Understanding the Passive Authorization Process from the Provider Perspective for the Ohio Cancer Incidence and Surveillance System

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Background

- Cancer survivors make up an estimated 5% of the population in the U.S.[1]
  - This number is rising with aging population.[2]
- As of 1992, all states are required to maintain a state-wide cancer registry - collects all incident cancer diagnoses within 6 months of the date of diagnosis or date it is first reported.[3-5]
- Infrastructure for state cancer registries is provided by the Centers of Disease Control and Prevention (CDC) through the National Program of Cancer Registries (NPCR).
- Policies regarding the education of providers and patients about the registry, and levels of approval needed by researchers to access data and contact patients for research, varies greatly by state.[3,9]
- The Ohio Cancer Incidence Surveillance System (OCISS) is Ohio's cancer registry run by the Ohio Department of Health.
- To contact patients listed in OCISS, researchers need passive approval of the patient's physician.
- Passive approval means that when the research team requests permission, they can contact any of the patients whose physician responds "yes" or do not respond at all.
- While this makes research on patients in the registry feasible, it does not consider the perceptions and beliefs of the patient.
- Passive consent in Ohio is not well understood in terms of how physicians are notified, what their knowledge level is about OCISS, and if their patients receive education about the cancer registry.

Purpose

- The purpose of this research is to begin to quantify the frequency of passive consent within Ohio and understand physician's knowledge on the passive consent process.
- Overall, this project is part of a larger study which aims to understand the cancer patient and survivor perspective on the social and ethical implications of inclusion in OCISS.

Population

- The survey was designed to be sent to a representative sample of providers listed in OCISS
  - In OCISS, providers receive research requests for patient contact.

Link for video walk-through:
https://youtu.be/QE76PYIAakM

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Learning Objectives

- To understand the data utilization process in OCISS and how passive consent for patient contact works in Ohio.
- To design a survey that will evaluate provider knowledge of OCISS and the research approval process.
- To identify the proportion of respondents who self-report passive approval.
- To understand the barriers from the provider perspective of granting researcher approval to contact their patients.

Activities

- Researching relevant topics of cancer registry ethics and Ohio's cancer research regulation (**Figure 1**).
- Designing the survey, email body, and consent form to be sent to providers (**Figure 2**).
- Completing the research proposals to Case Western Reserve University IRB, Case Comprehensive Cancer Center, and Ohio Department of Health IRB.

Deliverables

- The survey for providers designed to understand their knowledge of OCISS (**Figure 2**) on domains such as provider and patient knowledge of OCISS, data access, patient contact, and likelihood of approval.
- Obtaining IRB approval from CWRU and Protocol Review and Monitoring Committee approval from CWRU's Comprehensive Cancer Center.

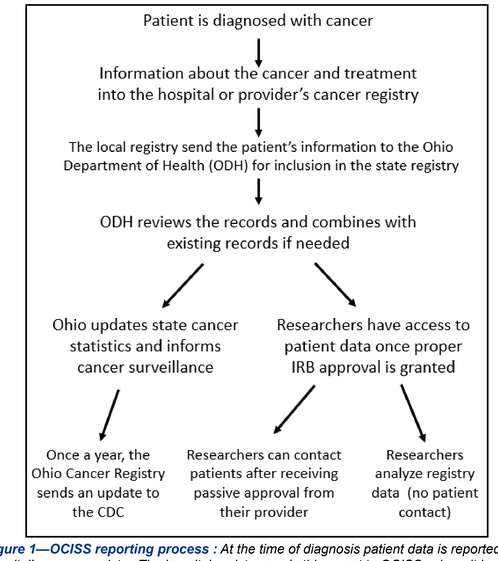
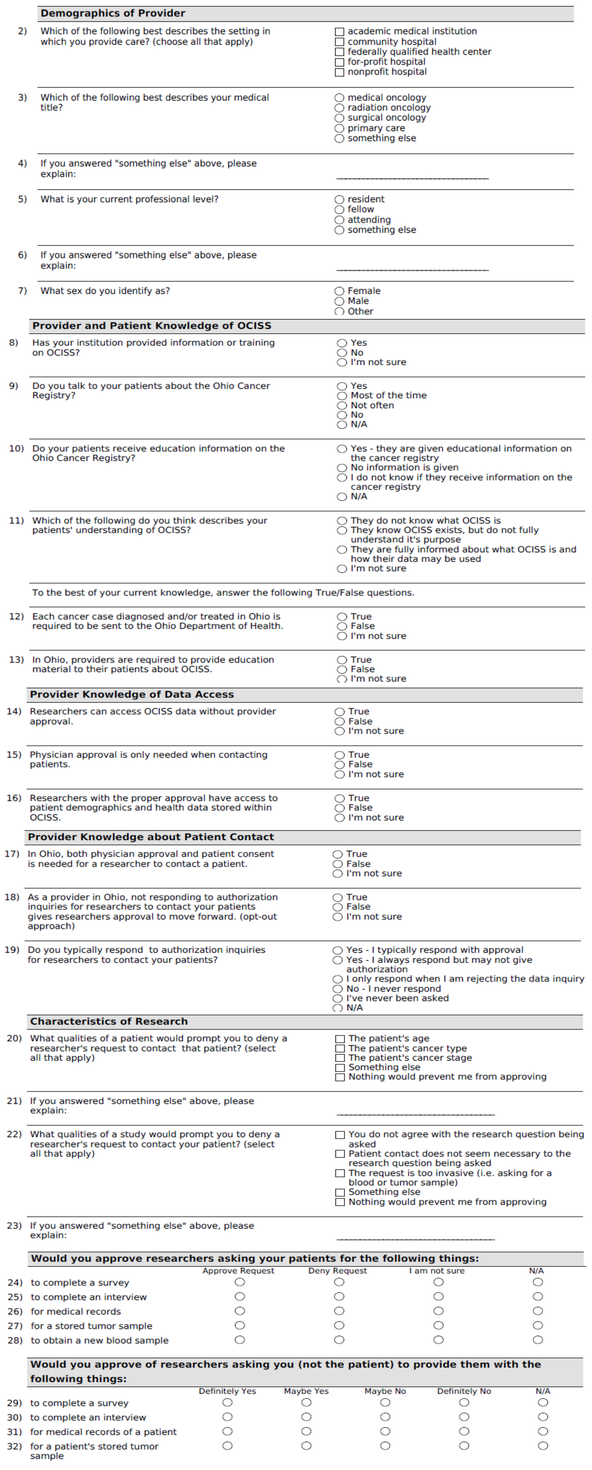


Figure 1—OCISS reporting process : *At the time of diagnosis patient data is reported to the hospital's cancer registry. The hospital registry sends this report to OCISS, where it is reviewed and combined with other existing records if needed. Ohio sends that information on to the CDC after updating their own records. Researchers can access patient information with proper IRB approval and can contact patients after perceiving passive contact from the patient's listed provider.*



Demographics of Provider

2) Which of the following best describes the setting in which you provide care? (choose all that apply)
☐ academic medical institution ☐ community hospital ☐ federally qualified health center ☐ for-profit hospital ☐ nonprofit hospital

3) Which of the following best describes your medical title?
◯ medical oncology ◯ radiation oncology ◯ surgical oncology ◯ primary care ◯ something else

4) If you answered "something else" above, please explain: _____

5) What is your current professional level?
◯ resident ◯ fellow ◯ attending ◯ something else

6) If you answered "something else" above, please explain: _____

7) What sex do you identify as?
◯ Female ◯ Male ◯ Other

Provider and Patient Knowledge of OCISS

8) Has your institution provided information or training on OCISS?
◯ Yes ◯ No ◯ I'm not sure

9) Do you talk to your patients about the Ohio Cancer Registry?
◯ Yes ◯ Most of the time ◯ Not often ◯ No ◯ N/A

10) Do your patients receive education information on the Ohio Cancer Registry?
◯ Yes - they are given educational information on the cancer registry ◯ No information is given ◯ I do not know if they receive information on the cancer registry ◯ N/A

11) Which of the following do you think describes your patients' understanding of OCISS?
◯ They do not know what OCISS is ◯ They know OCISS exists, but do not fully understand it's purpose ◯ They are fully informed about what OCISS is and how their data may be used ◯ I'm not sure

To the best of your current knowledge, answer the following True/False questions.

12) Each cancer case diagnosed and/or treated in Ohio is required to be sent to the Ohio Department of Health.
◯ True ◯ False ◯ I'm not sure

13) In Ohio, providers are required to provide education material to their patients about OCISS.
◯ True ◯ False ◯ I'm not sure

Provider Knowledge of Data Access

14) Researchers can access OCISS data without provider approval.
◯ True ◯ False ◯ I'm not sure

15) Physician approval is only needed when contacting patients.
◯ True ◯ False ◯ I'm not sure

16) Researchers with the proper approval have access to patient demographics and health data stored within OCISS.
◯ True ◯ False ◯ I'm not sure

Provider Knowledge about Patient Contact

17) In Ohio, both physician approval and patient consent is needed for a researcher to contact a patient.
◯ True ◯ False ◯ I'm not sure

18) As a provider in Ohio, not responding to authorization inquiries for researchers to contact your patients gives researchers approval to move forward. (opt-out approach)
◯ True ◯ False ◯ I'm not sure

19) Do you typically respond to authorization inquiries for researchers to contact your patients?
◯ Yes - I typically respond with approval ◯ Yes - I always respond but may not give authorization ◯ I only respond when I am rejecting the data inquiry ◯ No - I never respond ◯ I've never been asked ◯ N/A

Characteristics of Research

20) What qualities of a patient would prompt you to deny a researcher's request to contact that patient? (select all that apply)
☐ The patient's age ☐ The patient's cancer type ☐ The patient's cancer stage ☐ Something else ☐ Nothing would prevent me from approving

21) If you answered "something else" above, please explain: _____

22) What qualities of a study would prompt you to deny a researcher's request to contact your patient? (select all that apply)
☐ You do not agree with the research question being asked ☐ Patient contact does not seem necessary to the research question being asked ☐ The request is too invasive (i.e. asking for a blood or tumor sample) ☐ Something else ☐ Nothing would prevent me from approving

23) If you answered "something else" above, please explain: _____

Would you approve researchers asking your patients for the following things:

	Approve Request	Deny Request	I am not sure	N/A
24) to complete a survey	◯	◯	◯	◯
25) to complete an interview	◯	◯	◯	◯
26) for medical records	◯	◯	◯	◯
27) for a stored tumor sample	◯	◯	◯	◯
28) to obtain a new blood sample	◯	◯	◯	◯

Would you approve of researchers asking you (not the patient) to provide them with the following things:

	Definitely Yes	Maybe Yes	Maybe No	Definitely No	N/A
29) to complete a survey	◯	◯	◯	◯	◯
30) to complete an interview	◯	◯	◯	◯	◯
31) for medical records of a patient	◯	◯	◯	◯	◯
32) for a patient's stored tumor sample	◯	◯	◯	◯	◯

Figure 2—Provider Survey : *The provider survey looked to the major categories of demographic/provider characteristics (questions 2-7, not shown), provider and patient knowledge of OCISS (questions 8-13), provider knowledge of the data access and patient consent process (question 14-19), and barriers to approval (20-32). Question 1 was the electronic informed consent document.*

Lessons Learned

- In designing the survey, I learned the importance of question wording to reduce participant confusion and potentially decrease missing data and bias.
- Through my research and in conversations with OCISS staff, I learned more about OCISS and the passive consent process for research.
- I learned that the process of passive consent is nuanced- OCISS does not have contact information for the providers for researchers to contact. Instead, OCISS provides researchers with medical license numbers, and it is up to them to find contact information from there.
- This impacted our research since we were not able to get contact information from providers directly from them, we could have done this project without ODH IRB approval. The OCISS staff members suggested obtaining the medical license numbers for physicians in oncology, radiation oncology, and surgical oncology from the State Medical Board.

Public Health Implications

- This survey is part of a pilot study needed to contact and recruit OCISS registrants on their understanding and perspective of OCISS.
- My capstone project is also part of the pilot research, looking at cancer registry data accessibility and patient education standards within state cancer registries across the US, specifically highlighting where Ohio falls by state.
- Understanding the ethical concerns within cancer registry patient contact is important as technology continues to advance and genetic markers may soon be added to registry databases.
- It is important that patient education is not overlooked as access to important research tools become more widely available.

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