MTTS PROJECT DATA REQUEST FORM

Date of request: September 4th, 2020

**Name:** Ashley Lacombe-Duncan

**Contact phone:** 734-274-3371

**E-mail address:** [lacombed@umich.edu](mailto:lacombed@umich.edu)

**Instructions:**

Please complete an electronic copy of this form and submit to the TWIRI coordinator ([harshita.iyer@wchospital.ca)](mailto:harshita.iyer@wchospital.ca)) and copy the PI (mona.loutfy@wchospital.ca).

Please review the ‘MTTS Project and Data Request Policy’ section of this document before beginning. For most sections below you only have to write one or two sentences. If you have any questions, please contact the WHRP coordinator.

1. **Student-related work:**

Yes  No 🡪 If no skip to Question 2

Thesis related? Yes  No **If yes, Supervisor’s name & affiliation:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Student project for coursework?  Yes  No

Student project for practicum?  Yes  No

Other student project?  Yes  No **Details:**

1. **Provincial cohort inclusion:**

|  |  |  |
| --- | --- | --- |
| Ontario: | Yes | No |
| Québec: | Yes | No |

1. **Type of Knowledge translation:**

Journal Manuscript:  Yes  No **Which journal**:

Conference Abstract:  Yes  No **Which conference:** National Transgender Health Summit (https://prevention.ucsf.edu/transhealth/education/nths), National LGBTQ Health Conference (https://isgmh.northwestern.edu/events/national-lgbtq-health-conference/)

**If yes, please specify abstract submission deadline:** Not currently announced, will anticipating 2020 (December) or early 2021

Presentation:  Yes  No **Details**:

Community KTE:  Yes  No **Details**: Next TWIRI conference, perhaps we can do a Snapshot from MTTS findings

Other:  Yes  No **Details:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Suggested study title:** Access to Medical Gender Affirmation Among Trans Women With and Without HIV
2. **Suggested Lead Team and co-authors:**

Ashley Lacombe-Duncan, Yasmeen Persad, Mostafa Shokoohi, Angela Underhill, Pierre Coté, Nimâ Machouf, [research assistants], [participating site physicians], Mona Loutfy

1. **Description of Study (Maximum 200 words):**

Gender affirmation, a process whereby a person receives recognition and support for their gender identity and expression,1 is a social determinant of health for trans people.2 Medical gender affirmation may include hormone therapy, surgical care (e.g. breast augmentation) and/ or non-medical procedures (e.g. electrolysis)3 that support the alignment of one’s physical characteristics with one’s gender. Although not all trans people access medical gender affirmation, professional organizations recognise that access is medically necessary to support the health and well-being of those who require it,4 with manifold positive psychosocial effects including reduced suicidal ideation, depression, substance use and stigma, as well as increased quality of life and resilience.5,6 Preliminary evidence suggests that trans women living with HIV may experience poorer access to medical transition than trans women not living with HIV.7 Moreover, our prior qualitative work with trans women living with HIV identified the ways in which HIV stigma impeded and HIV health facilitated access to medical gender affirmation, in addition to multiple structural barriers (e.g., low income) to accessing medical gender affirmation.8 **As such, it is critically important to quantitatively explore differences in access to medical gender affirmation among trans women with and without HIV, and to identify any other factors (beyond HIV status) that may impact such access.**

1. Sevelius JM. Gender affirmation: a framework for conceptualizing risk behavior among transgender women of color. *Sex Roles* 2013; 68: 675–89.
2. Reisner SL, Radix A, Deutsch MB. Integrated and gender-affirming transgender clinical care and research. *J Acquir Immune Defic Syndr* 2016; 72: S235–42.
3. Coleman E, *et al*. Standards of care for the health of transsexual, transgender, and gender-nonconforming people, Version 7. *Int J Transgend* 2012; 13: 165–232.
4. World Professional Association for Transgender Health (WPATH). Standards of care for the health of transsexual, transgender, and gender nonconforming people, 7th edn. East Dundee: World Professional Association for Transgender Health; 2012.
5. Crosby RA, Salazar LF, Hill BJ. Gender affirmation and resiliency among Black transgender women with and without HIV infection. *Transgend Health* 2016; 1: 86–93.
6. Rotondi NK, Bauer GR, Travers R, Travers A, Scanlon K, Kaay M. Depression in male-to-female transgender Ontarians: results from the Trans PULSE project. *Can J Commun Ment Health* 2011; 30: 113–33.
7. Wilson EC, Chen YH, Arayasirikul S, Wenzel C, Raymond HF. Connecting the dots: examining transgender women’s utilization of transition-related medical care and associations with mental health, substance use, and HIV. *J Urban Health* 2015; 92: 182–92.
8. Lacombe-Duncan et al. (2020). Gender affirming healthcare experiences and medical transition among transgender women living with HIV: A mixed methods study. *Sex Health* 2020; 16: 367-376.
9. **Study objective(s) and hypotheses:**

**Objective 1:** To determine the prevalence of a) current feminizing hormone therapy use, b) ever feminizing hormone use; and, c) planned or completed gender affirming surgery (collectively referred to as medical gender affirmation) among trans women within the MTTS and the factors associated with medical gender affirmation, such as age, race, HIV status, etc..

* 1. **Hypothesis 1:** As this is an exploratory analysis, there is no specific hypothesis, other than that uptake of gender affirming surgery will be low among trans women (i.e., a low prevalence of planned or completed gender affirming surgery and a high number of missing variables). Variables of particular interest and that are hypothesized to be associated with medical gender affirmation are younger age, white race, and HIV negative status. A sensitivity analysis will need to be done with and without patients whose charts were collected from the Endocrinologist’s office. Also, sensitivity analyses: 1) excluding all those who had missing results (i.e., full case analysis, missing=excluded) and 2) counting all those who had missing results as no (i.e., missing=no) will need to be done in addition to the base multinomial analyses for current feminizing hormone use (Yes, No vs. missing), ever feminizing hormone use (yes, no vs. missing) and planned or completed gender affirming surgery (Yes, No vs. missing) being conducted.

**Objective 2:** To determine the prevalence of specific gender affirming surgeries, including: a) oriechtomy; b) chest surgery; c) vaginoplasty; d) facial surgery; e) body weight redistribution; and e) chondrolaryngoplasty and, where possible based on sufficient sample size, and the factors associated with medical gender affirmation, such as age, race, HIV status.

* + - 1. **Hypothesis.** As this is an exploratory analysis, there is no specific hypothesis, other than that the prevalence of each gender affirming surgery will be low among trans women and there will be a high number of missing variables. If the n of each of these outcomes is too small, no exploratory analyses will be conducted.

1. **Name and affiliation of person completing the analysis:** Ashley if data sharing agreement approved by WCH/U-M in time (with support of Mostafa), or Mostafa
2. **Study design, and participant inclusion and exclusion criteria:**

Participants are included in the analysis if they meet the following criteria:

Participants are included in the analysis if they meet the following criteria: all participants from the consolidated database are to be included.

Participants are excluded if they meet the following criteria: N/A

1. **Main outcome measure(s) and their definitions:**

***Please refer to the MTTS Data Collection Form. Please identify variable names, and also be as specific as possible (e.g., specify groupings, etc).***

|  |  |  |
| --- | --- | --- |
| Outcome for Objective 1 | Variable ID | Outcome |
| Current feminizing hormone use (row 286) | trans\_clin\_fem\_horm\_now | N (%)  1, Yes  2, No  999, Missing |
| Ever feminizing hormone use (row 284) *Note*: may not look at both current feminizing hormone use and ever feminizing hormone use, depends on the distribution of the variables including missing data. Maintaining in the DRF to explore. | trans\_clin\_fem\_hormone | N (%)  1, Yes  2, No  999, Missing |
| Planned or completed gender affirming surgery (row 43) | patient\_gender\_affirm\_surg | N%  0, No  1, Yes  999, Missing |
| Outcomes for Objective 2 | Variable ID | Outcome |
| Oriechtomy (row 45) | patient\_surg\_orch\_yn | N%  0, No  1, Yes  2, Planning  999, Missing |
| Chest surgery (row 48) | patient\_surg\_chest\_yn | N%  0, No  1, Yes  2, Planning  999, Missing |
| Vaginoplasty (row 51) | patient\_surg\_grs\_yn | N%  0, No  1, Yes  2, Planning  999, Missing |
| Facial surgery (row 54) | patient\_surg\_facial\_yn | N%  0, No  1, Yes  2, Planning  999, Missing |
| Body weight redistribution (row 57) | patient\_surg\_wt\_redist\_yn | N%  0, No  1, Yes  2, Planning  999, Missing |
| Chondrolaryngoplasty (row 60) | patient\_surg\_throat\_yn | N%  0, No  1, Yes  2, Planning  999, Missing |

1. **Explanatory variables of interest:**

***Please refer to the MTTS Data Collection Form. Please identify variable names, and also be as specific as possible (e.g., specify groupings, etc).***

N/A – however, a sensitivity analysis excluding those where data were **not** collected at the Endocrinologist only will need to be conducted as the Endocrinologist is most likely to record medical gender affirmation as not all primary care physicians provide this care. *Note:* this variable is not available to Ashley because of University of Michigan rules about de-identified data, so a derived variable of types of providers seen (GP only, Endo only, GP and Endo) will be used as as a proxy.

|  |  |  |
| --- | --- | --- |
| **Variables** | **Variable ID** | **Response Options** |
| Type of physician(s) seen | Derived from  patient\_have\_gp and  patient\_have\_endocrin  If Yes (1 or 2) to  patient\_have\_gp and No (0) to  patient\_have\_endocrin, Code as 1, GP only  If No (0) to patient\_have\_gp and Yes (1) to patient\_have\_endocrin, Code as 2, Endocrinologist Only  If Yes (1 or 2) to patient\_have\_gp and Yes (1) to patient\_have\_endocrin, Code as 3, GP and Endocrinologist | 1, GP only  2, Endocrinologist only  3, GP and Endocrinologist  999 or blank, Missing |

1. **Covariates:**

***Please refer to the MTTS Data Collection Form. Please identify variable names, and also be as specific as possible (e.g., specify groupings, etc).***

|  |  |  |
| --- | --- | --- |
| **Explanatory variables/covariates** | **Variable ID** | **Type of variable** |
|  | | |
| **Sociodemographic Factors** | | |
| Age (row 6) | Sociodemo\_age | Median [IQR]  N (%)  16-30  30-40  40-50  50-60  60+  *Note:* we will need to review overall proportion and collapse before conducting analyses. Plan to have a group meeting. |
| Race (row 8, 9) | Sociodemo\_race Sociodemo\_race\_other | N (%)  1, White  2, Black  4, Indigenous  4, Asian  5, South Asian  6, Hispanic  7, Other  999 or blank, Missing  and text (determine if other categories need to be added) |
| Legal status in Canada (row 10) | Sociodemo\_legal\_status | N (%)  1, Canadian Citizen  2, Landed Immigrant / Permanent Resident  3, Refugee / Protected Person  4, Refugee claimant / person in need of protection  5, Here with temporary work papers  6, Here with Humanitarian and compassionate approval  7, Here as a visitor  8, Here on a student visa  9, Undocumented / illegal immigrant|999, Missing |
| Birthplace (row 11, 12)  *Note:* During analyses, will need to choose one between birthplace and legal status in Canada and only use one for modeling due to high colinearity. | Sociodemo\_birthplace Sociodemo\_birthplace\_other | N (%)  1, Canada  2, Other  999 or blank, Missing  or text (determine if other categories need to be added) |
| Relationship status (row 13, 14) | Sociodemo\_relationship Sociodemo\_reship\_other | N (%)  1, Legally married  2, Common Law  3, In a relationship  4, Single  5, Separated / divorced  6, Widowed  7, Other  999 or blank, Missing  or text (determine if other categories need to be added) |
| Employment status (row 15) | Sociodemo\_employ\_status | N (%)  1, Employed  2, Not employed  999 or blank, Missing |
| Receiving social assistance (row 16, 17)  *Note:* During analyses, will need to choose one between employment status and receiving social assistance and only use one for modeling due to high colinearity. The distribution of all variables will be checked before making decisions about modeling. | Sociodemo\_rec\_assistance Sociodemo\_assistance\_other | N (%)  1, ODSP / FRSQ – Disability  2, Ontario Works  3, Quebec Social Assistance Benefits  4, Canada Pension Plan  5, Old Age Security  6, Other  7, Not receiving aid  999 or blank, Missing  or text (determine if other categories need to be added) |
| **Clinical and Healthcare Factors** | | |
| HIV status (row 39) | patient\_hiv\_status | N (%)  0, Negative  1, Positive  999 or blank, Missing |
| Ever diagnosed with a mental health condition (row 458) | addl\_mh\_condition | 0, No  1, Yes  999 or blank, Missing |
| Current other medical diagnoses (other than HIV and mental health, for example, arthritis, asthma, cancer, etc.) (row 461) | addl\_health\_condition | 0, No  1, Yes  999 or blank, Missing |
| Type of physician(s) seen | Derived from  patient\_have\_gp and  patient\_have\_endocrin  If Yes (1 or 2) to  patient\_have\_gp and No (0) to  patient\_have\_endocrin, Code as 1, GP only  If No (0) to patient\_have\_gp and Yes (1) to patient\_have\_endocrin, Code as 2, Endocrinologist Only  If Yes (1 or 2) to patient\_have\_gp and Yes (1) to patient\_have\_endocrin, Code as 3, GP and Endocrinologist | 1, GP only  2, Endocrinologist only  3, GP and Endocrinologist  999 or blank, Missing |

**15. Statistical analyses:**

***For each objective, please outline the proposed analyses.***

**Analysis 0 – Study population descriptive statistics:** The details regarding the initial total participants and specific frequencies (and proportions) of reasons for exclusion are to be provided if any were excluded. Descriptive statistics of the **socio-demographic and clinical and healthcare factors** listed above as covariates are to bedescribed in Table 1 (example below). These are to be summarized as the population as a whole as they will be summarized by groups in analyses 1 and 2. Continuous variables are to be summarized as medians [interquartile ranges (IQR)] and categorical variables as frequencies (N) and proportions (%).

**Table 1. Sociodemographic characteristics of entire cohort**

|  |  |  |  |
| --- | --- | --- | --- |
| **Variable** |  | **Variables** |  |
| Age (years) | Median [IQR] | Birthplace | N (%) |
| Race | N (%) | Relationship status | N (%) |
| Legal status in Canada | N (%) | Employment status | N (%) |
| All other covariates listed … | N (%) | All other covariates listed … | N (%) |
| Year of first visit (year) | Median [IQR] | Type of physician care  FP only  FP + Endo  Endo only | N (%)  N (%)  N (%) |
| Duration in care (years) | Median [IQR] | Time since last GP and/or Endo visit (years | Median [IQR] |

**Analysis 1:** The prevalence of the each primary outcome (current feminizing hormone therapy use, ever feminizing hormone therapy use, and planned or completed gender affirming surgery) is to be determined and reported as dichotomous variables – yes vs no and reported as N (%) with 95% confidence intervals (95% CIs). Then, in Tables 2 (current feminizing therapy hormone use), 3 (ever feminizing hormone therapy use), and 4 (planned or completed gender affirming surgery), the sociodemographic and clinical/healthcare factors are to be provided using medians (IQR) for continuous variables and N (%) for categorical variables and compared using Wilcoxon rank sum/t-tests and Chi-square testing, respectively. Finally, logistic regression, both univariate and multivariable, is to be done and reported as prevalence ratios and 95% CIs in Tables 5 (current feminizing therapy hormone use), 6 (ever feminizing hormone therapy use), and 7 (planned or completed gender affirming surgery).

Note, a sensitivity analysis will need to be done excluding those where data were collected outside of the the Endocrinologist as the Endocrinologist is most likely to report gender affirming medical care as some primary care physicians do not provide/manage gender affirming medical care. These Tables can be labeled as Tables 5b, 6b, 7b.

Also, two additional sensitivity analyses are to be carried out. The first one will exclude all those who had missing data on the primary outcomes (i.e., full case analysis, missing=excluded) and entered results in Tables 5c, 6c, and 7c. And then another sensitivity analysis counting all those who had missing data on the primary outcomces as no (i.e., missing=no) with results entered into 5d, 6d, and 7d. As a sensitivity analysis for the missing categories we can either create a missing-specific category and put that in the model or we can create a multiple imputation like model and then impute and run the model.

**Analysis 2:** The prevalence of the secondary outcomes (oriechtomy; chest surgery; vaginoplasty; facial surgery; body weight redistribution; chondrolaryngoplasty) will be determined and reported as as a categorical variable - yes vs planning vs no and reported as N (%) with 95% CIs. For variables with sufficient sample size, exploratory analyses will be conducted and reported in Tables 8+. Specifically, sociodemographic and clinical/healthcare factors are to be provided using medians (IQR) for continuous variables and N (%) for categorical variables and compared using Wilcoxon rank sum/t-tests and Chi-square testing, respectively. Finally, multinomial logistic regression, both univariate and multivariable, is to be done and reported as prevalence ratios and 95% CIs .

For internal use only

Co-Lead Decision

**\*Email approval okay in lieu of signatures\***

**\*Email approval okay in lieu of signatures**

**COMMENTS:**

**DECISION:**

Approved

Approved with modifications

Tabled; needs further clarification

Not approved

|  |  |
| --- | --- |
| **Date** | **Dr. Mona Loutfy** |
| **Date** | **Dr. Ashley Lacombe-Duncan** |
| **Date** | **Ms. Yasmeen Persad** |

NOTE TO COORDINATOR: Once approved, please complete this page and save to Y drive for our records.