CQ INSIGHTS

Distinction Between "Human Subjects Research" and "Clinical Quality Improvement" (CQI)

It is important to remember the origins of the need to develop "Human Subjects Research" protection. Many examples of unethical research studies performed on human beings without their consent, and even sometimes without their knowledge, were documented in Germany, the United States, and many other countries. The dominant thinking at the time was that intelligent governments and scientists had the authority to do research on groups of people deemed to be a lower class of human being. This was justified on the principles of eugenics, where this "more intelligent" class of people would be able to gain knowledge that could help the future of humanity.

Clearly, no person should dehumanize another person and assume that they should not have equal rights under the law in a free society. Appropriate Human Subjects Research protections have been implemented to protect study subjects who enter into Reductionist Science-designed studies such as prospective, randomized, controlled clinical trials where the patient does not have an informed choice about what treatment they will receive. Their choice is to participate in the experiment or not and they are informed about the different treatment options they might receive and the study protocol that will be followed.

"Clinical Quality Improvement" (CQI) is a completely different tool originating from Systems Science and is intended to be used as a part of real-world patient care by a clinical team. Instead of attempting to prove or disprove a hypothesis and to produce generalizable knowledge, CQI is applied as a part of actual patient care to improve the outcomes of any patient care process. Ideally, CQI is implemented by the clinical team to include the patient and family in a shared decision process. There are no inclusion or exclusion criteria and no static protocols. Instead, a dynamic and flexible care process is utilized. Patient and treatment factors thought to be the most impactful on outcomes are collected and outcomes that measure value are collected for each definable patient care process for the entire cycle of care. Then, a variety of types of analyses are performed for the clinical team to gain insight into how to improve outcomes and the overall value of care provided.

Reductionist Science	Systems Science
Assumptions	
Nothing changes All variables are known & controllable Results are generalizable to all environments	Constant change Variables are measured & managed Results might only apply in local environment
Tools	
Proving or disproving a hypothesis PRCTs Linear statistics Led by primary investigator Potential harm to patient in test arm	Improving a process & what is measured CQI Non-linear analytics Led by multi-disciplinary clinical team No significant potential for increased harm