician he wanted to discontinue this form of therapy. The physician threatened to have him committed if he refused to continue orthomolecular therapy. The physician called in the family and asked them to "create reasons" why the patient was not competent to make an informed decision about his medical treatment. Jan had developed a therapeutic relationship with the patient and knew he was competent. However, she was unsuccessful in advocating the patient's request with the physician. She put the patient in a conference room with a phone, although the physician had cut off his phone privileges. The patient contacted the state Guardianship and Advocacy (G'&'AC) Commission. An attorney from the commission came to the hospital the following day and talked to the patient and Jan. Privately, the lawyer advised Jan to contact the Human Rights Authority (HRA) about the unethical and illegal violations

occurring on her unit. Jan was a divorced, single parent caring for four children. She feared reprisal.

4. What action should Jan take?

A. Remain in her position and inform external authorities about the abuses.

B. Secure another job, resign and then report the misconduct to state and federal authorities.

C. Contact the state/national nurses' associations for advice.

D. Remain in her position until she is promoted.

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Part 5

Jan obtained a copy of the state agency's enabling statute and asked the G&A attorney if her story would be kept confidential. Jan was assured of complete anonymity and confidentiality. She contacted the HRA. The following day, agency representatives came to her house and for four hours taped her report of misconduct in the hospital.

Shortly thereafter, the DON called Jan into her office. The hospital administrator was present, and he informed Jan that she was "too intelligent for them." The HRA had disclosed to the hospital that she had reported unethical and illegal practices on her unit. The administrator offered Jan an entry-level position on another unit. Jan refused. He asked her if she would quit, and she said no. Jan decided to take a sick leave to buy some time. She got a doctor to legitimize a sick leave. Then Jan contacted her state nurses association. They attempted mediation with the hospital but were unsuccessful. They advised Jan to obtain written documentation of her employment status; if the administration refused to provide documentation, they told her to report to work. Jan went to the hospital and met with the DON and hospital administrator. When she asked what her employment status was, the administrator told Jan that she was trespassing on private property and should leave immediately.

Still lacking verification of her employment status, she told the DON and administrator that she would be reporting to work in the morning. She was told the police would be waiting for her the next day, and she would be arrested for trespassing.

5. What action should Jan take?

A. Report to work the following morning.

B. Resign and report the situation to state and federal authorities.

C. Go to the media/press and disclose her story and documentation.

D. Hire an attorney.

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Part 6

Jan was not permitted to return to work. She contacted the PHD for assistance and gave them all her documentation (i.e., all her memos and incident reports). No action was taken. Without a job or source of income, Jan sought other employment. She applied to numerous agencies without success. She discovered that the hospital was answering job-reference inquiries by describing her as a "psychotic" who was "professionally incompetent." Moreover, sympathetic agencies told her that they admired what she had done, but they did not want her working in their institutions. When Jan tried to apply for unemployment compensation, it was denied. The hospital said she had not been fired, but failed to report to work. Six months after blowing the whistle, Jan was awarded unemployment compensation.

Numerous employees from the hospital called Jan and came by her home to tell their stories of similar patient abuses. Jan and other employees of the hospital met with the HHS. Subsequently, the HHS conducted a surprise investigation of the psychiatric facility. Shortly thereafter, the orthomolecular program was shut down, and the hospital's licensure was temporarily suspended.

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Outcome

It was too late for the 36-year-old patient Jan had assisted to make an outside call. The lawyer from the G and A Commission did represent the patient in court arguing that the patient's right to informed consent had been violated. Nevertheless, the judge sent the patient back to the hospital and set another hearing date. The orthomolecular physician placed the patient on 15-minute checks around the clock; that is, he was awakened throughout the night every 15 minutes. By the time the court date arrived, the patient was truly psychotic. The judge ruled that the patient should remain at the facility and continue therapy

Jan decided to sue the hospital for reinstatement. Without the finances to hire an attorney, Jan represented herself. The judge ordered reinstatement, compensatory damages and punitive damages. The hospital appealed. Jan was told an appeal would be too complicated for her to handle. She borrowed money and hired an attorney. Two years later, the appeals court upheld the decision and in fact increased the amount of damages. The hospital took the case to the supreme court, which refused to hear the case, stating it had been "fully litigated." When the case was sent to the trial judge, the judge precluded Jan from getting an execution of the judgment. She was not notified of the court hearing date. When she did not show up for court, the case was thrown out. Jan contacted the Federal Bureau of Investigation and described the handling of her case in the court system. They assured her they would take care of the matter, since it appeared there was clearly judicial misconduct. Nothing was done. To this day, Jan has not received a penny of compensatory or punitive damages.

General Discussion Questions:

1. If you were presented with this situation today, what would you do?
2. What formal and informal institutional mechanisms are necessary to protect a health professional who is considering blowing the whistle on unethical or illegal behavior?
3. What changes are needed in state and federal legislation and/or enforcement practices to protect whistleblowers from retribution?
4. What curriculum changes are needed to prepare health care researchers and practitioners to effectively address unethical practices?

5. Historically, professional associations have set the standards for entry into professional practice and standards of practice. However, in this case the professional association had little impact on ensuring quality of care and enforcing practice standards. What measures, if any, could be taken to give professional associations the clout to enforce ethical and legal standards of care?

Notes

Brian Schrag, ed., Research Ethics: Cases and Commentaries, Volume 1, Bloomington, Indiana: Association for Practical and Professional Ethics, 1997.

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Topics

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