NAPCRG 52nd Annual Meeting — Abstracts of Completed Research 2024.

Submission Id: 6683

Title

Time to obtain ethics approval and sites authorization for research in the Cohort in Primary Care (COPRI)

Priority 1 (Research Category)

Observational study (cohort, case-control)

Presenters

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Abstract

Context: The Cohort in Primary Care (COPRI) is ongoing in 29 Family Medicine Groups (FMG) across Québec. The research ethics approval process must follow the 2016 Québec Ministry of Health framework for multicentric projects which specifies that Evaluating Research Ethics Board (EREB) must respond to evaluation requests within 5 days and evaluate the project within 30 days. Once ethics approval is obtained by the EREB, institutional feasibility approval and authorization to conduct research is required for each site. Objective: The objective of this analysis is to measure the time required currently to obtain authorization for research in a multicentric project in Québec. Study design and analysis: Time between each step of the submission process were measured in days and descriptive results will be presented with tables and figures. Population studied: COPRI is recruiting adults followed at FMGs, but the unit of measurement are here the FMGs. Outcome measures: Data collected consists of date of submissions and approvals for ethics and authorization for research, obtained through Nagano. Results: We submitted the COPRI protocol 1.0 (McGill GMFs only) for multicentric ethics approval to the selected EREB on 2022-FEB-18. The EREB accepted 4 days later and reviewed the project 94 days after accepting. The EREB final ethics approval was obtained 186 days after submission. The authorization to conduct research at the 7 McGill sites then took 1, 115, 164 (3 sites covered), 171 and 392 days. COPRI protocol version 2.0 included the expansion of the study to clinics affiliated with other universities, adding 21 GMFs. The amendment to the protocol took 111 days to be approved by the EREB, the new questionnaires and recruiting material took 80 days, and the request to add new sites took 11-23 days. The authorization to conduct research was obtained after 52 days for one site and remains pending for the others. Conclusions: It takes a minimum of 6 to 19 months to obtain authorization to conduct research at GMFs for a non-interventional observational study in primary care in Québec. The delays observed exceed the recommended delays by the provincial framework. These

create challenges to conduct research in primary care. Recognizing these delays can justify initiatives to improve the efficacy of the process and help plan realistic timelines with funding agencies.