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 that they were being studied were documented in the US and 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 human should dehumanize another human 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.

CQI is a completely different tool originating from complex systems science and is intended to be used as a part of actual patient care by the clinical care 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 any patient care process (pathway) and whatever is measured. Ideally, CQI is implemented with the clinical team and the patient and family are included in a shared decision process. There are no inclusion or exclusion criteria and no static protocol. Instead, a dynamic and flexible care pathway is utilized with data collected dependent on what matters to the outcomes and outcomes that measure value are collected for each definable patient care pathway for the entire cycle of care.

Reductionist Science

**ASSUMPTIONS**

Nothing changes
All variables are known and controllable
Results are generalizable

**TOOLS**

Proving or disproving a hypothesis
PRCTs
Linear statistics
Primary Investigator-led
Potential harm to patient in test arm

Complex Systems Science

**ASSUMPTIONS**

Constant change
Variables are measured and managed
Results might vary in each local environment

**TOOLS**

Improving a process and what is measured
CQI
Non-linear analytics
Clinical team-led
No significant potential for increased harm

At the University of Tennessee Medical Center, we are maturing our pathway effort to apply the principles of CQI based on measuring the value of care we provide for the entire cycle of care of a
definable patient care pathway. For the same reasons that IRB submission was not required when each multi-disciplinary clinical team defined the first iteration of the evidence-based pathways, no IRB submission is required when these same clinical teams measure value-based outcomes for the pathways. Each multi-disciplinary care team will work on improving how we measure value and identify what factors in the care process matter the most to the outcomes that measure value. Using this data as well as a variety of analysis and visualization tools, we will learn together how to improve the value of care we provide. This is a never-ending process for any learning organization. In addition to improving the value of care provided, the data, analysis and process improvement ideas that are implemented may also be used to enhance academic productivity. The application of value-based CQI for whole definable patient pathways will position our academic medical center as a leader in the transformation of our healthcare system from one based on volume to one based on value for all patients.