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Understanding the patient perspective on research access to national health records databases for conduct of randomized registry trials

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ABSTRACT

Background: Use of health administrative databases is proposed for screening and monitoring of participants in randomized registry trials. However, access to these databases raises privacy concerns. We assessed patient's preferences regarding use of personal information to link their research records with national health databases, as part of a hypothetical randomized registry trial.

Methods and results: Cardiology patients were invited to complete an anonymous self-reported survey that ascertained preferences related to the concept of accessing government health databases for research, the type of personal identifiers to be shared and the type of follow-up preferred as participants in a hypothetical trial. A total of 590 responders completed the survey (90% response rate), the majority of which were Caucasians (90.4%), male (70.0%) with a median age of 65 years (interquartile range, 8). The majority responders (80.3%) would grant researchers access to health administrative databases for screening and follow-up. To this end, responders endorsed the recording of their personal identifiers by researchers for future record linkage, including their name (90%), and health insurance number (83.9%), but fewer responders agreed with the recording of their social security number (61.4%, $p < 0.05$ with date of birth as reference). Prior participation in a trial predicted agreement for granting researchers access to the administrative databases (OR: 1.69, 95% confidence interval: 1.03–2.90; $p = 0.04$).

Conclusion: The majority of Cardiology patients surveyed were supportive of use of their personal identifiers to access administrative health databases and conduct long-term monitoring in the context of a randomized registry trial.

1. Introduction

Randomized controlled trials have been key to change clinical practice but are costly to conduct. As a result, clinical trials are declining, both in number [1] and overall patients' participation [2]. Pragmatic trials are gaining traction among investigators as they simplify the translation of innovative medical strategies, drugs or devices into clinical practice [3]. The term randomized registry trial (RRT) has been coined to describe the electronic surveillance of integrated national health record databases [4–6] or of multi-tiered query processes [7] to screen trial participants and confirm endpoints. In their simplest form, participants to randomized registry trials are screened from an existing dedicated clinical registry, enrolled in an embedded trial and followed up using public or administrative databases, such as national health records or claims databases (Fig. 1). Potential advantages of RRTs include reduced operational burden and costs, and increased external validity of the results. Randomized registry trial have been conducted

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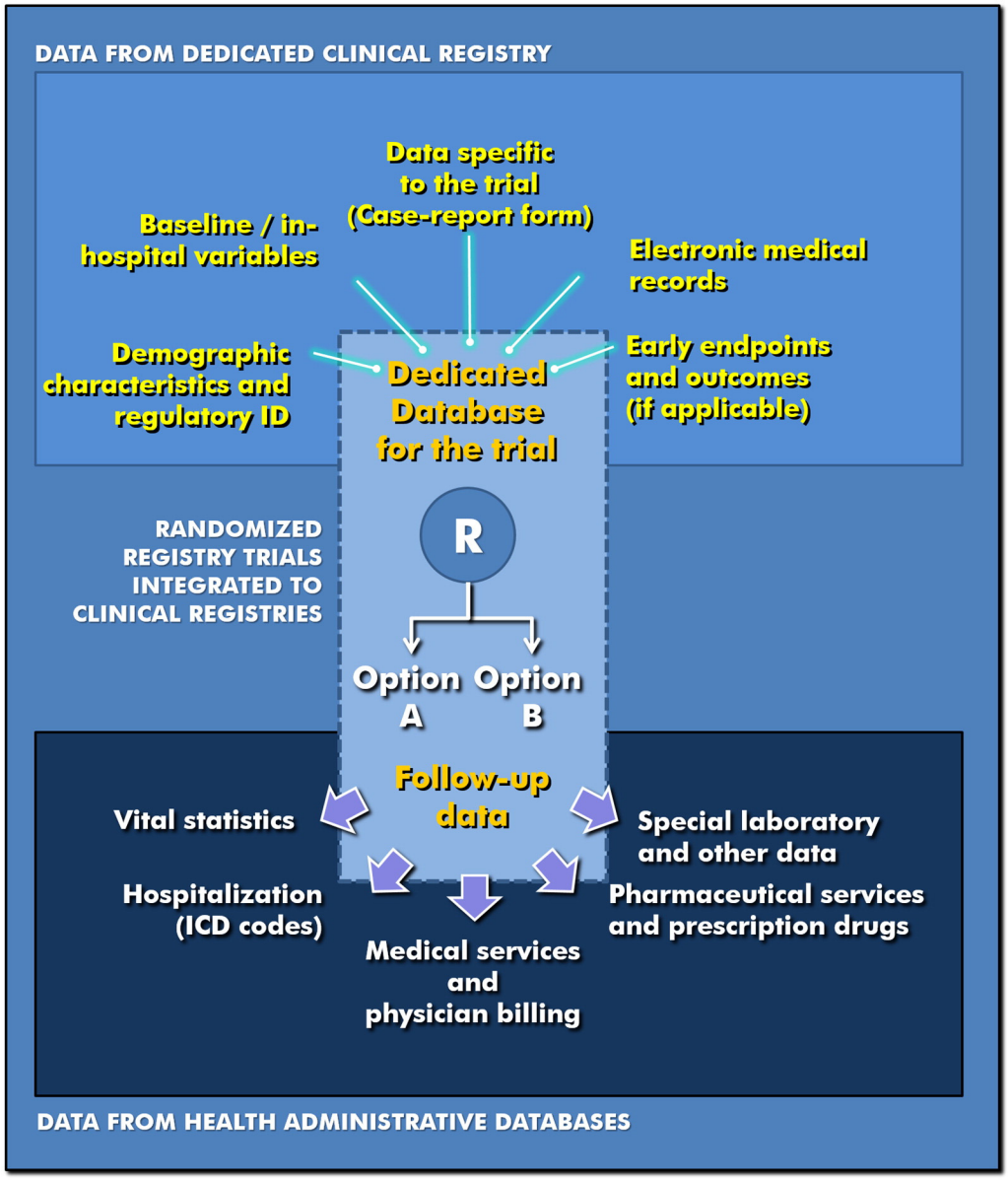

Fig. 1. Randomized registry trials combine dedicated clinical registry and health administrative databases.

successfully in Sweden, Scotland, and Denmark to solve medical conundrums and change the current practice [4,5,8,9]. The linkage of research records with administrative health databases raises ethical and legal challenges that are yet to be addressed. Limited information is available on the perspective of patients related to the protection of their privacy versus the use of their confidential data to address medical questions for the greater good.

This study surveyed patients' preferences on access to their confidential records in health administrative databases for clinical research. More specifically, the project aimed to ascertain whether patients, as eventual participants to randomized-registry trials, would accept that their confidential national health record be accessed to monitor the occurrence of adverse events during a trial, and if so, to assess the type of personal identifiers they would share with researchers to facilitate linkage.

2. Methods

2.1. Study population

Patients aged 18 years and older, able to communicate in English or French, and treated for a cardiac condition either as an in-patient or outpatient were eligible. Potential participants were randomly screened by cardiology fellows and attending in both cardiology outpatient and inpatient settings. Potential participants were given a facts sheet about the survey in five academic centers in the province of Quebec between October 2015 and November 2016. Patients who consented and were able to understand properly the survey in the opinion of the investigator were included. To allow a broad representativeness of patients with cardiovascular diseases, no other exclusion criteria were applied. A multicentric approval was granted by the Montreal Heart Institute Ethic Review Board, and patients provided consent to participate. The study was initiated, designed and conducted by cardiology residents and fellows in compliance with the Collectively-operated fellow-initiated research (COFIR) principles [10].

2.2. Survey design

The survey was adapted from an earlier iteration proposed by Hay et al. [11] for research in Oncology. Participants were instructed with a standardized script (available in Supplemental Material - Appendix A) and presented with the following hypothetical scenario, as if they were participating to an ongoing clinical trial: "*Once the study is completed, researchers can no longer collect data concerning your health. However, it could be interesting to have access to your health status beyond the duration of the clinical trial, to monitor for side effects that were unknown at the time of the study, but also to be informed on the evolution of the disease, as well as the additional costs incurred for the health care system. This long-term follow-up could be achieved by accessing your data collected in provincial and federal government healthcare databases, but would require the use of your personal information to link your medical records with the healthcare databases*". Based on