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A clinician may certainly try something novel in the context of good clinical care without REB oversight, under the authority of their license to provide clinical care and under the guidelines and (scientific) standards of their profession. Good clinical care often involves a "scientific" approach, including "N of 1" designs for clinical care as long as the guiding purpose of the intervention(s) is the best possible care of the patient. However, it becomes a different scenario when a clinician is intending a priori to perform an "N of 1" research project, using a clinical patient as a research subject with the intent to provide generalizable information to the scientific/professional community. Now the investigator is not guided only by the best care of the patient, but also by the intent to systematically collect data for the sake of a research project, an intention which might expose the subject to additional harms and/or benefits. Because of the shift in intention, the clinician is now operating presumably outside of the standard of practice (otherwise there would be no new generalizable information generated) and the patient should be informed that the doctor-patient relationship has been expanded to doctor/investigator-patient/research subject. In addition, the investigator must have REB approval to proceed.

The case of the "N of 1" study is a good example to use to draw the fine line between clinical care and clinical research. While both may have a prospect of benefit and both may have risks involved, there are differences that must be respected. One way to think of the differences is in terms of the societal "authority" to perform the intervention "on" the patient/subject. The line of authority to provide medical care is established in each country/province under its licensure laws or within a hospital/institution under its policies and license which are closely linked to professional societies that govern the practice of medicine, psychology, etc. The REB has nothing to do with the clinical care of patients when it is performed as a standard of care under the relevant statutory and professional regulatory guidelines. However, by definition, clinical research is an attempt to extend the activities of the clinician/researcher beyond the scope of standard of care. Wherever the intervention is intended to go outside of the published standard of care (and therefore contribute something new to generalizable knowledge), the activities enter the arena where they may fall under the oversight responsibility of the REB.

Consider the scenario where something goes wrong in a trial on hypotensives. If a physician modifies the patient's medications and carefully tracks the changes in blood pressure (purely clinical care--regardless of how "scientific" the practice is) and the patient faints and is injured during a hypotensive crisis, the complaint of the patient might be considered by the Hospital Medical Director, or Medical Staff, , as might the licensing board and the malpractice insurance company. They would all evaluate the intervention in terms of the published "standard of care" and the reasonable practice of medicine. However, if the clinician/investigator says a priori that she is going to try something novel in order to try and add something to generalizable knowledge, she is saying she is going outside of the standard of care. If the subject is injured as a result of participating in the research, then the REB should be involved in its evaluation, along with Health Canada if applicable and the standards of ethical human subjects research will be applied in review of the informed consent process and minimization of risks. The physician/investigator is still liable to the medical licensing bodies, but is also liable to the research "licensing" groups because she has stepped outside standard of care.

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The two criteria that designate the intervention as research are:

1. the intent to collect data for the purpose of sharing it with others (e.g. publication),
and
2. the intent to generate new, generalizable information that pushes the standard of care and, in the judgment of other care providers would fall outside of the current standard.

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