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| Researcher | Romana Pylypchuk |
| Date of request | 7 June 2019 |
| Proposed title | Development and validation of T2D risk prediction models in primary care patients in New Zealand |
| Proposed co-investigators or supervisors | Rod Jackson |
| Proposed analysts | Romana Pylypchuk |

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| Research questions / study objectives |
| Note: this project is one of the VIEW2020 milestones.  Research questions:   1. What is the performance of already available T2D risk prediction models in New Zealand’s primary care patients? 2. Can a better-performing model be developed using New Zealand’s routinely collected health data?   Objectives:   1. If possible, externally validate published models in the linked PREDICT dataset. 2. Investigate completeness of a range of previously published predictor variables (to be used as pre-specified predictors), in the linked PREDICT dataset. 3. Use multiple imputation methods to replace missing values for the pre-specified predictors. 4. Using the imputed datasets, build sex-specific T2D risk prediction models which include the pre-specified predictors and a composite outcome of HbA1c, diabetes medications and hospital/mortality ICD codes. 5. Assess the explained variation, discrimination, calibration and net benefit of the new T2D prediction models, and compare with the existing models’ performance indicators. |
| Rationale for research |
| 1. **What is already known?**   The incidence of T2D is increasing in New Zealand and worldwide. T2D is associated with serious long-term complications, such as CVD, neuropathy, nephropathy, retinopathy, foot damage, Alzheimer’s disease, hearing loss and depression. These complications are largely preventable if T2D is detected early and managed adequately. Identification of those at high risk of developing diabetes would help target the screening and preventive efforts more efficiently. Established predictors of risk of developing T2D are age, sex, ethnicity, obesity, elevated blood glucose, family history of T2D, smoking, high systolic blood pressure, and abnormal cholesterol and triglycerides levels. Potential additional predictors are markers of inflammation, renal health, and a number of comorbidities and medications.   1. **What are the gaps?**   Validated, easy to use T2D prediction models are not available in New Zealand’s primary care.   1. **What will this study add?**   This study will provide validated T2D prediction models, relevant in contemporary New Zealand’s primary care. Later studies can validate these models in other independently collected datasets. |

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| Type of output proposed (e.g. journal article, conference presentation, thesis) | Journal article, T2D risk prediction models |
| Proposed timeline – month and year (e.g. analysis, first draft, submission) | Analyses start in July 2019 (if the dataset is linked by then)  First draft of results October 2019  Manuscript submission December-January 2019 |

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| Datasets required |

ANZACS-QI ☐

CANCER REGISTRY ☐

HOSPITALISATIONS ☑

IDI ☐

MORTALITY ☑

NATIONAL LAB MONITORING ☑

PHARMS ☑

PREDICT ☑

PRIMARY CARE ENROLMENT ☑

TESTSAFE ☑

OTHER ☐

*If other, describe dataset:*

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| Description of cohort / population | The study cohort is the PREDICT-1O patients, 25-74 years old and diabetes-free at baseline assessment. The risk assessments from January 2006 (or even later?) onwards will be included.  Variables of interest are as follows:   1. eNHI 2. Sex 3. Age at baseline CVD risk assessment 4. Ethnicity 5. NZDep 6. CVD events + dates 7. Mortality status + dates 8. Smoking status 9. BMI 10. History of CVD 11. History of heart failure 12. History of atrial fibrillation 13. History of gestational diabetes 14. History of severe mental illness 15. History of rheumatoid arthritis 16. History of asthma 17. History of hyperthyroidism 18. Hepatitis C 19. Diagnosed polycystic ovary syndrome 20. Systolic blood pressure 21. Lipid ratio (TCL:HDL) 22. Triglycerides 23. HbA1c 24. eGFR 25. ACR 26. Use of blood pressure lowering (beta-blockers, diuretics) medications 27. Use of lipid lowering (statins) medications 28. Use of antipsychotic medications 29. Use of corticosteroids medications 30. Use of immunosuppressant (anti-rejection) medications 31. Use of anti-seizure drugs 32. Use of second generation of ‘atypical’ antipsychotics (amisupride, aripiprazole, clozapine, lurasidone, olanzapine, paliperidone, quetiapine, risperidone, sertindole, zotepine) 33. Use of diabetes drugs (oral hypoglycaemic, insulin) |
| Key analyses |  |

**Data Release Agreement**

We the undersigned understand pending approval that we will:

1. Only use the data that has been approved and released in relation to this agreement.
2. NOT distribute data for any reason, to any person(s), without permission from the VIEW programme;
3. Disclose to the VIEW programme any potential conflict of interest (such as a funder with commercial interests in the project);
4. Store all data and documentation in a secure environment protected from access by any unauthorised person(s);
5. Take all reasonable steps to prevent unauthorised, either deliberate or unintentional, access to Data Set(s) e.g. the dataset will not be emailed, or saved onto a USB stick
6. Ensure all Data Set(s) are be password-protected
7. NOT share the Data Set(s) with anyone outside of the research team named within this Data Access Application Form
8. Update and resubmit the Data Access Application Form if the research objectives, methods and anticipated outputs and/or Researchers change during the proposed timeline
9. Provide a draft outline of any verbal or written presentation of the results to the VIEW programme prior to submission/presentation;
10. Provide reports to the VIEW programme on progress in analyses and preparation of articles, reports or presentations when requested;
11. Acknowledge the source of the data and the role of VIEW named investigators, funders and/or sponsors in any written or verbal presentation;
12. Provide copies of analysis code and a summary of the results to the VIEW programme on completion of the work
13. Destroy the data on completion of the research

I have read the *VIEW Code of Practice for Investigators* and the terms and conditions described above and agree to abide by them (tick here). ☑

*Name Romana Pylypchuk*

*Organisation UoA*

*Date 07/06/2019*

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| Comments from VIEW Investigators *(to be completed by VIEW project manager)* |
| 1. **Feasibility of project** 2. **Potential overlap with other projects** 3. **Relevant ethics approval** |

DAP approved on: Click here to enter a date.

DAP approved by: email ☐ meeting ☐