

Impact of feedback of prescribing portraits for individual prescribers - opioid naivete

Submission date 30/03/2020	Recruitment status No longer recruiting	☒ Prospectively registered ☒ Protocol
Registration date 10/04/2020	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/12/2023	Condition category Signs and Symptoms	☐ Individual participant data

Plain English summary of protocol

Current plain English summary as of 26/01/2022:

Background and study aims

Prescription opioid addiction due to unsafe prescribing is associated with considerable harm and economic cost. If left untreated, the mortality rate is high. Individualized prescribing portraits are letters that aim to identify unsafe prescribing and motivate an individual physician to do something about it. They have been shown to reduce injudicious prescribing for patients with chronic diseases, but they have never been tested in people being initiated on opioids for pain. Among opioid-naïve patients being initiated on opioids for pain, previous work conducted by members of this team highlighted a dearth of valid ways to identify at-risk patients, the importance of opioid-sparing approaches to evidence-based pain management, and significant beneficial effects of individualized prescribing portraits on new prescribing for both chronic and acute conditions. The aim of this study is to determine whether a 'complex' intervention that includes i) individualized prescribing portraits, ii) online training on safer prescribing, and iii) academic detailing (by the British Columbia Centre on Substance Use), can reduce the proportion of new opioid prescriptions for people with pain. The study is being conducted with family physicians in British Columbia and will involve distributing individualized prescribing portrait to all family physicians, optional academic detailing and training of prescribers. The study is being conducted by experts responsible for research, planning and delivery of addiction treatment/primary care in Canada.

Who can participate?

Primary care prescribers in British Columbia. The researchers are not asking physicians to participate. They will mail portraits to as many as 6500 primary care prescribers. The prescribers who receive the Portrait are not regarded as participants in research because they have the option of ignoring any or all 'Letters', and do not submit any data or do anything that might be called "participation." In addition, prescribers are offered a low-barrier chance to "opt-out" of receiving Portrait, at any time using phone, fax, email or an online portal for withdrawal. The recipients of portraits can decide instantaneously to stop reading at any time.

What does the study involve?

Participants are randomly allocated to one of two groups. An early group receives the intervention first and a delayed group receives the intervention 6 months later. The intervention

consists of four steps. Step 1: The analyst with the research group develops prescribing portraits. A pdf file of all individual portraits is produced with only a code number on each portrait. The Portrait will have no identifying information on it, only a code number will be printed also on the sealed envelope with no identifying information. The Portrait ID code number on the sealed envelope is used to match the Portrait with the addressed envelope. There is no collection of information from the prescribers associated with the mailing of the Portraits. Step 2: The analyst provides the pdf of coded Portraits to the printer (British Columbia, BC, Mail) via SFTP, who automatically stuffs them into envelopes labelled with the code number. On the envelope is printed a diagram showing how the researchers preserve data privacy. Step 3: Once the envelopes are sealed, the team then provides BC Mail with an address list that matches the Portrait ID code # on the exterior of the privacy envelope with the address of the prescriber. A small number of prescribers have requested to not receive the Portraits, these addresses have been flagged and they will not receive any Portrait materials. Step 4: Prescribers open the de-identified coded envelope and look at their portrait. The covering letter gives contact information for requests to be excluded. Ancillary online training via virtual webinars on safer prescribing will be available to all prescribers within BC, regardless of whether they were in the early or delayed group for intervention. The links for the webinars will be distributed separately from the Portrait intervention. Webinars have been delivered from September to November 2021, recorded, and posted online.

What are the possible benefits and risks of participating?

The benefits include safer, more effective and more cost-effective prescribing for patients, and more informed prescribers. There are no risks. Occasionally a prescriber might feel uncomfortable about receiving a portrait of his/her prescribing even when no one else has seen it. Should that level of discomfort remain, they may opt-out of the program at any time.

Where is the study run from?

Department of Family Practice, University of British Columbia (UBC) (Canada)

When is the study starting and how long is it expected to run for?

October 2020 to December 2023

Who is funding the study?

Canadian Institutes of Health Research (CIHR) (Canada)

Who is the main contact?

1. Dr Rita McCracken
rita.mccracken@ti.ubc.ca

2. Jan Klimas
jan.klimas@ubc.ca

Previous plain English summary as of 03/09/2021:

Background and study aims

Prescription opioid addiction due to unsafe prescribing is associated with considerable harm and economic cost. If left untreated, the mortality rate is high. Individualized prescribing portraits are letters that aim to identify unsafe prescribing and motivate an individual physician to do something about it. They have been shown to reduce injudicious prescribing for patients with chronic diseases, but they have never been tested in people being initiated on opioids for pain. Among opioid-naïve patients being initiated on opioids for pain, previous work conducted by members of this team highlighted a dearth of valid ways to identify at-risk patients, the importance of opioid-sparing approaches to evidence-based pain management, and significant beneficial effects of individualized prescribing portraits on new prescribing for both chronic and

acute conditions. The aim of this study is to determine whether a 'complex' intervention that includes i) individualized prescribing portraits, ii) online training on safer prescribing, and iii) academic detailing (by the British Columbia Centre on Substance Use), can reduce the proportion of new opioid prescriptions for people with pain. The study is being conducted with family physicians in British Columbia and will involve distributing individualized prescribing portrait to all family physicians, optional academic detailing and training of prescribers. The study is being conducted by experts responsible for research, planning and delivery of addiction treatment/primary care in Canada.

Who can participate?

Primary care prescribers in British Columbia. The researchers are not asking physicians to participate. They will mail portraits to as many as 6500 primary care prescribers. The prescribers who receive the Portrait are not regarded as participants in research because they have the option of ignoring any or all 'Letters', and do not submit any data or do anything that might be called "participation." In addition, prescribers are offered a low-barrier chance to "opt-out" of receiving Portrait, at any time using phone, fax, email or an online portal for withdrawal. The recipients of portraits can decide instantaneously to stop reading at any time.

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What are the possible benefits and risks of participating?

The benefits include safer, more effective and more cost-effective prescribing for patients, and more informed prescribers. There are no risks. Occasionally a prescriber might feel uncomfortable about receiving a portrait of his/her prescribing even when no one else has seen it. Should that level of discomfort remain, they may opt-out of the program at any time.

Where is the study run from?

Innovation Support Unit, University of British Columbia (UBC) (Canada)

When is the study starting and how long is it expected to run for?

October 2020 to October 2023

Who is funding the study?
Canadian Institutes of Health Research (CIHR) (Canada)

Who is the main contact?

1. Dr Rita McCracken
rita.mccracken@ti.ubc.ca
2. Jan Klimas
jan.klimas@ubc.ca

Previous plain English summary:

Background and study aims

Prescription opioid addiction due to unsafe prescribing is associated with considerable harm and economic cost. If left untreated, the mortality rate is high. Individualized prescribing portraits are letters that aim to identify unsafe prescribing and motivate an individual physician to do something about it. They have been shown to reduce injudicious prescribing for patients with chronic diseases, but they have never been tested in people being initiated on opioids for pain. Among opioid-naïve patients being initiated on opioids for pain, previous work conducted by members of this team highlighted a dearth of valid ways to identify at-risk patients, the importance of opioid-sparing approaches to evidence-based pain management, and significant beneficial effects of individualized prescribing portraits on new prescribing for both chronic and acute conditions. The aim of this study is to determine whether a 'complex' intervention that includes i) individualized prescribing portraits, ii) online training on safer prescribing, and iii) academic detailing (by the British Columbia Centre on Substance Use), can reduce the proportion of new opioid prescriptions for people with pain. The study is being conducted with family physicians in British Columbia and will involve distributing individualized prescribing portrait to all family physicians, optional academic detailing and training of prescribers. The study is being conducted by experts responsible for research, planning and delivery of addiction treatment/primary care in Canada.

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of the prescriber. A small number of prescribers have requested to not receive the Portraits, these addresses have been flagged and they will not receive any Portrait materials. Step 4: Prescribers open the de-identified coded envelope and look at their portrait. The covering letter gives contact information for requests to be excluded as well as links for online training on safer prescribing an invitation to academic detailing session in their community. The prescriber decides which training they complete, if any. There will be a qualitative assessment of the complex-intervention experience among a purposive sample of end-users.

What are the possible benefits and risks of participating?

The benefits include safer, more effective and more cost-effective prescribing for patients, and more informed prescribers. There are no risks. Occasionally a prescriber might feel uncomfortable about receiving a portrait of his/her prescribing even when no one else has seen it. Should that level of discomfort remain, they may opt-out of the program at any time.

Where is the study run from?

Therapeutics Initiative, University of British Columbia (Canada)

When is the study starting and how long is it expected to run for?

October 2020 to October 2023

Who is funding the study?

British Columbia Ministry of Health - F17-04802 Therapeutics Initiative – Shared cost arrangement (Canada)

Who is the main contact?

1. Dr Rita McCracken
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2. Ian Cooper
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Contact information

Type(s)

Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Optimizing strategies to reduce inappropriate initiation of prescription opioid analgesics to opioid-naïve patients in primary care (REDONNA)

Acronym

REDONNA

Study objectives

Current hypothesis as of 04/08/2023:

This study is taking place to examine the rates of newly prescribed opioids by primary care prescribers in British Columbia prior to, and following, an educational intervention using an audit and feedback tool, and an academic detailing session. It is hypothesized that the educational intervention will decrease the rate of opioid initiation to opioid-naïve patients.

Previous hypothesis:

This study is taking place to examine the rates of newly prescribed opioids by primary care prescribers in British Columbia prior to, and following, an educational intervention using both an audit and feedback tool, and an online training course. It is hypothesized that the educational intervention will decrease the rate of opioid initiation to opioid-naïve patients.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 06/03/2020, Clinical Research Ethics Board at the University of British Columbia (Clinical Research Ethics Board, Room 210, 828 West 10th Avenue, Vancouver, BC, V5Z 1L8, Canada; +1 (0)604 875 4149; ors@ors.ubc.ca), ref: H20-00656

Study design

Single-blind two-arm randomized controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Opioid-sparing pain management

Interventions

Current intervention as of 04/08/2023:

Intervention 1: Complex intervention (prescribing portrait and optional academic detailing session).

Intervention 2: Usual care followed by delayed complex intervention.

Data extraction following administration of the Portrait intervention will be executed through Population Data BC's (PopDataBC) health administrative databases. The researchers will also conduct an ancillary qualitative study to explore the feasibility and acceptability of the intervention among a purposive sample of end users following an optional academic detailing session.

Previous intervention as of 03/09/2021:

Intervention 1: Complex intervention (composed of academic detailing or an online training course, a prescribing portrait).

Intervention 2: Usual care followed by delayed complex intervention.

Data extraction following administration of the Portrait intervention will be executed through Population Data BC's (PopDataBC) health administrative databases. The researchers will also conduct an ancillary qualitative study to explore the feasibility and acceptability of the intervention among a purposive sample of end users.

We will also access publicly available directory, via the College of Physicians and Surgeons of BC (CPSBC), of family physicians in the province to collect prescriber characteristics (e.g., gender, number of years in practice) of all registrants and their street address, to which we will apply a sorting algorithm and create a list of all primary care clinics in the province. These data are required to evaluate prescriber and practice features that may be associated with a larger magnitude of positive change to the intervention.

Previous intervention as of 06/01/2021:

Intervention 1: Complex intervention (composed of academic detailing or an online training course, a prescribing portrait).

Intervention 2: Usual care followed by delayed complex intervention.

The research component of this project is the impact evaluation to determine the impact of personalized prescribing feedback Portraits on primary care prescriber initiation of opioid prescription. This will entail: a) a sophisticated data analysis to produce a more accurate elucidation of the effect of anonymous Portraits on prescribing, b) paired matching of

communities in the mailing list with randomization into Early and Delayed communities (by a third-party statistician, using random sequence generator software), and c) statistical analyses comparing Early versus Delayed groups. An early group receives the intervention first and a delayed group receives the intervention six months later. The researchers hypothesize that the personalized prescribing-portrait intervention will be associated with a decrease in the number of opioid prescriptions initiated in 'opioid naïve' patients. They will extract administrative health data to determine the total number of opioid prescription initiations per prescriber in 'opioid naïve' patients. The Ministry of Health has given the Therapeutics Initiative's team permission to use its databases for the Portrait project. The purpose of dividing prescribers into an early and delayed group is to provide evidence of the impact of receiving the portrait and educational materials on prescribing. Optional safer-prescribing educational opportunities will be provided by the British Columbia Centre on Substance Use. Analysing trends in aggregate data from the two groups will demonstrate impact (separate from other factors in the prescribing environment).

Randomization. Groups were further balanced on the following variables:

1. Physician sex (M/F as per CPSBC listing)
2. Year of medical school graduation
3. Graduation from Canadian vs. International medical school
4. Total prescription count for 2019
5. Number of office visits (total and number of patients) in 2019
6. Number of MSP encounters (total and number of patients) in 2019
7. Number of opioid naïve patients aged 19+ initiated on opioids in 2019
8. Median age of opioid naïve patients initiated on opioids in 2019
9. Distribution of male vs. female opioid naïve patients initiated on opioids in 2019
10. Percent change in opioid initiations to opioid naïve patients between 2018 and 2019
11. Physician location, rural vs. urban vs. large urban (Vancouver, Victoria, Surrey)

Previous intervention:

Intervention 1: Complex intervention (composed of academic detailing or an online training course, a prescribing portrait).

Intervention 2: Usual care followed by delayed complex intervention.

The research component of this project is the impact evaluation to determine the impact of personalized prescribing feedback Portraits on primary care prescriber initiation of opioid prescription. This will entail: a) a sophisticated data analysis to produce a more accurate elucidation of the effect of anonymous Portraits on prescribing, b) paired matching of communities in the mailing list with randomization into Early and Delayed communities (by a third-party statistician, using random sequence generator software), and c) statistical analyses comparing Early versus Delayed groups. An early group receives the intervention first and a delayed group receives the intervention six months later. The researchers hypothesize that the personalized prescribing-portrait intervention will be associated with a decrease in the number of opioid prescriptions initiated in 'opioid naïve' patients. They will extract administrative health data to determine the total number of opioid prescription initiations per prescriber in 'opioid naïve' patients. The Ministry of Health has given the Therapeutics Initiative's team permission to use its databases for the Portrait project. The purpose of dividing prescribers into an early and delayed group is to provide evidence of the impact of receiving the portrait and educational materials on prescribing. Optional safer-prescribing educational opportunities will be provided

by the British Columbia Centre on Substance Use. Analysing trends in aggregate data from the two groups will demonstrate impact (separate from other factors in the prescribing environment).

Intervention Type

Behavioural

Primary outcome(s)

Current primary outcome measure as of 03/09/2021:

The number of new opioid prescriptions initiated in opioid-naïve patients in the 6 months following the intervention, as recorded in the BC Ministry of Health administrative claims databases

Previous primary outcome measure:

The number of new opioid prescriptions to opioid-naïve patients in the last 12 months, calculated based on the administrative claims databases of the Ministry of Health in the last 6 months at the 6-month follow up.

Key secondary outcome(s)

Current secondary outcome measures as of 04/08/2023:

Quantitative physician outcomes:

1. Estimated length of opioid use, measured in days from the first to the last prescription plus 'days supply' of the last dispensing at baseline and 6-month follow up
2. Median (and quartile ranges) for Morphine Equivalent Daily (MED) dosage, of all new opioid prescriptions initiated within the reporting period, prescribed by the provider

Previous secondary outcome measures as of 03/09/2021:

Quantitative physician outcomes:

1. Estimated length of opioid use, measured in days from the first to the last prescription plus 'days supply' of the last dispensing at baseline and 6-month follow up
2. Median (and quartile ranges) for Morphine Equivalent Daily (MED) dosage, of all new opioid prescriptions initiated within the reporting period, prescribed by the provider

Quantitative patient outcomes:

1. Number of hospitalizations and emergency department visits measured using data from the National Ambulatory Care Reporting System (NACRS) database, looking at the binary outcome ED visit (Yes/ No). This is a very limited measure that is applicable only to urban settings because small hospitals are not included in the database.

Previous secondary outcome measures:

1. Length of opioid prescriptions measured by counting the number of days of uninterrupted prescribing from initiation to cessation at baseline and 6-month follow-up
2. Average dose of opioid prescriptions measured by summing up the dose from all prescriptions and dividing the sum of all doses by the number of prescriptions at baseline and 6-month follow-up
3. Intervention experience measured using semi-structured focus groups among a purposive sample of end-users at 6-month follow-up

Completion date

12/12/2023

Eligibility

Key inclusion criteria

Current participant inclusion criteria as of 03/09/2021:

Physicians:

1. Currently actively treating patients (active prescriber is defined as having prescribed any medications at least 100 times in 2019 to eliminate retired or mostly retired physicians. For the 100 prescriptions, we counted only the number of dispensations recorded in the database without any restriction on patients)
2. Physicians defined as a 'General Practitioner' with a license status of 'Private Practice' according to Medical Services Plan (MSP = BC's public insurance program)
3. Physicians who have a functioning postal address.

Patients:

1. Aged ≥ 19 years

Previous participant inclusion criteria as of 06/01/2021:

1. Physicians currently treating patients (defined as having prescribed any medications at least 100 times in 2019)
2. Have prescribed at least one opioid during the study period

Previous participant inclusion criteria:

1. Physicians currently treating patients (defined as having written at least 25 prescriptions, for any drug, in the preceding 12 months)
2. Have prescribed at least one opioid during the study period

Participant type(s)

Health professional

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

4416

Key exclusion criteria

Current participant exclusion criteria as of 03/09/2021:

Physicians:

1. Currently residing outside of BC
2. Prescribed less than one opioid analgesic to an opioid-naïve patient during the study period
3. Opted out of the Portrait program or recorded as retired or deceased in the database

Exclusion criteria - Participating patients:

1. Have been dispensed any opioids or opioid agonist therapies in the last six months (i.e., during the washout period)
2. Have been on Plan B (long term care) or Plan P (palliative care) at any time during the washout period or study period (as a proxy for non-cancer causes)
3. Have been without continuous Medical Services Plan (MSP = BC's public insurance program) during the washout period and study period
4. Have had a cancer diagnosis or record of chemotherapy recorded in MSP fee-for-service claims, the hospital discharge abstract database, or the National Ambulatory Care Reporting System database during the study period or the preceding six months. Skin cancers (Basal Cell Carcinoma, Squamous Cell Carcinoma) were not excluded.

Previous participant exclusion criteria as of 06/01/2021:

Prescribers:

1. Currently residing outside of BC
2. Unavailable contact information (e.g., deceased, retired)
3. Not currently practicing (are retired), or who have not prescribed at least one opioid during the study period

Patients:

1. Have been dispensed any opioids or opioid agonist therapies in the last six months (during the washout period)
2. On Plan B (long term care) or Plan P (palliative care) at any time during the washout period or study period (as a proxy for non-cancer causes)
3. Have been without continuous Medical Services Plan (public insurance program) during the washout period and study period
4. Have had a cancer diagnosis (not including skin cancers) or record of chemotherapy recorded in MSP fee-for-service claims, the hospital discharge abstract database, or the National Ambulatory Care Reporting System database during the study period or the preceding six months

Previous participant exclusion criteria:

1. Currently residing outside of BC
2. Unavailable contact information (e.g., deceased, retired)
3. Not currently practicing (are retired), or who have not prescribed at least one opioid during the study period

Date of first enrolment

04/01/2021

Date of final enrolment

02/01/2023

Locations

Countries of recruitment

Canada

Study participating centre

Therapeutics Initiative, University of British Columbia
2176 Health Sciences Mall
Vancouver
Canada
V6T 1Z3

Sponsor information

Organisation

Therapeutics Initiative, University of British Columbia

ROR

<https://ror.org/0517h6h17>

Funder(s)

Funder type

Government

Funder Name

Canadian Institutes of Health Research

Alternative Name(s)

Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

Canada

Results and Publications

Individual participant data (IPD) sharing plan

The authors do not have permission to share data from this study. The administrative health data used for this project will be stored on a remote server at the British Columbia Ministry of Health with a high level of security, including encrypted identifiers. Access to the data will be

password protected. All data will be encrypted and password protected. Only files that are de-identified will be used by the PI, and CO-I's and analysts, for analysis. The impact evaluation analyses will also be done in the Ministry's secure data environment, and only aggregate data (tables with cell sizes 5+) will be exported, to prevent re-identification of data. The de-identified impact evaluation analyses will be held in the Ministry's secure data environment until 2023 for the purposes of publication.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	primary outcome for a 6-month window before vs. after each mailed intervention	04/10/2023	10/10/2023	Yes	No
Results article	incidence of opioid analgesic initiations	31/03/2022	21/12/2023	Yes	No
Protocol article		31/05/2021	04/06/2021	Yes	No
Other publications	Development of intervention and results of pilot study	11/05/2022	12/05/2022	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol (other)	Poster for the virtual Addiction Health Services Research (AHSR) conference 2020	24/09/2020	26/01/2022	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes