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Retrospective study of biochemical and haematological changes in diabetes mellitus: The protocol

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We use this protocol and it's working

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Abstract

The research will analyze 10 years clinical laboratory data to evaluate the changes in routine hematological parameters and haemorrheology, as well as routine dyslipidemia and liver function test, in diabetes management. This is a laboratory-based clinical observational study involving retrospective longitudinal analysis using secondary data (archived clinical pathology data) from two health facilities. Mixed methods' statistical designs for analyses of data would be adopted. The broad focus is haematology in diabetes mellitus and potential for whole blood viscosity in cardiovascular complications management.

Abstract

1 The research will analyze 10 years clinical laboratory data to evaluate the changes in routine hematological parameters and haemorrheology, as well as routine dyslipidemia and liver function test, in diabetes management. This is a laboratory-based clinical observational study involving retrospective
longitudinal analysis using secondary data (archived clinical pathology data) from two health facilities. Mixed methods' statistical designs for analyses of data would be adopted. The broad focus is haematology in diabetes mellitus and potential for whole blood viscosity in cardiovascular complications management.

Introduction

2 The need to associate red blood cell indices in diabetes has remained imperative (Obeagu, 2024). This proposed research will therefore determine the correlation of HbA1c changes with haematological parameters and biochemicals such as lipid profile. There is one longitudinal research that determined the correlation between changes in some haematological and biochemical parameters (Ngwu, 2022). This study would benefit with contribution from another longitudinal retrospective study. Further, there is dearth of longitudinal study of blood viscosity in diabetes population, with perhaps the latest PubMed-archived report recommendation being over 16 years ago (Kearney-Schwartz et al., 2007), and yet to be followed up. The rationale for a longitudinal study is establishing a simple and universally available laboratory test method for antiplatelet medicine monitoring in diabetes management. The hypothesis is perhaps changes in eWBV and related haematological parameters will not be significantly different between groups of HbA1c levels. Another hypothesis is levels of eWBV may not be significantly different between subgroups of age, gender, comorbidities, or time points.

The protocol

3 ***Study design:*** This is a laboratory-based observational study involving retrospective longitudinal analysis. Mixed methods statistical analyses of data include cohort and period measures (Dattani, 2023), as well as correlation, cross-sectional and descriptive evaluation approaches (Table 1).

Table 1: Summary of research design and data to be analysed.

SN	Specific research objectives	Design	Statistical Method	Rationale	Data
1	Assess changes in haematological and lipid profiles relative to HbA1c variations in diabetes management.	Descriptive	Central tendencies of FBC& Lipid profile and MANOVA	To advance the case for inclusion of Hematology parameter in the guideline of diabetic management	HbA1c, routine FBC, Lipid profile, Serum protein
		Longitudinal	Retrospective time-series		
	To evaluate how HbA1c levels correlate with haematological and lipid profile parameters.	Correlational	Pearson correlation	Highlight the use of Hematology parameter to manage dyslipidaemia in diabetes management	
2	To investigate the epidemiology of diabetes mellitus regarding eWBV between periods and within cohort.	Longitudinal	Retrospective time-series	Generating epidemiological data useful in predicting the risk of diabetes and its associated complications, for instance the odd ratio for people with prediabetics progressing to diabetes and to cardiovascular complications.	HbA1c, routine FBC, Lipid profile, Serum protein; clinical information including age, comorbidity & gender
		Descriptive (periodic)	Central tendencies of eWBV and MONOVA		
3	To evaluate how hematology parameters and lipid profiles confound HbA1c	Cohort study	Student t-test and ANOVA	Using a large sample size to address the confounding issue of anaemia in diabetes diagnosis thereby reducing error in interpretation of laboratory test result.	Haematology, HbA1c
		Outcome study	Regression analysis		
		Longitudinal	Retrospective time-series		

Setting: Secondary data are archived clinical pathology records from South Western Region of New South Wale health (NSW Health) (Nwose et al., 2010), and a general practice (The wellness House) in Orange. Data from the NSW Health comprises a 10-year pool from Southwest Pathology Service include records of de-identified individuals in regional NSW who were managed for diabetes.

Data: This retrospective study would be utilizing secondary data from archived clinical pathology laboratory information systems (Nwose et al., 2010), as well as from private General Practice (Anyasodor et al., 2021). Variables are as indicated on Table 1.

Ethics clearance: The collections of the two datasets were approved by relevant authorities. The 10 years dataset NSW pathology was cleared and authorized by the then Greater Southern Area Health Service (GSAHS) of NSW through the laboratory management, as previously published. The dataset from private GP had ethical approval (H2014158) from Charles Sturt University human research ethics committee.

The process

4

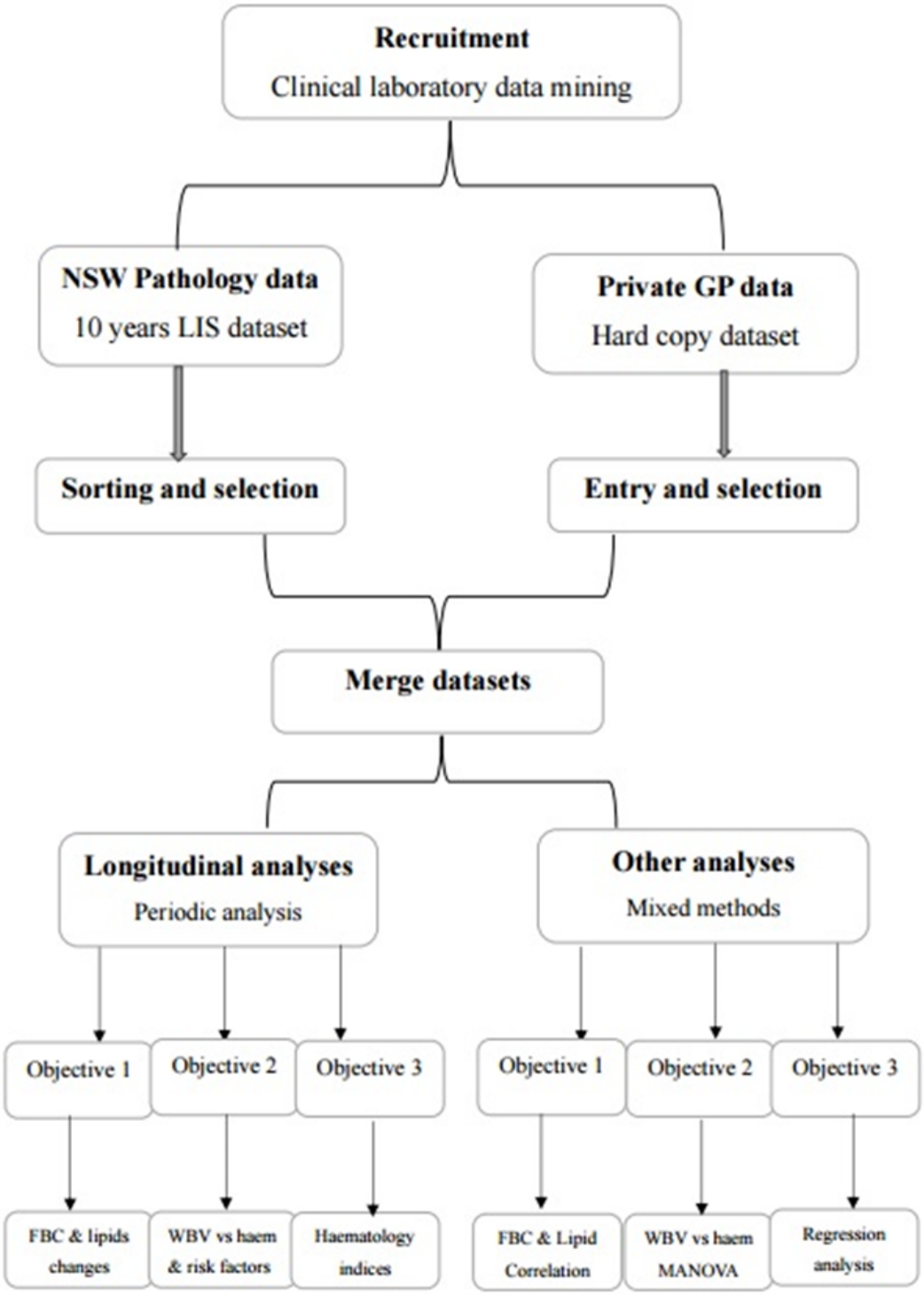

Fig 1: Dynamic flow chart

Conclusion – statement of significance

5 Diabetes is characterized by changes in hematology and lipid profiles and understanding of these changes could be utilized in routine evaluation of subjects in prediabetes as well as managing complications in diabetes. Furthermore, correlation between hematological and lipid profiles over the course of diabetes progression using HbA1c as index of glucose control is necessary for additional empirical data and update. Generated epidemiological data will provide tool for health promotion on progression of the disease leading to how it can be slowed, for instance empirical data on distribution of at-risk groups and risk factors thus allowing for tailoring of interventions. Secondly, this will devise a tool to detect and manage diabetes to prevent of slow adverse complications. Abnormalities such as dyslipidemia are modifiable risk factor in the development of cardiovascular disease. The results/data will highlight changes that will lead to cardiovascular disease and how the progression can be slowed.

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