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It's not research; it's quality improvement

by Mark J. Fox

Organizations often struggle to navigate the fine line between research activities and quality improvement activities. This can be complicated by a lack of coordination between the quality improvement and research departments in both large and small organizations. In this article, we will explore the differences between these two disciplines and how to appropriately determine if an activity is quality improvement or research.

Quality improvement defined

The Centers for Medicare & Medicaid Services define quality improvement as "the framework used to systematically improve [the ways] care [is delivered to patients]."[1] The Common Rule does not define quality improvement activities. The lack of a definition in the Common Rule requires individuals to rely on the definitions of research and human subjects. Because the lines between quality improvement and research often blur, it is imperative that there is interinstitutional collaboration and coordination between the quality improvement department, the human subject protection office, and the institutional review board (IRB).

Definition of research

The Common Rule defines research as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge."[2] The concept of generalizable knowledge is important as it is often the determining factor in defining an activity as research. There is often an argument that if you publish the activity, the activity is no longer considered a quality improvement because dissemination of results potentially promotes generalizable knowledge—especially when new findings are not previously published. IRBs can assist stakeholders by evaluating an activity.

Definition of human subjects

The Common Rule defines human subjects as "a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens."[3] It should be noted that the application of the Common Rule is only required when the research is federally funded. However, most institutions apply the definition to all conducted research. Keep in mind that when the Common Rule is applicable, the definitions of both research and human subjects must be met. An example where the definition of human subjects would not be met is in a study where no information or biospecimens are captured through intervention or interaction, and no identifiable data or biospecimens are collected. As previously

mentioned, IRBs generally have processes for determining nonhuman subject research. This documentation clears the ambiguity and is useful when one questions if an activity is human subject research or if the activity does not meet such definitions.

The intersection of HIPAA

Quality improvement is also not defined under HIPAA but falls under the definition of health care operations. HIPAA does not define human subjects. The definition of research under HIPAA is the same as the definition under the Common Rule. When individuals work in HIPAA-regulated entities, they must evaluate permissible uses and determine if an authorization or waiver of authorization is needed. Use of protected health information for healthcare operations does not require authorization. However, research may require an authorization or a waiver unless the research is conducted on a limited data set. In instances where the research is conducted on a limited data set, authorization from individuals is not necessary; however, the recipient of a limited data set must sign a data use agreement containing the required elements under HIPAA.

Application of research definition to quality improvement activities

When evaluating if the activity meets the definition of research, the following questions must be asked:

1. Is the activity federally funded, or does institutional policy require the application of the Common Rule?
2. Does the activity meet the definition of research?
3. Are human subjects involved?
4. Does an exemption apply?

If the answer to the first three questions is yes, the activity is human subject research. The Common Rule has a set of exemptions that one may evaluate. If the activity meets the exemption criteria, IRB review and oversight may be limited or completely eliminated after the exemption determination.

Although a quality improvement exemption or even an exception to the Common Rule was discussed in the notice of proposed rulemaking for the Common Rule prior to revision in 2018, the exemption was not included in the final rule. You must rely on existing exemptions when evaluating potentially exempt human subject research. The revised Common Rule expanded some of the existing exemptions and added additional parameters for exemptions.

Common Rule exemption 4

One exemption to look to especially if your institution is a HIPAA-regulated entity is exemption 4:

> Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met: (i) The identifiable private information or identifiable biospecimens are publicly available; (ii) Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects; (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated

> under 45 CFR parts 160 and 164 , subparts A and E, for the purposes of 'health care operations' or 'research' as those terms are defined at 45 CFR 164.501 or for 'public health activities and purposes' as described under 45 CFR 164.512(b); or (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.[4]

Often, despite an activity meeting the definition of human subject research, an investigator may rely on the previously mentioned criteria. IRBs are there to assist stakeholders in determining if an exemption applies and the requirements of each exemption.

Examples

Let's explore a few examples to apply the definitions to real-life examples.

Door to EKG

The emergency department (ED) is evaluating the performance of electrocardiograms in patients who present with chest pain. Established clinical guidelines state that an electrocardiogram should be performed within 10 minutes of arrival at the ED. The team leader of the ED measures conformance to the guidelines by conducting rational sampling. One day a week, door to EKG is measured on all patients who present to the ED with chest pain. The patient's identity and the observed door to EKG time are collected. In this instance, the department is measuring conformance to an established guideline and is not capturing any information that would contribute to new findings. The identity of the subjects is captured. This activity would not be considered human subject research as the data collected is not contributing to generalizable knowledge and is measuring conformance to established guidelines for purposes of improving the care delivered to patients.

Prolonged ventilation in CABG patients

The respiratory therapy department evaluates patients with prolonged ventilation following coronary artery bypass graft (CABG) surgery. Established clinical guidelines state that patients who are ventilated for greater than 24 hours following CABG surgery meet the criteria for prolonged ventilation and put patients at risk for respiratory complications. Respiratory therapy measures all patients who are ventilated for an entire year. Patients who are ventilated for longer than 24 hours are flagged, and a therapist conducts a retrospective chart review to evaluate factors that may have contributed to prolonged ventilation. The chart review includes evaluating factors already identified in the guidelines; however, therapists are also asked to explore the identification of any new factors that may have contributed to prolonged ventilation. The data collected is limited to indirect identifiers, and data collection is limited to the existing medical record. The lead respiratory therapist may document findings for potential publication in a journal. The activity is conducted at a HIPAA-covered entity, and the level of identifiers collected meets the definition of a limited data set. This activity meets both the definitions of research and human subjects, as the purposes of capturing the data include measuring new factors

that contribute to prolonged ventilation that are not documented in guidelines; there is the potential for such findings to be published. The activity also meets the criteria for exemption 4 under the Common Rule because the activity is being conducted at a HIPAA-covered entity; the activity involves only secondary information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 C.F.R. Parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 C.F.R. § 164.501.

Conclusion

The line between research and quality improvement continues to be extremely grey. Did you agree with the determinations made by the writers of this article? When case examples are shared with interactive audiences, there is often a healthy discussion on whether an activity goes over the line. One must carefully evaluate the activity to determine if the activity meets the definition of human subject research. This requires careful evaluation of the Common Rule definition for research and human subjects. One must not rely on defining an activity as a quality improvement due to the lack of clarity in applicable regulations.

Do not rely on a simple assertion that an activity is quality improvement without first carefully assessing the activity's intent and if the human subject and research definitions are met.

Takeaways

- Quality improvement is not defined in the Common Rule.
- The definition of research is harmonized in both the Common Rule and HIPAA.
- One must evaluate if an activity meets both the definition of research and human subjects before asserting that it is not research because it is quality improvement.
- If an activity meets the definition of human subject research, one should evaluate if an exemption is met.
- There continues to be a fine line between research and quality improvement.

1 Centers for Medicare & Medicaid Services, "Quality Measurement and Quality Improvement," last modified September 6, 2023, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Quality-Measure-and-Quality-Improvement-#:~:text=Quality%20improvement%20is%20the%20framework.
2 45 C.F.R. § 46.102(i).
3 45 C.F.R. § 46.102(e)(1).
4 45 C.F.R. § 46.104(d)(4).