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Title: The Quebec Low Back Pain Study (QLBPS): A platform for the continuous enrolment and longitudinal epidemiological evaluation of individuals with LBP.

Short title: Quebec Low Back Pain Study (QLBPS): Core Dataset

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1. INTRODUCTION

Low back pain (LBP) is reported by approximately 20% of North Americans, the majority of whom experience both pain and physical impairment (*1, 2*). Patients with chronic LBP have an increased utilization of medical services, and higher incidence of lost workdays and long-term disability, representing a significant burden to the healthcare system and the economy (*1-3*).

It has been estimated that up to 84% of people will experience an episode of acute LBP in their lifetimes (*4*), and recovery rates range from 39% to 76% (*5, 6*). The neurobiological mechanisms underlying recovery or persistence of the condition remain to be understood, and identification of such mechanisms would allow early intervention, interruption, and prevention of progression to a chronic state.

The existence of a platform for the continuous enrolment of LBP patients to which pain researchers would have access would greatly facilitate the investigation of key research questions including what factors (e.g. genetic, epigenetic, neurobiological, biomechanical, psychological) contribute to the transition from acute to chronic LBP, how these factors might change with time as pain progresses, and what are the health care utilization and medication patterns associated with that progression.

The Quebec Pain Research Network has developed a Strategic Initiative funded by the FRQS to the QPRN to facilitate research on chronic LBP. The QPRN LBP Scientific Committee has been meeting regularly since 2015 to develop this shared vision. The committee includes experts from throughout the province in physical therapy, neurobiology, psychology, genetics, epigenetics, physicians, chronic pain perspective partners and a full time scientific coordinator. Please see Appendix 1 for further details on The Team.

The current proposal is designed to establish a province-wide online database for longitudinal studies of individuals with LBP (The Core). The Core Database will not only be a valuable research tool itself, but we will use The Core to facilitate recruitment for a series of affiliated projects, including a biobank that will be covered under an independent protocol but integrated with The Core.

2. OBJECTIVE

SPECIFIC AIM 1 (Tier 1) - Develop a province-wide, community-based, longitudinal cohort of individuals initially reporting acute LBP to achieve a comprehensive biopsychosocial understanding of factors underlying LBP trajectories.

SPECIFIC AIM 2 (Tier 2) - Build capacity in acute and chronic LBP research through integration of hypothesis-driven satellite projects.

3. **DESCRIPTION OF STUDY POPULATION.** *The QLBPS will enroll adult women and men with self-reported LBP.*

3.1 Inclusion Criteria for potential LBP participants

1. At least 18 years old;
2. Internet access;
3. Fluent in English or French;
4. Self-reported LBP.

3.2 Exclusion Criteria for potential LBP participants

No exclusion criteria will be adopted in this study. *Note: While our recruitment efforts will focus on the acute or subacute phases, previous experience suggests that individuals with chronic LBP (cLBP) will also respond. While not the focus of the Study, their longitudinal data will be valuable and affiliated projects may be interested in also recruiting cLBP participants. We will therefore accept all individuals who self-register for the study and will then filter the data based on specific research questions.*

4. **RECRUITMENT AND ENROLLMENT** *A flowchart describing all study procedures is provided in Appendix 2. These procedures are described in detail below.*

4.1 Recruitment strategy A broad recruitment strategy (initially limited to the Montreal area, but ultimately aimed at all major urban areas in the province of Quebec and Canada), is planned for the QLBPS and may include advertisement in newspapers, public means of transportation, social media such as Facebook and through list servers, patient advocacy organizations or professional societies, unions of workers at risk for LBP and medical populations.

Consent Advertisements will contain the electronic address to the **QLBPS Landing Page,** which will be accessible through to the Quebec Pain Research Network (QPRN) website.

4.2 The Landing Page will ask the participant if he has back pain and to indicate his postal code, sex, age (to evaluate the relevance of our advertising and adjust if necessary) and if he is interested in participating to research.

Participants at this point will receive an email inviting them to access the **Baseline Online Survey.** This email will also include a link to the informed consent form.

Once on the baseline online survey, 3 questions will be asked :

Question 1: I have read the information about the study in the previous email and I agree to participate in the study: Yes/No. If No, the website will post "Thank you for your time". If Yes, individuals will be asked **Question 2:**

Question 2: I accept to be contacted regarding participation in additional studies: Yes/No The answer will be recorded in the core database and will be used to filter participants that may be contacted in the future by other QPRN-approved Investigators.

Question 3: I would consider donating blood: Yes/No.

4.3 **Enrolment** At the completion of the 3 Questions, individuals who answered Yes to Question 1 (regardless of answers 2 or 3) are enrolled in the study.

After the participant has consented to be contacted for other studies, the researchers that had their project approved by the QLBPS scientific committee and the McGill University ethics committee will be able to contact selected participants. The research projects must meet the following conditions in order to be granted access to contact participants:

- The research project must coincide with the objective of the Bank;
- The research project must have scientific value and be scientifically sound;
- The research project must be presented and performed by qualified researchers.
- The research project must be approved by a duly constituted REB.

5. EXPERIMENTAL PROCEDURES QLBP Study participants will be asked to complete the following Surveys.

5.1 Baseline Online Survey After consenting to participate in the QLBPS, participants will gain access to the following set of online questionnaires available in English and French:

1. PERSONNAL INFORMATION SURVEY (Appendix 5). Personal information such as date of birth, sex, gender, race and geographic region. The section will also ask the participant for permission to access their medical data through the Régie de l'assurance maladie du Québec (RAMQ).
2. QUEBEC LOW BACK PAIN CORE DATASET. The content of the QLBP Core Dataset was

developped by the Quebec Pain Research Network, Low Back Pain Consortium Scientific Committee using an Iterative consensus-building process (Appendix 6).

- CHARACTERIZATION SURVEY: A set of 6 questions that allow us to classify all participants into acute or chronic LBP according to agreed-upon definitions.
- CANADIAN MINIMUM DATASET FOR RESEARCH STUDIES ON LOW BACK PAIN. The Canadian dataset was adapted from the recommendations of the NIH task force on research standards for chronic LBP in order to advance the field, solve controversies, and facilitate future research. This questionnaire assesses core domains recommended by IMMPACT, namely pain frequency and intensity, physical and emotional functioning, as well as it collects detailed demographic and general health measures, and has been culturally adapted and translated to be used for low back pain for research among English and French-speaking populations in Canada.
- DN4 (validated questionnaire assessing the neuropathic component of chronic pain)
- EQ-5D-5L (validated questionnaire for overall quality of life)
- Other medical conditions

Completion of all questionnaires is expected to take no more than 30 minutes. Those who self-enroll in the QLBPS but do not complete all abovementioned questionnaires will be contacted by the study coordinator by phone and/or e-mail to be reminded to complete the surveys.

5.2 Follow-up Online Surveys At 3, 6, 12, and 24 months after completing the baseline online procedures, participants will complete follow-up survey online. At each of these time points, participants will receive an e-mail with a link to complete the questionnaires listed below.

1. QUEBEC LOW BACK PAIN CORE DATASET
2. PATIENT GLOBAL IMPRESSION OF CHANGE (PGIC) (Appendix 7

Completion of all questionnaires is expected to take no more than 30 minutes. At each time-point, participants who do not complete all abovementioned questionnaires will be contacted by the study coordinator by phone and/or e-mail to be reminded of completing them.

6. DETAILS ON CONFIDENTIALITY

6.1 Confidentiality, de-identification and transfer

Confidentiality Participant confidentiality will be strictly held in trust by the investigators, study staff, and the representatives of McGill University and the MUHC-RI (where the data is held). This confidentiality is extended to cover testing of biological samples and genetic tests in addition to any study information relating to participants.

Data transfer Data transfers on will only be done to researchers who a) obtain ethical approval to access the QLBPS data through their home IRB's and b) approval of the scientific committee of the QPRN LBP Consortium.

For the purposes of recruitment to subprojects, basic information including email and phone number, age, sex, duration of low back pain will be shared with approved subproject investigators ONLY if the participant has agreed to be contacted by other studies. In the event that a participant is ultimately recruited to a subproject and signs the corresponding consent, the PI of the subproject will have access to The Core Database information for those individuals only, by request.

6.2 Health Care information

Participants are asked to provide their unique health insurance number to allow the linkage between patient-reported outcomes and Quebec administrative databases. Dr Anais Lacasse (Université du Québec en Abitibi-Témiscamingue) will be the sole designated researcher responsible for the analysis and conservation of such administrative data and will submit an application for approval at the Comission d'accès à l'information du Québec and Régie de l'assurance maladie du Québec. This information will also be sent to reMed, a research team that automatically receives data on medications from electronic service providers of community pharmacies so that patients can be reimbursed for their insurance claims. All transfers of information will be done via registered mail and secured electronic files.

9. REFERENCES

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