



Family & Community Medicine
UNIVERSITY OF TORONTO



Letter of Information and Physician Consent

Study Title: **The UTOPIAN Data Safe Haven**

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Thank you for your interest in our UTOPIAN electronic medical record (EMR) database. UTOPIAN is the University of Toronto Practice-Based Research Network at the Department of Family and Community Medicine. 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 to participate in the UTOPIAN Data Safe Haven. The UTOPIAN Data Safe Haven is a researchable database comprised of de-identified information extracted from electronic patient records in primary care practices in Ontario associated with the University of Toronto and beyond. To study patient care, the project will include non-identifying information on demographics and health conditions for which you are seeing your patients.

The objectives of this database include:

- To derive descriptive measures of primary health care, including:
 - Volume per provider of single encounters and episodes of care
 - Frequencies of disease diagnoses in primary care
 - Quality of care for health conditions
 - Comprehensiveness of care for health conditions
- To assess the validity of the above measures of primary care by:
 - Comparing the measures using electronic patient record data with related health administrative data-bases.
- To assess the ability to generalize the above measures of primary care by comparing electronic patient record data received from this study with other sources of health information (for example provincial or federal health administrative data).

Methods

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

1) Health Professional information and Questionnaire:

Participating physicians and nurse practitioners (Sentinels) will be asked to:

- Complete a questionnaire, which will include items such as gender, hours spent in patient care, and year of graduation from professional school, as well as aspects of the health care team. 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 health professional's completed questionnaire. We are also asking you to provide your email address. This will be used for 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 also to support research and quality improvement 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 Practice Coordinator 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 Practice Coordinator or their family physician if they prefer that their information not be included in the UTOPIAN Data Safe Haven (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 Practice Coordinator. You may do so by contacting us at 416-978-7017. 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 electronic patient records will be gathered in the following manner:

For each family practice:

- The UTOPIAN Data Analytics Manager oversees the extraction, as well as cleaning, coding and uploading health data onto the UTOPIAN Data Safe Haven server. The extraction and data transformation process occurs approximately every three months. Data used for research on the server has been anonymized (as defined by the TCPS2ⁱ)
- 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 UTOPIAN ID.
- The two IDs together are saved in a file called "EMR Data Linkage File" which is stored on the UTOPIAN 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

ⁱ "Anonymised Information" is defined in the Tri-Council Policy Statement, *Ethical Conduct of Research Involving Humans, 2010* (TCPS2), as "the information is irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low."

ability to re-identify at your site makes it possible to have quality improvement projects or Research Ethics Board approved projects that require patient re-identification at the site. All research projects require project specific approval from a Research Ethics Board. 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, essentially all clinically relevant information contained within the EMR are extracted, along with demographic and socio-economic status information from Statistics Canada that is tied to the patient's postal code. We use several de-identification and data transformation steps to ensure that your patients cannot be re-identified in conjunction with the anonymized 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 main UTOPIAN research database. 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 UTOPIAN Data Safe Haven, University of Toronto:

- Following extraction, the data from each participating Sentinel's EMR will be transferred to the UTOPIAN Data Safe Haven server through an encrypted internet connection or virtual privacy network (VPN) for aggregation, 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 UTOPIAN server is done within encrypted folders that are accessible only by UTOPIAN Data Analytics Manager.
- 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 a UTOPIAN Data Analytics Manager through secure download methods.
- The UTOPIAN Data Analytics Manager will store the health data on a secure computer protected with a strong password, housed in a secure locked facility. This facility is Compute Canada's high security Centre for Advanced Computing at Queen's University, Kingston, Ontario.
- The data from each participating practice will be combined to create the UTOPIAN Data Safe Haven. The UTOPIAN Data Safe Haven will be used by researchers approved by the Department of Family and Community Medicine, University of Toronto, 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 research database.

For Linkage to the Institute for Clinical Evaluative Sciences (ICES) or other prescribed entities (organizations deemed under PHIPA as authorized to hold personal health information for the purposes of evaluation of our healthcare system)

- 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 or other prescribed entities, , a separate linkage file with patient unique identifier will be generated and will be securely transferred to ICES or other prescribed entities for linkage to administrative databases. This file will include patient UTOPIAN 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 or other prescribed entity, the linkage file will be used to link UTOPIAN data (that is transferred separately to the relevant organization) to ICES or other prescribed entity data holdings including administrative health databases.
- No data identifying you or your patients will be released from ICES or other prescribed entity.
- Withdrawal of consent shall not have a retrospective effect. ICES' or other prescribed entities authority to use and disclose data previously disclosed to ICES or other prescribed entity will continue and will not be affected

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

- After the data in the UTOPIAN Data Safe Haven 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 form a 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 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 data centre. **It will not include any personally identifiable information.**

We intend to present results of studies done using UTOPIAN Safe Haven data 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, 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 UTOPIAN Data Safe Have 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 UTOPIAN DSH REB approval. If there is REB approval for recruitment to interventional studies data may be re-identified solely at each site where sentinels (family physicians contributing data) 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 UTOPIAN to conduct a preliminary search of the Data Safe Haven 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 UTOPIAN 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 participate in the Sentinel Survey, you may refuse to answer any questions, and you may 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.

Clinical Trials Ontario

Representatives of Clinical Trials Ontario, a not-for-profit organization, may see study data that is sent to the research ethics board for this study.

Confidentiality

The UTOPIAN Data Safe Haven is stored on a secure computer protected with a strong password, housed in a secure locked facility. This facility is Compute Canada's high security Centre for Advanced Computing at Queen's University, Kingston, Ontario. Only approved UTOPIAN Data Analytics staff and Manager have direct access to de-identified health data of patients.

Your site 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.