POPLAR Data Platform

Letter of Information and Physician Consent

Study Title:	Primary Care Ontario Practice-Based Learning and Research Network (POPLAR) Data Platform
UTOPIAN Director:	Dr Michelle Greiver Department of Family and Community Medicine University of Toronto
UTOPIAN Associate Director	Dr Karen Tu Department of Family and Community Medicine University of Toronto
UTOPIAN Data Analytics Manager	Babak Aliarzadeh UTOPIAN University of Toronto

Thank you for your interest in participating in the POPLAR Data Platform.

The Primary Care Ontario Practice-Based Learning And Research Network (POPLAR) brings together Practice-Based Learning and Research Networks (PBLRNs) across Ontario to provide a central hub and platform for primary care health data, research, and innovation. See https://www.poplarnetwork.ca/. The POPLAR Data Platform contains a secure, provincial data repository allowing the analysis of primary care health data extracted from the EMRs of participating physicians.

The University of Toronto Practice-Based Research Network (UTOPIAN) is one of the Networks participating in POPLAR. UTOPIAN is based at the Department of Family and Community Medicine at the University of Toronto, serving primary care across the GTA and beyond.

Before agreeing to participate in this study, we ask that you read this letter of information. You will be given this letter as well as a copy of the consent form for your own reference.

Purpose

You are being invited by UTOPIAN to participate in the POPLAR Data Platform. The purpose of this project is to create a de-identified, standardized, and researchable database called the POPLAR Database, using health data from the EMRs of participating primary care providers. To study patient care, the POPLAR Database will include non-identifying information on demographics and health conditions for which you are seeing your patients.

Project Objectives:

1. To create an Ontario primary care data platform to support research, epidemiology, health system monitoring and quality improvement activities.
2. To provide secure, accessible data options for the purposes of acute and chronic disease surveillance and research, and provide timely, high quality analysis and feedback reporting for participating providers as well as other stakeholders
3. To devise computerized algorithms and/or use other information technology processes to enhance data collection and quality processes
4. To share data in privacy-protecting ways with approved health entities
5. To enable more efficient methods of recruitment to approved clinical trials in Ontario
6. To work with stakeholders, including patients, primary care providers and their representative organizations, and ministries, on alignment of strategy, goals and objectives for the POPLAR Data Platform and POPLAR Database

Methods

If you agree to participate, we are asking your permission, as health information custodian of your patient records, to collect information from two sources within your practice:

1) Provider and practice information through the Provider Questionnaire:

Participating physicians and nurse practitioners (Sentinels) will be asked to complete a short information questionnaire, which will be provided with this letter of information. This questionnaire will take approximately 15 minutes to complete.

A unique study identification number (Sentinel ID#) will be assigned to each Sentinel after signed, informed consent is received. This will be used to enter the information received from each sentinel's completed questionnaire.

We are also asking you to provide your email address. This will be used for important communication and to send you your practice report. The practice report will not contain your name.

2) Patient Data collection:

The custodian, or a delegate, will grant the UTOPIAN Data Analytics Manager or delegate read only access to the EMR to extract health information to achieve objectives outlined above and to support research and quality improvement (QI) projects at your site that will use this extracted data. In cases where practices use an ASP (Application Service Provider) model, in which the EMR software is hosted on a remote server, the custodian or a delegate grants the EMR vendor or intermediary company, permission to extract the data and submit it to the Sentinels or to the UTOPIAN Data Analytics Manager directly on the Sentinels' behalf.

Relevant information from electronic patient records will be extracted to create a secure database that is de-identified and is stored in secure computers inside encrypted drives. Patients in each primary care practice will be informed of the study through posters in the waiting areas. Please contact the UTOPIAN Research Officer if you need to refresh the supply of posters. Please ensure that the posters are always remain in place and visible.

It is important that you alert your patients to these posters as they inform patients about the database, what the database is about, how their health data is used, and who to contact for further information about the study. The posters will also inform patients that they may contact the UTOPIAN Research Officer or their family physician if they prefer that their information not be included in the POPLAR Data Platform (opt-out).

If approached by a patient to opt-out of the data extraction, either you or a delegated member of your staff must notify the UTOPIAN Research Officer. You may do so by contacting us at 416-978-7017 or dfcm.utopian@utoronto.ca. No data relating to patients who decline to participate will be extracted and used once we receive an opt-out request from a patient.

Information from the EMR will be gathered in the following manner:

For each family practice:

- The UTOPIAN Data Analytics Manager (UTOPIAN DAM) oversees the extraction, as well as cleaning, coding and uploading health data onto the POPLAR Data Platform server. The extraction and data transformation process occurs approximately every three months. Frequency of extraction may increase (e.g., weekly, or daily).
- Patient direct identifiers such as name or health cards numbers will be collected and partitioned upon receipt to a secure area and are inaccessible to the researchers and unauthorized staff. These identifiers are only accessible to authorized personnel; they are used for purposes of improving de-identification processes and for permitted linkage to other databases. At the Sentinel practice, a system generated number for each patient is extracted from the practice's EMR. It is called the EMR ID. The EMR ID is an arbitrary number assigned to each patient within an EMR database; it is considered unique for each patient and will be used to generate another random number that is unique for each patient and is used as a patient study number. We call this ID patient POPLAR ID.

- The two IDs together are saved in a file called "EMR Data Linkage File" which is stored on the POPLAR server. The EMR Data Linkage File is important because this is a longitudinal and ongoing database and we therefore need to be able to reliably monitor patients over time and recognize new patients who are being added to Sentinel's patient population during each extraction or "cycle", without directly identifying patient information or without creating a risk of re-identifying the patient from the anonymized health data. It is not possible to re-identify the patient from these two IDs unless this file is linked back to the source EMR data, so this protects the confidentiality of the patient whose data are included. At the same time, the ability to re-identify at your site makes it possible to have quality improvement projects or Research Ethics Board (REB) approved projects that require patient re-identification at the site. All research projects require project specific approval from a REB . The EMR Data Linkage File also helps identify and remove a patient who has notified you that she or he does not wish to participate.
- Health data such as conditions, encounters, prescriptions, referrals, laboratory tests, diagnostic tests, consult and referral letters, immunization data, and essentially all clinically relevant information contained within the EMR are extracted. We use several de-identification and data transformation steps to ensure that your patients cannot be re-identified in conjunction with the de-identified clinical health data extracted from your EMR.
- All documents stored in a picture-like format such as pdf, tiff, jpeg will also be stored separately and securely apart from the final POPLAR Database used for research and QI. Access to these documents will only be by designated personnel and staff and researchers with required signed confidentiality agreements for projects with REB approval.

For the POPLAR Data Platform and POPLAR Database:

- Following extraction, the data from each participating Sentinel's EMR will be transferred to the POPLAR Data Platform server through an encrypted internet connection or virtual privacy network (VPN) for aggregation. This is followed by removal of identifiers that may inadvertently have been entered in free text fields of the records (i.e., phone numbers, physician names). Data processing in the POPLAR server is done within encrypted folders that are accessible only by the POPLAR Data Analytics Team which consists of authorized personnel of POPLAR networks, including the UTOPIAN DAM.
- For Sentinels that are using Application Service Provider (ASP) model of EMR, a copy of the Sentinel's consent form will be provided to the EMR vendor and data extraction will be done by the vendor and then delivered to the Sentinel or the UTOPIAN DAM through secure data transfer methods.
- The UTOPIAN DAM will store the health data on a secure computer protected with a strong password, housed in a secure locked facility: Compute Canada's high security Centre for Advanced Computing (CAC) at Queen's University, Kingston, Ontario.
- The de-identified data from each participating practice will be combined to create the final **POPLAR Database**, which will be used by authorized researchers and their teams to answer questions about health care and our healthcare system.
- The data will be retained for the duration of the database, which is intended to be ongoing, for all patients that do not opt out, and for all providers that do not withdraw consent.
- No data that can identify patients or their primary care providers will be part of the POPLAR Database.

For Linkage to the Institute for Clinical Evaluative Sciences (ICES) or other prescribed entities[i]

- We will securely transmit your College of Physicians and Surgeons of Ontario (CPSO) number for linkage to data held at prescribed entities. These linked data will be used to study health services and outcomes within physicians' practices. No data identifying you will be released. Physical security measures, technological safeguards like encryption and a robust framework of policies and procedures work together to protect information.
- To allow linkage of data to databases held in ICES, a separate linkage file with patient unique identifier will be generated and will be securely transferred to ICES for linkage to administrative databases. This file will include patient POPLAR ID and patient health card number (OHIP number) or other necessary identifiers. We call this file (relevant organization name) linkage file.
- Once data are securely at ICES, the linkage file will be used to link POPLAR data to ICES or other data holdings including administrative health databases.
- No data identifying you or your patients will be released from ICES. Withdrawal of consent shall not have a retrospective effect. ICES' authority to use and disclose data previously disclosed to ICES will continue and will not be affected
- Linkage to data held at other prescribes entities will be conducted in the same or similar method described above

For National Level data at the Canadian Primary Care Sentinel Surveillance Network (CPCSSN):

- After the data in the POPLAR Data Platform has been further de-identified, cleaned, coded and formatted to mitigate any risk of patient re-identification from the anonymized health data, a copy will then be forwarded to and merged with the databases of other Networks participating in CPCSSN to form a National CPCSSN Data Repository.
- The CPCSSN Central Data Repository may be used by approved researchers to answer questions about primary care of chronic diseases and related conditions.
- Researchers will not be able to use data from the CPCSSN Central Data Repository, for linking or matching with other data bases that could result in the re-identification of your patients.

For participation in the Diabetes Action Canada to form a Diabetes Data Repository

- Diabetes Action Canada (DAC) is a CIHR-funded Chronic Disease SPOR project that aims to improve the care of patients with diabetes through a comprehensive program of research, quality improvement and service.
- We request your permission to forward a copy of data for those patients identified as having diabetes, to the National Diabetes Data Repository for the prevention of the complications of diabetes for Canadians. Patients who are not diagnosed with diabetes will be selected at random from the entire database, that may or may not include your patient(s), as a comparator (control group). The combination of the exposure group (patients with diabetes) and the control group (patients without diabetes) will enable researchers to design cohort or case-control studies and test

[i] Prescribed entities: organizations deemed under PHIPA as authorized to hold personal health information for the purposes of evaluation of our healthcare system. See: https://www.ontario.ca/laws/regulation/r18523

their hypothesis against similar patients with or without complex needs which will provide validity to study results.

- This will be a subset of data for diabetes and will be held in a virtual research environment hosted at the **secure** Centre for Advanced Computing. **It will not include any personally identifiable information.**

We intend to present results of studies done using the POPLAR Database at conferences and other venues and to publish them in peer-reviewed publications. Reports, publications, and presentations will be made for groups of people only; no information will be released in which it is possible to identify you, your patients, or other members of the health care team directly or indirectly.

The research team will send each physician a confidential practice report comparing their practice results and aggregate results for other participating practices. When available, the Sentinel's data that has been cleaned and standardized by the research team, along with software capable of generating customized reports using the improved data (the Data Presentation Tool or DPT) may be returned to the practice.

The research team agrees to report to you any breach of confidentiality and/or security respecting your patients' health data where such breach may result in the identification of one or more of your patients. Regardless of whether or not the data involved in the breach results in identification of your patient or patients, POPLAR, UTOPIAN, and/or CPCSSN, as the case may be, will take immediate and reasonably necessary steps to both remedy the breach and prevent similar occurrences in the future. You will be notified as soon as reasonably possible if such breach involves one or more of your patients' data.

Potential uses of data in Clinical Research

The POPLAR Database may be used for additional research studies, serving as a recruitment database for interventional studies conducted in primary care. This would allow an enlargement of the pool of potential participants and an increase in recruitment rates for approved clinical research. Prior to any recruitment, additional REB approval will be sought to permit the recruitment of physicians and patients; this will be in addition to the POPLAR Data Platform REB approval (this protocol). If there is REB approval for recruitment to interventional studies, data may be re-identified solely at each site where sentinels agree to participate in a particular study. Family physicians may provide permission to trained UTOPIAN staff to do the work to enable and facilitate this process.

Preliminary queries – strategy for targeted recruitment for interventional studies

The study team may approach POPLAR or UTOPIAN to conduct a preliminary search of the POPLAR Database to identify the approximate number of potentially eligible patients and the general location of sites/physicians with the highest concentration of these patients. The UTOPIAN Data Analytics Manager does not share details of the query with the study team; the study team is given approximate numbers and sites of interest. This preliminary search allows the study team to develop an efficient target strategy and confirm study feasibility.

Post-REB approvals and consents – recruitment for interventional studies

Once the study team has obtained REB approvals at sites and individual physicians have agreed to participate in the study, the study team may request a list of de-identified POPLAR IDs (as described in Appendix A, page 3) for potentially eligible patients for each participating physician who has agreed to take part in the study. The study team or UTOPIAN staff member(s) then work with the site (physicians, site data manager, EMR lead, other administrative staff, etc. – role depends on each site) to generate a list for potential recruitment at the site, through re-identification of the codes at the site.

Based on a specific REB, each physician would be provided with a list of their potentially eligible patients for review to determine whether their patients may be appropriate for the study. With appropriate REB approvals and permissions, an additional screening may be done at the site level to confirm eligibility (i.e., chart review).

Once patients are identified and eligibility is confirmed, the study team will proceed with recruitment as per the study specific REB approval.

Voluntary Participation

Participation in this project may be terminated by either party at any time. Taking part in this study is voluntary. If you do give your consent to complete the Provider Questionnaire, you may refuse to answer any questions, and withdraw from participation at any time.

Risks and Benefits

There is very little risk to you in participating in this study, although there is the chance that you may be uncomfortable with the results for your own practice. The benefit is that you will receive useful information on chronic diseases that may inform your practice and may be used to plan, measure and monitor quality improvement efforts that are relevant to you.

Confidentiality

The POPLAR Data Platform is stored on a secure computer protected with a strong password, housed in a secure locked facility: Compute Canada's high security Centre for Advanced Computing at Queen's University, Kingston, Ontario. Only authorized POPLAR staff have direct access to de-identified heath data of patients.

[Insert research site name] has direct access to participant medical/clinical study records.

Questions:

If you have questions about taking part in this study, you may contact the UTOPIAN Director: Dr Michelle Greiver, at michelle.greiver@nygh.on.ca or call 416-978-7017.

If you have questions about your rights as a research participant or how the study is being conducted please feel free to contact the Health Sciences Research Ethics Board at the University of Toronto, ethics.review@utoronto.ca or 416 946 3273.

POPLAR Data Platform Consent Form

Title of Project: POPLAR Data Platform
Principal Investigator: Dr. Michelle Greiver
Contact Information: dfcm.utopian@utoronto.ca or 416-978-7017

Please complete the following (check Yes or No)	Yes	No
Do you understand that you have been asked to contribute EMR data to the POPLAR Data Platform?	○	○
Have you read and received a copy of the attached Letter of Information?	○	○
Do you understand the benefits and risks involved in taking part in the POPLAR Data Platform?	○	○
Have you had an opportunity to ask questions and discuss this?	○	○
Do you understand that you are free to withdraw at any time without having to give a reason and without it affecting you?	○	○
Has the issue of confidentiality been explained to you?	○	○
Do you understand who will have access to the records of your patients, and what information they are seeking to obtain?	○	○

Copies of the final POPLAR Database will be forwarded from the POPLAR Data Platform, with appropriate safeguards and permissions, to the following organizations:

1. The Institute for Clinical Evaluative Sciences (ICES) or other prescribed entity
2. The Canadian Primary Care Sentinel Surveillance Network (CPCSSN)
3. Diabetes Action Canada (DAC)

If you **do not** agree to have copies forwarded, please indicate:

I do not agree to have a copy of data for my practice forwarded to ICES or other prescribed entity ☐

I do not agree to have a copy of data for my practice forwarded to CPCSSN ☐

I do not agree to have a copy of data for my practice forwarded to DAC ☐

I agree to take part in this study: ☐ **YES** ☐ **NO**

Name: _____ **Email*:** _____

Signature of Research Subject: _____ **Date:** _____

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

Signature of Investigator or Designee: _____ Date:_____

* Provider email is collected for communication and in order to return individual feedback reports. These reports are confidential and will be sent directly to the participating physician.