

# Status, determinants and interventions on cardiovascular disease & diabetes in Sri Lanka: a desk review of research

**2000 – 2018**



**October 2019**



**Ministry of Health,  
Nutrition and  
Indigenous Medicine**



**World Health  
Organization**  
Sri Lanka



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Joint publication with Ministry of Health, Nutrition and Indigenous Medicine, Sri Lanka

# Message from the WHO Representative to Sri Lanka



Non-communicable diseases (NCDs) are a major threat to global health, accounting for nearly 72% of all deaths in 2016, of which nearly three quarters occurred in low- and middle-income countries. NCDs are to a large extent preventable, but little has been done to convert available knowledge or evidence into effective policies and actions. It is therefore important to prioritize issues pertaining to NCDs for research in the development of evidence-based interventions, with a view to translating these into action.

In this backdrop, the comprehensive desk review on the Sri Lankan research evidence on cardiovascular diseases and diabetes and related risk factors, interventions and health system response during 2000-2018 is timely and valuable. It will help guide researchers, policy makers and administrators, and other stakeholders on evidence-based interventions to combat the burden of NCDs in the country.

I congratulate the review team and the lead consultant for their effort in bringing out this publication. I am confident that this will serve as a valuable resource for tackling NCDs in Sri Lanka and beyond.

**Dr Razia Pendse**

World Health Organization Representative to Sri Lanka

# Foreword from Director General of Health Services



I am pleased to send this message witnessing the successful completion of the bibliographic database related to research on major non-communicable diseases (NCDs), risk factors and interventions that prevent and control such diseases in Sri Lanka, as well as the desk review of research conducted on cardiovascular disease and diabetes during the period 2000-2018 in Sri Lanka.

This comprehensive desk review gives us an overview of two major causes of premature mortality and extensive morbidity in the country. It elaborates the disease & economic burden imposed on individuals, family and the country. It further highlights the risky and protective health behaviour of apparently healthy adults as well as patients, through which at-risk population groups could be identified and activities prioritized, so that the onset of diseases and complications could be minimized or delayed. Finally, the review will enable us to revisit the health system response to ensure that no one is excluded in the provision of health care services across all age groups. Another unique outcome of this project would be the updates planned of the bibliography beyond 2018 at regular intervals, so that it would enable us to formulate timely evidence-based interventions.

As the Director General of Health Services, I congratulate the review consultant and her team, and all those who had contributed to the scientific content, compilation and critical review of the bibliographic database and desk review of NCD related research for their enormous contribution

## **Dr Anil Jasinghe**

Director General of Health Services  
Ministry of Health, Nutrition & Indigenous Medicine

# Message from Deputy Director General (Education, Training & Research)



Health research is one of the most essential components towards enhancement of a health system. In accordance, the Ministry of Health Sri Lanka has identified the importance of developing a sustained research culture among healthcare professionals. To this end, collation and review of the available evidence-base is a priority, as it is the key for incorporating extensive, complex and unique evidence into policy and practice. This approach would further guide future research, providing clear insights into the gaps in knowledge that require further researching into.

An increasing trend of non-communicable diseases has been noted over the recent past, which is expected to rise amidst newer threats in the disease epidemiology of Sri Lanka. To face this challenge, the delivery of healthcare is evolving, with more emphasis on primary care. In this backdrop, health research enriched both in quantity and quality could address some of the crucial issues pertaining to major NCDs in Sri Lanka. I congratulate the timely move of the Ministry of Health and World Health Organization, and the review team for undertaking this project. It is fervently hoped that utilization of this review for appropriate evidence-based decisions on the health system, would enhance the health of Sri Lanka.

## **Dr Sudath Samaraweera**

Deputy Director General (Education, Training & Research)  
Ministry of Health, Nutrition & Indigenous Medicine

# Acknowledgements

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The exceptional role played by Dr Nalika Gunawardena, National Professional Officer (Health Systems Analysis and Evidence) of the World Health Organization Country Office, Sri Lanka has been tremendous in giving the technical guidance to the review team, coordinating the work between the Ministry of Health and review team. I also thank the WHO Country Office Sri Lanka especially Dr Razia Pendse, WHO Representative for Sri Lanka for her support in making this publication a reality.

I profusely thank Prof. Jennifer Perera, Dean of the Faculty of Medicine and Prof. MC Weerasinghe, Head of the Department of Community Medicine of the University of Colombo for facilitating this project including the hosting of the bibliographic database in future. I sincerely thank the academic staff members of the Department of Community Medicine for providing insights on the current literature and inputs on recommendations. I specially thank Dr Aruni Gallage, Lecturer in Community Medicine for assisting diligently in the collation of research publications during the initial phase, and Ms S R Marasinghe, Ms H P Uthpala Udayanganie and Ms S N Senadheera for their commitment towards the meticulous preparation of scientific content in a presentable manner for the database.

I sincerely thank Ms. Nadeesha Perera, Senior Assistant Librarian, University of Colombo for her genuine contribution and support extended for conducting the review using Mendeley software, and also the guidance provided by Dr D C Kuruppu, Deputy Librarian, University of Colombo.

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## **Dr S C Wickramasinghe**

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# Status, determinants and interventions on cardiovascular disease & diabetes in Sri Lanka: a desk review of research 2000 – 2018

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**“ I agree that we can always have more evidence, but I am emphatic that we now have enough evidence to take action. ”**

**- SIR GEORGE ALLEYNE**

*Independent High-level Commission on Non-Communicable Diseases 2018-2019*



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# List of Abbreviations

AAQ-CHD- Access to Ambulatory Care Questionnaire for CHD	DBP- Diastolic Blood Pressure
ABI- Ankle Brachial Pressure Index	DCS- Department of Census & Statistics
ACE- Angiotensin Converting Enzyme	DENO- Diabetes Mellitus Educator Nursing Officers
ACEI- Angiotensin Converting Enzyme Inhibitors	DGH -District General Hospital
ACS- Acute Coronary Syndrome	DM- Diabetes Mellitus
ACTH- Adrenocorticotrophic Hormone	DNI- Diabetic Neuropathy Index
ADA- American Diabetes Association	DS- Divisional Secretariat
AHB- Annual Health Bulletin	DTM- Digital Thermal Monitoring
AL- Advanced Level	E Copies- Electronic Copies
ALT- Alanine Aminotransferase	ECG- Electrocardiogram
aOR- Adjusted Odds Ratio	eGFR- Estimated Glomerular Filtration Rate
AR- Androgen Receptor	EPI- Expanded Program of Immunization
ASMR- Age Standardized Mortality Rates	FBS- Fasting Blood Sugar
AST- Aspartate Aminotransferase	FIM- Functional Independence Measure
AUC- Area Under Curve	FMD- Flow Mediated Dilatation
BCC- Behavioural Change Communication	FPG- Fasting Plasma Glucose
BH- Base Hospital	FRS- Framingham Risk Score
BI- Barthel Index	GBOD NutriCoDE- Global Burden of Diseases Nutrition and Chronic Diseases Expert Group
BMI- Body Mass Index	GBOD- Global Burden of Disease Study
BP- Blood Pressure	GDP- Gross Domestic Product
CABG- Coronary Artery Bypass Grafting	GH- General Hospital
CAD- Coronary Artery Disease	GIS- Geographical Information System
CCA- Coronary Cine Angiograms	GN- Grama Niladhari
CFU/mL- Colony-Forming Units per ml	GNI- Gross National Income
CG- Control Group	GNP- Gross National Product
CHD- Coronary Heart Disease	GPAQ- Global Physical Activity Questionnaire
CI- Confidence Interval	GRACE- Global Registry of Acute Coronary Events Risk Score
CIMT- Carotid Intima Thickness	HbA1c- Glycated Haemoglobin
CMC- Colombo Municipal Council	HDL-C- High Density Lipoprotein Cholesterol
CME- Continuous Medical Education	HDL-High Density Lipoprotein
CNTH- Colombo North Teaching Hospital	HES-RAQ- Health System Responsiveness Assessment Questionnaire
COTASS- Colombo Twin and Singleton Study	HFSS- High Fat, Salt and Sugar
CRS- Cambridge Risk Score	HLC- Healthy Lifestyle Centres
CS- Cushing Syndrome	HOMA-IR- Homeostasis Model Assessment of Insulin Resistance
CSHW- Castle Street Hospital for Women	HP- Health Promotion
CSMS- Chronic Stress Measurement Scale	HRQOL- Health Related Quality of Life
CSTH- Colombo South Teaching Hospital	hsCRP- High Sensitivity C Reactive Protein
CT- Computerized Axial Tomography	HT- Hypertension
CVA- Cerebrovascular Accident	iAUC- Incremental Area Under the Curve
CVD- Cardiovascular Disease	IBMBB- Institute of Biochemistry, Molecular Biology
dABI- ABI Measured by Doppler Method	
DALY- Disability-Adjusted Life Years	



and Biotechnology

IDF- International Diabetes Federation

IDRS- Indian Diabetes Risk Score

IFG- Impaired Fasting Glucose

IG- Intervention Group

IGT- Impaired Glucose Tolerance

IHD- Ischaemic Heart Disease

IHME- Institute of Health Metrics and Evaluation

IHP- Institute of Health Policy

IMMR- Indoor Morbidity and Mortality Registers

ICHS- Intra-Cerebral Haemorrhagic Stroke

IPAQ- International Physical Activity Questionnaire

IQR- Inter Quartile Range

IRP- International Reference Price

IS- Ischemic Stroke

ITAS- Insulin Treatment Appraisal Scale

IV- Intravenous

JICA- Japan International Cooperation Agency

KAP- Knowledge, Attitude and Practices

LAD- Left Anterior Descending Artery

LBW- Low Birth Weight

LDL- Low Density Lipoprotein

LDL-C- Low-Density Lipoprotein Cholesterol

LMIC- Low- & Middle-Income Countries

LPG- Lowest Priced Generic

LUNS- Longer Term Unmet Needs after Stroke

MACE- Major Adverse Cardiac Events

MAI- Medication Appropriateness Index

MA- Managerial Assistants

MCH- Maternal & Child Health

MCS- Mental Component Score

MD- Doctor of Medicine

MeSH- Medical Subject Headings

MET- Metabolic Equivalent of Task

MMR- Maternal Mortality Rate

MMSE- Mini Mental Score Examination

MMSE-M- Mini Mental State Examination-Modified

MNSI- Michigan Neuropathy Screening Instrument

MOH- Medical Officer of Health Area

MOH- Ministry of Health

MPhil- Master of Philosophy

MRI- Magnetic Resonance Imaging

mRS- Modified Rankin Scale

MSc- Master of Science

MUFA- Mono-Unsaturated Fatty Acids

n-6 PUFA- n-6 Polyunsaturated Fatty Acids

NAFLD- Non-Alcoholic Fatty Liver Disease

NCD- Non-Communicable Diseases

NCEP-ATP III- National Cholesterol Education Programme- Adult Treatment Panel III

NGO- Non-Governmental Organisations

NHS- National Health Science

NHSL- National Hospital of Sri Lanka

NIROGI Lanka- National Initiative to Reinforce and Organize General Diabetes Care in Sri Lanka

NPP-JICA- NCD Prevention Project Under the Japan International Cooperation Agency (JICA)

NPP- NCD Prevention Project

NSF- National Science Foundation

NSTEMI- Non-ST Elevation Myocardial Infarction

OB- Originator Brand

ODST- Overnight Dexamethasone Suppression Test

OGTT- Oral Glucose Tolerance Test

OHD- Oral Hypoglycaemic Drugs

OPD- Out Patient Department

PCA- Principal Component Analysis

OR- Odds Ratio

P- Probability

pABI- ABI Measured by Pulse Palpation Method

PAD- Peripheral Arterial Disease

PA- Physical Activity

PAT- Peripheral Arterial Tonometry

PCI- Percutaneous Coronary Intervention

PCS- Physical Component Score

PGIM- Postgraduate Institute of Medicine

PHQ-9- Personal Health Questionnaire- 9

PPBS- Postprandial Blood Sugar

PPS- Probability-Proportionate-to-Size

PSN- Peripheral Sensory Neuropathy

PTCA- Percutaneous Transluminal Coronary Angioplasty

PUFA- Poly-Unsaturated Fatty Acids

QOL- Quality of Life

ROC- Receiver Operating Characteristic

RRR- Relative Risk Reduction

SA- Senior Administrative

SBP- Systolic Blood Pressure

SD- Standard Deviation

SDG- Sustainable Development Goals

SF-36- Short Form-36

SFA- Saturated Fatty Acids

sICAM-1- Soluble Intercellular Adhesion Molecule 1

SJGH- Sri Jayewardenepura General Hospital

SLDC- Sri Lanka Diabetes and Cardiovascular Study

SLDHS- Sri Lanka Demographic Health Survey

SLYDS- Sri Lanka Young Diabetes Study

STEMI- ST Elevation Myocardial Infarction

STEPS- STEPwise Approach to NCD Surveillance

TB- Tuberculosis

TC- Total Cholesterol

TFR- Total Fertility Rate	WDI- World Development Indicators
TG- Triglycerides	WMC- Well Men Clinic
TH- Teaching Hospital	WHO- World Health Organisation
TIA- Transient Ischaemic Attacks	WHO/ISH- World Health Organisation/International Society of Hypertension
TICS-M- Telephone Instrument for Cognitive Status-Modified	WHO-PEN- WHO Package of Essential NCD Prevention Interventions for Primary Health Care in Low-Resource Settings
TIMI- Thrombolysis in Myocardial Infarction Scores	WHOQOL-BREF- World Health Organization Abbreviated Generic Quality of Life Scale
UA- Unstable Angina	WHR- Waist to Hip Ratio
UHC- Universal Health Coverage	WHtR- Waist to Height Ratio
UK- United Kingdom	YLL- Years of Life Lost
UKPDS- UK Prospective Diabetes Study	ZDS- Zung Depression Scale
UN- United Nations	Zn- Zinc
UPoD- Unconditional Probability of Dying	
USDA- United States Department of Agriculture	
WC- Waist Circumference	

## List of Annexures

Annexure 1: Key studies on knowledge, attitudes and self-management practices in the management of CVD and DM

# Executive Summary

## Preamble

Major NCDs, namely CVD, DM, cancer and chronic respiratory diseases are increasingly becoming a threat to the world. Each year, 80 million die from these diseases, while those surviving undergo serious morbidity owing to life-long clinical care and disability. This epidemic is propelled by behavioural risk factors accumulated since childhood in adults, such as unhealthy diet, physical inactivity, tobacco consumption and harmful use of alcohol, giving rise to metabolic risk factors, such as hypertension, dyslipidaemia, overweight/obesity and dysglycaemia. Sedentary lifestyles introduced in the last few decades have been responsible for this surge in risk factors among people and the resultant major NCDs in most developing countries, including Sri Lanka.

Despite the impressive health indicators, Sri Lanka is not yet fully geared to tackle the burden of major NCDs, as done with the control of communicable diseases and maternal & child health issues. Health system should be restructured to provide services for patients as well as populations at risk. In line, the Multi-sectoral Action Plan drawn for prevention and control of NCDs needs to be strengthened by low-cost and effective practices and strategies, which are to be identified based on local evidence; and implemented to bridge the gaps in existing healthcare. Currently, there is a wealth of research conducted in this area, which has not been collated in a bibliography during last 20 years. Therefore, a bibliographic and a desk review was undertaken to enable researchers to identify the knowledge gaps for further research, as well as the policy makers in translating the available evidence into an 'implementable' platform.

## Review process

A desk review was undertaken to collate, summarize and analyse the local evidence available from 2000-2018 on the following aspects:

- A. Characteristics and trends in the burden of major NCDs in Sri Lanka
- B. Prevalence and associations of the major NCD risk factors in Sri Lanka
- C. Magnitude of the risk factors in determining major NCDs in Sri Lanka
- D. Curative and preventive interventions on major NCDs and their effectiveness in Sri Lanka

This review was undertaken as follow-up of a bibliographic database that was developed by Health System Research Unit of the Department of Community Medicine, Faculty of Medicine, University of Colombo in collaboration with the WHO Country Office. Literature included in the database was on major NCDs and risk factors, interventions to prevent and control such diseases, and health system response in Sri Lanka for the period 2000-2018.

The desk review was limited to studies conducted on health-related aspects of two of the four major NCDs, namely CVD (stroke, CHD and peripheral artery disease) and DM. Studies where the data were collected in small samples with poor generalizability of the study setting and sampling; case studies and series; studies on children, adolescents, pregnant women and migrant populations; animal-studies; studies on Ayurvedic, complementary or traditional treatment methods; and laboratory-based non-plant therapeutics were excluded. International and local journal articles; postgraduate academic work available in local higher education institutes; abstracts presented at international (if available online) and local conferences; and locally relevant reports published by governmental or non-governmental organizations on routinely collected data (wherever relevant) were perused. Also, studies outside the 2000-2018 period were perused, if shown to be highly relevant. Of the 1359 publications screened, approximately 650 publications are included in the current review.

## Key findings

### Trends in the major NCDs in Sri Lanka

- Several social investments since independence, have led to improvements in the economy and living standards of people in Sri Lanka, resulting in a gradual reduction of communicable diseases and improved maternal & child health. Though still at a higher level, this decline in communicable diseases is coupled with a sharp increase in major NCDs during the last few decades, depicting an epidemiological transition in the country. As in many other developing countries, the causes underlying this epidemic are the demographic transition towards rapid aging of the population in Sri Lanka and sedentary lifestyles, which are the effects of rapid and unplanned urbanization taking place over the last few decades, along with globalization on marketing and trade, leading to an accumulation of multiple risk factors responsible for NCDs.
- According to the latest WHO estimates for 2016, over 80% of the mortality in Sri Lanka is due to major NCDs. This mortality is relatively higher than in the region and closer to that of developed countries. Yet, the probability of premature death before 70 years is 17% in Sri Lanka, which is much higher than in developed countries as well as the forecasted global targets for Sri Lanka in 2020-2025, highlighting a greater burden in Sri Lanka.

### Characteristics of CVD and DM in Sri Lanka

*Quality of the available evidence* - Trends in CVD and DM are well-evident, based on a few surveys and epidemiological studies particularly on DM conducted at national (SLDC Study), provincial and district levels. Conducting follow-up studies as well as national level epidemiological studies in future especially on CHD and stroke is highly recommended for identifying the long-term outcomes of these conditions.

- Over the last few decades, NCDs have shown a sharp increase in the burden of mortality in the country. CVD has been the leading cause of death during last 40 years, with DM and cancer almost doubling in its mortality. Further, compared to the region as well as developed countries, contribution of CVD and DM to the NCD mortality is much greater in Sri Lanka.
- With regards to morbidity, hospital admissions due to major NCDs are increasing every year, with IHD as the leading cause, highlighting the economic burden of these life-long diseases.
- In the absence of surveillance data, the prevalence of major NCDs is mainly estimated based on well-designed epidemiological studies. Accordingly, the following observations are made on DM:
  - Diabetes has demonstrated increasing trends over the years, with marked variation at provincial and district levels.
  - The current prevalence is shown to increase progressively with age in both males and females.
  - It is significantly higher in urban districts as well as in the urban sector within districts, and follows a consistent pro-rich (wealthy and educated) distribution, which is more apparent in females compared to males. These findings suggest that Sri Lanka is still in an early stage of the epidemic, where shifting of the disease prevalence to lower income communities is yet to become prominent at area level.
  - Raised fasting plasma glucose seen in higher proportions in the relatively young high-risk population is remarkable.
  - Another salient finding is the upward trend noted with pre-DM, and its majority as well as a considerable proportion of DM, remaining undetected both in well-established urban settings and those in transition.

- Based on limited epidemiological data, CHD is shown to have fluctuated within a narrow range (6.4%-10.2%) over time, in parallel with stroke (1.4%-1.61%). Consistently, CVD has been more prevalent among the females, whereas stroke is predominantly of ischaemic type with a distinct male predominance and relatively delayed age of onset.
- Unlike the evidence available on the prevalence, evidence on complications caused by NCDs is scarce. Based on available evidence, consequences of DM and CVD are found to be extensive.
  - There is increased prevalence of a wide range of complications among DM patients, some of which are relatively common (e.g. retinopathy and neuropathy in 1/4th of clinic patients, CVD, diabetic foot); rather disabling (e.g. sexual and psychological issues); under-diagnosed in clinic settings; relatively early in onset; and associated with poor glycaemic control and other risk factors.
  - There is evidence on substantial disability following stroke, affecting their physical and mental wellbeing, employment and quality of life.
- With regards to the economic burden, out of pocket payments for NCD related health care, especially for CVD are creating a financial burden in vulnerable households and with advancing life expectancy, patients tend to suffer more with disability, escalating health care cost on life-long treatment and loss of productivity. Costing studies need to be given priority to analyse in-depth the financial burden faced at household level.

## Prevalence and associations of the NCD risk factors in Sri Lanka

*Quality of the available evidence* - STEPS Survey is a commendable effort and an opportunity to capture the trends in major NCD risk factors in Sri Lanka. It is recommended that the NCD Directorate continues to lead this task, while maintaining its quality and consistency of indicators. There had also been several well-designed epidemiological studies on individual or multiple risk factors in apparently healthy populations representative of Sri Lanka, major districts and of high-risk groups, providing solid evidence for prioritizing healthcare services among the vulnerable populations and sectors identified. In addition, a plethora of clinic-based studies is available on the risk factors and underlying associations in patients with DM or CVD.

### Metabolic risk factors

- Of the four metabolic risk factors of CVD and DM, HT, IFG and generalized/central obesity have shown a clear upward trend in prevalence over the years in Sri Lanka. This trend however is not distinctly replicated for dyslipidaemia mainly because of the inconsistency in lipid cut-off levels used in different studies.
- All four risk factors were closely associated with urban living, as evident by higher prevalence seen in relatively urban districts or in urban sector within districts, and furthermore in high-risk occupations.
- Of the risk factors, consistent and significant pro-rich relationships were noted with FPG, and generalised and central obesity in both males and females, however social inequalities may become prominent in future.
- With a slight gender variation, the current prevalence of HT ranges within 25-30%, however remains undiagnosed in a large proportion even in rural settings, highlighting the need for more innovative screening approaches to cover the unreachable. In addition to sedentary workers, the estate workers being at higher risk for HT needs to be explored. Also, the underlying causes of resistant HT and the role of low birth weight for HT should be further investigated.
- The current literature identifies females as having a higher prevalence of dyslipidaemia across all age groups and imparting a significant risk especially for low-HDL-C, reflecting their sedentary lifestyle compared to males. In addition, DM and obesity were significant determinants of high TG and LDL-C.
- With regards to the prevalence of obesity (generalized and central), a marked urban-rural disparity is apparent. Female gender is a significant determinant of both types of obesity. Further, it is closely associated with several metabolic CHD risk factors, as well as with a diet rich in carbohydrates and physical inactivity, explaining its increasing prevalence in parallel with sedentary lifestyle. This points to

the obesity-related CHD risk being high among Sri Lankans. Further, the newly identified serum leptin, FTO gene and near MC4R variant may explain to some extent their genetic predisposition to obesity. Another salient feature to consider when designing preventive programs is the gender-specific nature of the determinants of abdominal obesity.

- Remarkably higher prevalence of metabolic syndrome is noted in relatively young adults, however its role in increasing the CVD risk among South Asians as an ethnic entity has not been studied in detail.
- Evidence reveals that there is a considerable proportion of men and women in community with metabolic derangements undiagnosed and untreated. Re-orientation of screening programs such as in healthy lifestyle centres is required in this regard.

### **Behavioural risk factors**

- Of the behavioural risk factors of CVD and DM, a drastic increase in sedentary behaviour is noted over the years, predominantly among females. In this regard, novel influences on lifestyle, such as body image and perception, technology-enabled recreation and eating out should be explored in depth in young adults.
- Especially related to diet and physical activity, it is shown that education provided is not well translated into healthy practices, owing to cultural barriers and poor motivation. Thus, empowerment through health promotion may exceptionally help in this regard.
- Domestic work and active transport are the main contributors for being active, while sedentary occupations and lack of outdoor recreation have been the main barriers. Physical inactivity being associated with psychological barriers such as self-efficacy is noteworthy, but not with barriers such as vehicular traffic safety, neighbourhood walkability, aesthetics and facilities for cycling, low residential density and environmental factors. Health education should encourage household and transport related activities, while find ways to counter-act the influences of media and peer pressure for being inactive.
- According to the STEPS surveys, an improvement in the intake of five fruits & vegetables per day is seen over time. However, studies reveal that 71% of the total dietary energy is from carbohydrates, with the number of starch portions well-above the national recommendation. A slightly worse diet was seen with housewives, which was also associated with obesity.
- Further, an obesogenic diet (low-fibre and energy-dense food) is apparent in urban areas, highlighting a significant inter-sectoral difference. Reporting the highest fruits, vegetables and whole grain intake, the rural sector remains protected, yet this difference is less apparent for sugar-sweetened drinks and processed products. Interestingly, over-consumption of energy-dense food is more prevalent in non-CMC than in CMC sector.
- Research shows that focusing on the overall lifestyle, instead on individual domains may provide better opportunities to change. To this end, three independent lifestyle patterns have been recognized.
- Higher risk for all behavioural risk factors is occupation-specific; yet comprises both white collar workers and estate workers in the risk category.
- Despite the anti-tobacco and alcohol prevention activities in the country, the ever- and current-smoking rates are reported to be as high as 54% and 37% according to latest epidemiological data on males. As for alcohol, the evidence is inconsistent owing to poorly defined 'hazardous drinking', but both habits were more prevalent in poorly educated groups. Qualitative assessments among females are much needed for capturing the changing attitudes and behaviour related to smoking and alcohol among them.
- The prevalence of major NCD risk factors is shown to vary among patients having DM and CVD. However, differences in prevalence with the general population were not obvious in relation to central obesity, diet and physical inactivity. These factors should be specifically addressed with targeted programs among patients for better outcomes.

## Determinants of CVD & DM and risk prediction

*Quality of the available evidence* - Within the given epidemiological background, studies highlight the risk imparted by each risk factor in the development of CVD and DM. Furthermore, especially with relevance to low-resource settings, some studies provide evidence on low-cost, simple and valid tools for predicting the risk of CHD, DM or its outcomes.

- Determinants of CVD and DM have been many, of which the greatest risk is imparted by family history for insulin resistance and DM, reflecting the shared risk; and others such as increasing age, SBP, urban residency, sedentary lifestyle and higher BMI & WHR, in line with other South Asian countries. There is relative lack of evidence with regards to diet related risk of DM.
- DM imparts a significant risk for CAD, along with current smoking and HT. As newer risk factors, apo-lipo proteins B and A-1 and psychological factors have been proven. For PAD, it has been DM, HT, smoking and CRP. Anaemia is shown to be a predictor of stroke severity. Of the specific food items, coconut seemed to impart non-significant risk for CHD.
- CHD risk estimates were relatively high in urban communities and varied according to the prediction tool used, with comparatively higher estimates given by NCEP-ATP III charts. However, these charts not being validated for Sri Lanka should be considered, highlighting a major gap in research knowledge.
- BMI, WC as well as WHR and WHtR are shown to be valid in predicting the obesity related CHD risk in adults at lower BMI levels. Several prediction models have been developed with optimal cut-off values, which are different from the Asian cut-offs.
- Central obesity is shown to impart a greater risk for CHD in Sri Lankans than BMI. Risk is greater at lower BMI levels.

## Interventions of CVD and DM

*Quality of the available evidence* - A multitude of studies have been conducted in clinic settings related to secondary prevention of CVD and DM, however most are limited to abstract presentations of single-centre small samples, with poor generalizability. A major proportion of these studies have focused on self-management, self-monitoring and patient education. Of these, KAP studies take the lead on adherence to medication and lifestyle modifications. Furthermore, pharmacological interventions conducted on indigenous plants are highly commendable, while technology-assisted non-pharmacological methods have been explored moderately in relation to patient management aspects. Good quality placebo controlled trials are fewer in number, but remarkable in providing evidence on the effectiveness of primary preventive strategies such as health promotion. In contrast, studies on tertiary prevention including rehabilitation, quality of life, disability, patient safety, health rights and survival are grossly inadequate.

### Primary prevention

- Screening for CVD and DM risk factors; promotion of healthy lifestyles; and improving the knowledge, attitudes and preventive practices among apparently healthy adults are the main strategies under this.
- A structured NCD screening program for apparently healthy adults has been initiated in Healthy Lifestyle Centres, based on local evidence from three pilot projects conducted in highly urban as well as rural settings in Sri Lanka (WHO-PEN, NPP-JICA and NIROGI Lanka project). Though effective in detecting a substantial proportion of risk factors especially obesity and HT, this program faces several challenges, the main being poor attendance. To improve this aspect, evidence is available on more pragmatic approaches such as introducing diabetes educator nursing officers (DENO) in primary healthcare settings, and well-men clinics and universal screening for gestational diabetes in MOH settings.
- Population-based approaches to promote healthy lifestyles have been reported, including newer approaches on food labelling and environmental modifications. Further, locally relevant, culturally appropriate and low-cost health promotional models have been tested in highly urban, semi-urban and rural settings in communities, workplaces and schools among high risk populations, providing mixed results.

- Trials have indicated the usefulness of stage-matched approach in modifying complex dietary behaviour; favourable effects of MUFA-rich meals on postprandial BP; and beneficial effects of Zn on the glycaemic control and promotion of healthy lipid parameters.
- Role played by the education level of healthy persons on improving the knowledge, practices and attitudes on CVD and DM risk factors appears to be inconclusive.

## Secondary prevention

- Early detection, adequate treatment and follow-up of CVD, DM and related conditions among patients are the main strategies under this.
- Several tests/techniques have shown greater diagnostic power (e.g. HbA1c against OGTT or FPG; non-invasive risk scores to detect DM early; non-invasive method to identify endothelial dysfunction and coronary artery obstruction in early stage of CVD); accuracy in monitoring for disease control (e.g. PPBS against FBS); and applicability of DM screening tests in other disease conditions (e.g. TB). As for tests to screen for complications, less sophisticated tools (e.g. pulse palpation method, monofilament) have shown to be useful in low-resource settings. Furthermore, the applicability of technology-enabled (web or electronic based) non-invasive real-time investigations that could be used safely and effectively in the diagnosis and management of CVD and DM (e.g. wireless sensor networks, mobile and telemedicine applications) has been demonstrated.
- Self-management practices of patients with CVD and DM have shown wide variation.
  - It was relatively poor in term of adherence to medication and healthy lifestyles, and self-monitoring of the disease.
  - Cost, poly-pharmacy and side effects have been identified as the major barriers for adherence to medication. In this regard, ward-based clinical pharmacy service has been effective in reducing drug-related hospital re-admissions and pharmacist counselling in improving knowledge on adherence.
  - As for adherence to healthy lifestyles, patients showed better knowledge on dietary practices and physical activity than the general population, however the majority faced barriers in translating this knowledge into action. Cultural and religious constraints, being poorly empowered, lack of motivation and negative attitudes were some of these barriers.
  - Limited evidence is available on self-monitoring practices of patients, however there is room for improvement based on new evidence generated on technology enabled equipment.
  - Many knowledge gaps exist on important aspects in patients, such as on warning symptoms on stroke that may influence their health seeking behaviour.
- Service provision in health care settings also showed wide variation.
  - The availability of essential NCD drugs has been highest in semi-government community pharmacies (>80%), while it was around 50-80% in outdoor pharmacies of public and private hospitals, and private pharmacies. Nifedipine shows the highest price inflation (285%) followed by aspirin (135%) and atenolol (94.3%) with brand substitution.
  - With regards to access, ambulatory care appears to be sought by only half of the patients with CHD, DM, HT or dyslipidaemia, which was predominantly from non-specialists (80%); and almost equally from the private and government sector facilities.
  - Research points to variation in the availability of services according to the type of health care facility. This reflects the need for strengthening primary healthcare settings to ensure universal health coverage, and for establishing patient-centred care.
  - Despite the treatment coverage remaining high in Sri Lanka, regular screening of DM patients for complications is at a sub-optimal level in the state health sector. However, a major deficiency in DM foot care has been addressed by providing patient support care by trained prosthetic and orthotic technicians and initiatives taken on DM-specific protective footwear.



- In stroke management, numerous unmet needs have been identified, as evident by satisfactory level of essential follow-up care services to limit disabilities, prevent complications and modify lifestyle, social welfare being as low as 5%.
- Many deficiencies in the quality of services provided have been identified during audits, which should be made mandatory to generate new evidence for further improvement.
- Despite having free health services, a considerable amount of out of pocket expenditure is still incurred by people for managing CVD, DM and risk factors.

### **Tertiary prevention**

- Evidence is limited on follow-up of patients for survival and disability following rehabilitation.
- CVD and DM are diseases with a multitude of complications. The Sri Lankan Health system should be re-organized to deliver health care to cater to their needs.

Disease burden in terms of mortality as well as morbidity including the complications and disability is shown to be substantial and increasing over the years, along with the economic burden due to increasing out-of-pocket expenditure and clinical care. Both CVD and DM in Sri Lanka are characterized by early age of onset, severe course of disease leading to disabling complications and premature death. The prevalence of metabolic and behavioural risk factors of NCDs varies widely from some being relatively low to most being moderate-high. The identified underlying factors need to be addressed in health programs. The health care system has taken many novel initiatives to promote healthy lifestyles and to enhance secondary prevention of CVD and DM, but not to the same extent in tertiary prevention. The quality of current programs as well as the coverage need to be focused upon in order to achieve the maximum at low cost.

“We can no longer ignore the burden that cardiovascular disease, diabetes, cancer and chronic respiratory diseases is placing on countries that are least equipped to deal with them.”

PEKKA PUSKA

President, World Heart Federation



# CHAPTER ONE

## Introduction to the Review

### 1.1 Background

Each year, 80 million die from four major non-communicable diseases (NCDs), namely cardiovascular disease (CVD), cancer, diabetes (DM) and chronic respiratory disease in the world, of whom 15 million die before the age of 70 years. Over 80% of these premature deaths take place in low- and middle-income countries (LMIC). In concurrence, major NCDs are responsible for a substantial proportion of mortality and morbidity in Sri Lanka, signifying excessive losses to the family and society in terms of lives, productivity and societal responsibility. It is projected that, along with the doubling of people over 60 years of age by 2040 in Sri Lanka, the epidemic would gradually shift towards the poor social strata, highlighting an overwhelming economic as well as public health issue in Sri Lanka.

As in other developed as well as developing countries, major NCDs are increasingly becoming a threat to the health system of Sri Lanka. In response, the current NCD activities in Sri Lanka are guided by the National Multisectoral Action Plan for Prevention and Control of NCDs 2016-2020, which is consistent with the Global NCD Action Plan. This action plan focuses on the

total risk approach and has set 10 national targets, including a target to reduce premature NCD mortality.

The public sector provides preventive care, a large portion of inpatient care and less than half of outpatient curative care, free at the point of delivery. Though the health system of Sri Lanka has received many accolades for providing the best health indicators in South Asia at such low cost, it is not fully geared to combat NCDs as it is a more complex and demanding task compared to the control of communicable diseases and maternal & child health (MCH) agenda. There is growing concern over social inequity in health financing and service provision related to NCD care. Thus, services need to be recognized and re-organized to minimize its impact on health and development of the country. This requires low-cost and effective practices and strategies to be identified based on local evidence; and implemented to bridge the gaps in existing healthcare.

Professionals from many disciplines and fields engage in research related to NCDs in Sri Lanka. Accordingly, there is a plethora of evidence available on the current status of NCDs in Sri Lanka. However, the health system's response to the increasing burden of NCDs in the country has not been adequately supported by this evidence base. One constraint has been owing to the absence of a bibliography of literature compiled within the last 20 years. Further, the existing literature has not been reviewed critically, in order to appraise the existing clinical and preventive strategies & practices adopted and to develop research priorities, based on the gaps identified in the scientific work. Such a review would also minimize the substantial replication of studies by researchers. Therefore, this review was undertaken to enable researchers as well as policy makers to translate the available evidence into an "implementable" platform enriched to support local best buys in NCDs in Sri Lanka.

## 1.2 The terms of reference

As per the terms of reference, a desk review was undertaken to collate, summarize and analyze the local evidence available from 2000-2018 on the following aspects:

- a. Characteristics and trends in the burden of major NCDs in Sri Lanka
- b. Prevalence and associations of the major NCD risk factors in Sri Lanka
- c. Magnitude of the risk factors in determining major NCDs in Sri Lanka
- d. Curative and preventive interventions on major NCDs and their effectiveness in Sri Lanka

Considering the large number of publications available (in full papers and abstract format) on this topic, the review was limited to literature related to CVD and DM, which are known as the two NCDs currently having a greater impact in Sri Lanka over other major NCDs. In addition, there are review reports currently available on the evidence pertaining to cancer and chronic kidney disease, while chronic respiratory disease was not considered for this review as it had several risk factors which are not shared with other NCDs to a great extent (e.g. air pollution, housing).

Wherever relevant, the quality of evidence, gaps in the evidence-base and deficiencies in the health system response were to be critically assessed.

## 1.3 Methodology

### 1.3.1 Process followed

This desk review was carried out as an extension of a project undertaken by the Health Systems Research Unit of the Department of Community Medicine, Faculty of Medicine, University of Colombo in collaboration with the World Health Organization (WHO) Country Office for developing a comprehensive bibliographic literature database related to major NCDs and risk factors, interventions to prevent and control such diseases, and health system response in Sri Lanka. This database is composed of scientific literature based on the research studies conducted during 2000-2018 period in Sri Lanka.

For the purpose of developing the bibliographic database, the review team carried out discussions with the chief librarians of the Faculty of Medicine, University of Colombo and National Science Foundation (NSF) on data retrieval for the bibliography to finalize the scope

of the bibliography, with due consideration given to the practical constraints involved in retrieving the evidence. The review team also had several rounds of discussions with an expert panel representing different medical specialties to identify the search terms/ medical subject headings (MeSH) terms to be used for reviewing publications for the database.

One full-time bio-medical graduate was employed to obtain the relevant information via online sources as well as by visiting the relevant institutions and meeting the key resource persons. The work was carried out over four months.

### **1.3.2 Selection criteria of the data perused**

The following criteria were considered for inclusion of publications in this desk review.

#### **Inclusion criteria:**

- Studies conducted on health-related aspects of CVD, DM and related risk factors
- Studies conducted in Sri Lanka (including multi-centre studies done in collaboration with other countries)
- Studies based on primary data collected for a research purpose or secondary data that are routinely collected in Sri Lanka

#### **Exclusion criteria:**

- Studies conducted after 2018 or those prior to 2000 \*
- Animal studies
- Studies conducted on Ayurvedic, complementary or traditional treatment methods (e.g. alleviation and purification therapy, yoga exercises, meditation, physiotherapy, acupuncture) used in the management of NCDs
- Laboratory-based studies on the molecular, chemical or pharmacological properties of non-plant based therapeutics (prepared in medicinal form) used in the management of NCDs
- Studies conducted on children & adolescents
- Studies conducted on pregnant women related to gestational diabetes, pregnancy induced hypertension and heart disease
- Studies conducted on migrant populations (e.g. Sri Lankans living overseas or comparisons with other populations)
- Case studies and case series
- Epidemiological studies conducted in the general population in samples smaller than 1000 \*



- Studies in which there is poor representation of the target population (e.g. data collection limited to small samples, in small administrative area/unit (e.g. one clinic, ward or small administrative area) and using non-probability sampling methods), thus having poor generalizability of the findings \*
- Studies conducted on cancer, chronic respiratory diseases, chronic kidney or liver disease, road traffic accidents & injuries, mental disorders, suicides

\* Excluded unless the studies were considered highly relevant for the current review

Cardiovascular diseases (CVD) comprise coronary heart disease (CHD), stroke and peripheral arterial disease (PAD). In literature, the terms coronary artery disease (CAD) and ischaemic heart disease (IHD) are used interchangeably for CHD.

### 1.3.3 Sources of publications

The following sources were perused for inclusion of a publication in the desk review:

- Full paper articles published in scientific journals (available as e-copies)
- Full paper articles published in Sri Lankan journals not available online (retrieved as hard copies from the relevant libraries)
- MPhil, MD and MSc academic work in thesis or dissertation format available in higher education institutes in Sri Lanka (retrieved as hard copies from e-repositories or from relevant university libraries)
- Abstracts of oral or poster presentations of international conferences (available as e-copies)
- Abstracts of oral or poster presentations of annual academic sessions, scientific workshops or local conferences held in Sri Lanka (retrieved as hard copies from the proceeding books of conferences held by professional colleges and health institutes)
- Wherever relevant, reports based on routinely collected population-based survey data or data collated from returns and registers and other locally relevant reports compiled by governmental or non-governmental organizations (NGOs)

Please note that abstracts presented in international conferences outside Sri Lanka but currently not available online as e-copies were not considered for this review.

The desk review collated evidence since year 2000 mainly on the status of CVD and DM, their determinants and interventions including the health system response related to CVD and DM, based on the following sources:

- a. Published as research articles and abstracts presented in scientific forums
- b. Unpublished research data in the form of dissertations/ thesis available in local library repositories
- c. Relevant country reports and survey reports published by the Ministry of Health, other government agencies, UN agencies and NGOs

#### **1.3.4 Sources used for data retrieval**

For online retrieval of data, the following databases were used (these databases were identified as the main sources linked to other databases):

- PubMed
- HINARI
- GIFT
- Scopus
- Google Scholar
- Taylor and Francis
- E-repositories of the universities, institutions and professional colleges in Sri Lanka: University of Colombo, University of Peradeniya, University of Jaffna, University of Sri Jayewardenepura, Eastern University, University of Kelaniya, Sir John Kotelawala Defence University, Open University, NSF, Post Graduate Institute of Medicine (PGIM) and Ministry of Health

For retrieving the literature presented in abstract form in local conferences, the relevant institutions were visited to obtain hard copies. These included the following:

- Sri Lanka Medical Library
- PGIM
- Institute of Biochemistry, Molecular Biology and Biotechnology (IBMBB)
- Medical Research Institute
- NSF
- Sri Lanka College of Community Physicians
- Ceylon College of Physicians
- College of Surgeons of Sri Lanka
- The College of Pulmonologists of Sri Lanka

- College of General Practitioners of Sri Lanka
- Sri Lanka College of Radiologists
- Sri Lanka College of Dermatologists
- Sri Lanka College of Endocrinologists
- College of Pathologists of Sri Lanka
- Sri Lanka College of Obstetricians and Gynecologists
- The Association of Sri Lankan Neurologists
- Sri Lanka Heart Association

For retrieving the literature presented in survey reports, annual reports and online databases, online search engines were used; if not available, the relevant institutions were visited to obtain hard copies. Some of the reports and databases perused were:

- Annual Health Bulletin (AHB)
- WHO Country Reports and other relevant report
- STEPwise approach to NCD Surveillance (STEPS) Survey Sri Lanka Reports
- Sri Lanka Demographic & Health Survey (SLDHS) Reports
- World Bank Health Expenditure Database
- World Development Indicators (WDI) Database
- Institute for Health Policy (IHP) Reports
- Institute of Health Metrics and Evaluation (IHME) Reports

## **1.4 Results**

The database was managed using Mendeley Reference Management Software (Desktop Version 1.19.3). Most of the data were retrieved from online data sources, while some were obtained by perusing literature published in annual reports, survey reports and abstract books of conference proceedings and scientific journals.

### **1.4.1 Summary of the data retrieval**

At the initial screening carried out for developing the comprehensive bibliographic literature database related to NCDs and risk factors, interventions to prevent and control such diseases, and health system response in Sri Lanka, 1750 publications were retrieved from the identified sources. After removing duplicates, the selected articles were scrutinized independently by

two reviewers, so as to exclude the articles not fulfilling the pre-determined criteria for inclusion in the review.

After scrutiny, 1359 publications were finalized, which comprised 800 from online sources, 98 from the PGIM and the rest retrieved as hard copies by visiting the colleges and relevant institutions. Table 1.1 highlights the distribution of the 1359 finalized publications considered for the bibliographic review.

**Table 1.1: Summary of the data extraction for the NCD bibliographic review \***

Description	No.
<b>Type of publication</b>	
• Full article (International & Local)	573
• Conference proceedings/abstracts	686
• Thesis/Dissertations	100
<b>By classification</b>	
• Burden of chronic NCDs	241
• Risk factor burden	153
• Risk assessment/associations	250
• Screening for NCD or complications	140
• Clinical/histological/genetic presentations of NCDs/Complications	42
• Management and follow-up	256
• Interventions- Pharmacological/Non-pharmacological	20
• Quality of care/Audit	69
• Side effects/complications of interventions/treatments	33
• Treatments for chronic NCDs/Complications/risk factors	97
• Utilization of services	105
• Survival analysis	82
• Lifestyle related behaviours- health promotion and education	58
• Costing	16
• Laboratory-based experiments and innovations	48
• Health information systems	10

The publications were classified according to the main topic covered in each publication.

Of the above, approximately 650 publications were screened to be included in the desk review. These comprised 100 on the burden of CVD, DM and complications; 300 on the determinants (i.e. risk factors) and risk prediction of CVD and DM; and 250 on the management of CVD and DM. Full list is available under references.

### 1.4.2 Limitations of the review

The review of literature was not 100%, owing to the following limitations pertaining to non-availability of publications, and therefore not included in the review:

- Proceeding books of abstracts presented at annual academic sessions of professional colleges were not available for some years.
- E-repositories of universities were not updated for some years within the review period; and theses and dissertations were not available in hard copies for some years (e.g. PGIM). In such instances, relevant theses were hand-searched through authors.
- Abstracts presented in overseas conferences were not included in this review, unless they were available in e-repositories or online.

Of the screened publications, those available in full paper articles were given priority when reviewing the evidence, and have been cited in best capacity in this review. Those available only in abstract form of oral/ poster presentations have been cited if they were considered highly relevant. This was done in view of the large number of publications available for the current review.

### 1.4.3 Main sources of data used in the review

Several sources of information were perused during this review.

#### 1.4.3.1 Studies in apparently healthy adults

Evidence was based on population-based data collected in national surveys and epidemiological studies conducted in samples representative of regional populations on major NCDs and risk factors.

##### a. Nationally representative surveys

Nationally representative information was available from surveys conducted at regular intervals in Sri Lanka, namely the STEPS Survey Sri Lanka (2003, 2006, 2015, 2018) and SLDHS (1993, 2000, 2006-07, 2016).

- The STEPS Survey conducted by the NCD Unit of the Ministry of Health is the only population-based survey that gathers nationally representative data at regular intervals on the behavioural and metabolic risk factors of major NCDs in Sri Lanka. Designed by the WHO, it has been identified as the most appropriate method for estimating the prevalence of risk factors in a country. Sri Lanka has conducted one sub-national STEPS Survey in 2003 (Western Province) and three national STEPS Surveys in 2006, 2015 and

2018. As shown in Table 1.2, there had been variation in the target groups considered for the surveys over the years and consistency of the indicators used.

**Table 1.2: Prevalence of DM according to STEPS surveys conducted in Sri Lanka**

Survey year	Sample size	Age (years)	Sampling method	Measurements
2003	3000	15-74	Population-based sampling from Western Province	<ul style="list-style-type: none"> <li>• Socio-demographic &amp; behavioural</li> <li>• Physical (height, weight, BP)</li> </ul>
2006	12,500	15-64	Population-based multi-stage sampling representing every district and province	<ul style="list-style-type: none"> <li>• Socio-demographic &amp; behavioural</li> <li>• Physical (height, weight, BP)</li> </ul>
2015	5188	18-69	Population-based multi-stage cluster sampling representing every district and province	<ul style="list-style-type: none"> <li>• Socio-demographic &amp; behavioural</li> <li>• Physical (height, weight, BP)</li> <li>• Biochemical (glucose, cholesterol)</li> </ul>

The first STEPS Survey was carried out in 2003 in two steps: socio-demographic and behavioural information (Step 1) and physical measurements such as height, weight and blood pressure (BP) (Step 2). A total of 3000 adults aged 15-74 years residing in Western Province participated in the survey. The overall response rate was 100% (Ministry of Health, 2003).

The 2006 STEPS Survey was conducted among adults aged 15-64 years. Like the previous, this survey was also conducted in two steps. However, this survey adopted multi-stage sampling to recruit 12,500 adults to represent every district of Sri Lanka (Ministry of Health, HSDP & World Bank, 2008).

The 2015 STEPS Survey was carried out in three steps: socio-demographic and behavioural information was (Step 1); physical measurements (Step 2); and biochemical measurements on blood glucose and cholesterol (Step 3). Multi-stage cluster sampling was used to produce representative data for Sri Lanka. A total of 5188 adults aged 18-69 years participated in the survey representing every district. The overall response rate was 72% (Ministry of Health, 2015a).

The 2018 STEPS Survey also followed a similar methodology as in 2015 and was conducted among adults aged 18-69 years representing every district in the country. The full report is not yet released.

### **b. Epidemiological studies at national and provincial levels**

During the last 20 years, there had been three large-scale epidemiological studies conducted in the general population on DM, CVD and related risk factors in Sri Lanka.

- One was a population-based study conducted among 6047 adults aged 30-65 years to estimate the prevalence of CVD and related risk factors during 1998-2002 period (Wijewardene et al., 2005). This study was limited to four provinces (Western, North Central, Uva, Southern), thus the findings cannot be generalized to all ethnic and socio-economic strata of Sri Lanka. However, the sampling adopted in this study has been rigorous, in which the number of clusters to be allocated for each district depended on its population size; the required number of clusters from each district was randomly selected from its grama-niladhari (GN) divisions; and 60 individuals were selected from each GN division using systematic sampling of households, thus data disaggregated at GN division, district and provincial levels. To reduce the cluster effect, a large number of small clusters was selected (130 clusters x 60 cluster size) and the sample size inflated by a substantial allowance. The study did not however apply probability-proportionate-to-size (PPS) technique when selecting the GN divisions, and stratification by urban-rural sectors when obtaining the sample within each district, both of which could have further improved the precision of sampling.
- With similar objectives, almost five years later, another population-based study named Sri Lanka Diabetes and Cardiovascular (SLDC) Study was conducted during 2005-2006 period in seven provinces (except North & East Provinces) by Katulanda et al. (2008a), thus providing national estimates for Sri Lanka. The study is also highly acclaimed for collecting a wide range of data on DM, CVD and related risk factors. The sample consisted of 4485 adults aged over 18 years, selected using cluster sampling (100 clusters x 50 cluster size). The sample sizes for individual provinces and for the urban/rural sectors within each province were determined using PPS; and the clusters within each province were selected randomly from the 'village office units', thus well-representing all major provinces in Sri Lanka. However, considering the wide disparity of the socio-economic profile of districts within the same province, applying PPS at district level would have been more appropriate, so that findings could also be disaggregated at district level. Further, applying only an arbitrary design effect of 2 and the precision not reduced to half of the expected prevalence when calculating the sample size (the method to follow when assumption of normal approximation is not met, whenever the expected prevalence is below 10%) could have marginally affected the power of this study.

Several publications are available based on the SLDC Study data pertaining to DM (Katulanda et al., 2008a; Katulanda et al., 2011a); hypertension (HT) (Katulanda et al., 2014a); dyslipidaemia (Herath et al., 2010a (abstract); Katulanda et al., 2018); alcohol intake (Katulanda et al., 2014b); smoking (Katulanda et al., 2011b); physical inactivity (Katulanda et al., 2013); obesity (Katulanda et al., 2010a; Jayawardena et al., 2012a; Jayawardena et al., 2014a); metabolic syndrome (Katulanda et al., 2012a); diet (Jayawardena et al., 2013a); family history (Katulanda et al., 2015; Ranasinghe et al., 2014a (abstract); Ranasinghe et al., 2014b (abstract); Ranasinghe et al., 2015a); molecular and genetic aetiology (Katulanda et al., 2008b; Katulanda et al., 2008c; Katulanda et al., 2008d (abstract); Katulanda et al., 2008e (abstract); Katulanda et al., 2010b; de Vas Gunawardena et al., 2010 (abstract)); ischaemic heart disease (IHD) (Katulanda et al., 2010c) (abstract); stroke (Wijesundara et al., 2012) (abstract); retinopathy (Katulanda et al., 2014c; Katulanda et al., 2014d); neuropathy (Katulanda et al., 2012b); sexual dysfunction (Katulanda et al., 2014e); risk prediction scores for CVD (Katulanda et al., 2016; Jayawardena et al., 2013b; Katulanda et al., 2010d); and deriving cut-off values on obesity & CVD risk (Jayawardena et al., 2013c; Katulanda et al., 2011c).

- During the last 10 years, there has been a multi-centre study (WHO Risk Prediction Study) (N=8625) conducted by Mendis et al. (2011) to determine the population distribution of CVD risk in eight LMICs including Sri Lanka, in order to develop predictions on the 10-year CVD risk using WHO risk prediction approach. The Sri Lankan sample consisted of 1099 adults (800 females; 299 males) aged 40-80 years drawn using cluster random sampling of households from geographically defined municipal wards and GN divisions, which have urban/rural and socioeconomic representation comparable with that of the general population. Whether this sample represents national data is not well-described.

### **c. Epidemiological studies at district level**

During the last 25 years, there had been several epidemiological studies confined to one district of Sri Lanka, but conducted in samples well-representative of the general population.

- There were only a few epidemiological studies conducted on the prevalence of DM at district level, such as one study among 1234 adults aged 35-64 years in Kalutara District (De Silva, 2010) and another among 2800 women aged 30-45 years who were not previously diagnosed of DM in Colombo Municipal Council (CMC) area (Waidyatilaka et al., 2013); both samples were recruited using cluster sampling with PPS. Another was on



metabolic syndrome among young (10-40 year old) urban population in Colombo District (Wijesuriya et al., 2012).

- Epidemiological studies on CVD were scarce at district level. There was one recent community-based study (Liyanapathirana, 2014) to determine the prevalence of CHD among 1143 adults aged 30-64 years in Gampaha District selected using multistage cluster sampling (40 GN divisions x 30 cluster size) with PPS and design effect of 2 (95.3% response rate); and another on stroke prevalence (Chang et al., 2015) among 2313 adults aged  $\geq 18$  years in Colombo District selected using multistage cluster sampling (46 GN divisions x 51 cluster size) with PPS and design effect of 6 (96.9% response rate).
- Majority of the epidemiological studies at district level have been designed to assess the prevalence and associations of CVD/DM risk factors, each predominantly on a single factor, such as abdominal obesity (Arambepola, 2004), physical activity (de Silva, 2011), tobacco smoking (Chulasiri, 2014) and metabolic syndrome (Amarasinghe et al., 2015a; Amarasinghe et al., 2015b) or on multiple risk factors (Fernando, 2016). Further, these studies had over 1000 participants selected using stringent sampling methods; some of which were sampled by precise age, sex and urban-rural sector representation of the district population (Arambepola, 2004; De Silva, 2010). Hence, the study findings had greater internal validity and applicability in prioritizing and implementation at district level.

#### **d. Population- or hospital-based studies in geographically defined smaller areas or institutions**

The published research studies on CVD, DM and risk factors in Sri Lanka were mostly confined to smaller administrative areas, such as medical officer of health (MOH) areas and wards or clinics, which was a major drawback in generalizing the study findings to the population of Sri Lanka. Majority were on management of NCDs in apparently healthy as well as diseased populations, thus useful in program planning and action at local level.

Studies carried out in special population groups are noteworthy (Harshani & Abeysena, 2011; Pinidiyapathirage et al., 2013; Abrew et al., 2010 (abstract); Booso, 2012; Sasrubi et al., 2013; Gamage & Seneviratne, 2016; Ubeysekara, 2017; Jayaweera & Joseph, 2018; Rambukwella & Dissanayake, 2018), such as in university employees, nurses, army soldiers, estate workers, fishermen and sedentary occupational groups. Some had relatively small sample sizes. These studies were useful in ascertaining associations and management.

### e. Cohort studies

Sri Lanka lacks methodologically sound long-term follow-up studies on DM, CVD and related risk factors. There was only one population-based cohort study reported on the prevalence of major metabolic disorders used to establish diagnostic criteria for metabolic syndrome (Kasturiratne et al., 2013; Wickremasinghe et al., 2008 (abstract); Pinidiyapathirage et al., 2013). The sample recruited consisted of 3500 adults aged 35-64 years confined to one MOH area in Ragama representing a suburban population, who were selected from the electoral registers. Data on a variety of variables were obtained through detailed history and investigations including a liver ultrasound scan and blood count, blood picture and genetic analysis. All subjects with abnormal results of investigations have been followed-up.

#### 1.4.3.2 Studies in patients having CVD or DM

Evidence was available based on a large number of clinic-based studies conducted on the prevalence of risk factors and complications among patients having DM, of which the study by Sujanitha et al. (2015) in a sample of 8401 DM patients is striking. Hospital-based studies conducted in relation to stroke and CHD were sparse, of which the study by Pathirana et al. (2014) in 526 CHD patients is noteworthy. Two follow-up studies on stroke have been reported (Wellapuli, 2018; Mallawaarachchi, 2006), while no major studies were available on the long-term follow-up of CHD or DM patients. Despite the availability of a stroke registry, publications related to post-stroke outcomes were not available.

In contrast, numerous studies were available on patient related factors, such as knowledge, attitudes and self- or hospital- management practices (KAP studies) in relation to DM and CVD, however most of these were available in abstract publications and limited to small samples, non-probability sampling and with poor generalization of the target group. A substantial number of studies on the availability and costing, including a few audits were available on primary care and tertiary care clinic services.

With regards to experimental studies conducted on the effectiveness of preventive options, management options or diagnostic accuracy of DM or CVD, some were of good quality design and rigorous data collection methods. Availability of plant-based studies on interventions for DM is impressive. As for interventions on tertiary prevention including rehabilitation, a limited number of studies were available.



“Four in five deaths from NCDs now occur in low- and middle- income countries. Without decisive action, the NCD burden threatens to undermine the benefits of improving standards of living, education and economic growth in many countries.”

MARTIN SILINK

President, International Diabetes Federation





## CHAPTER TWO

### Status of major NCDs in Sri Lanka

This chapter presents evidence available on the causes underlying the surge in NCDs in the last few decades in Sri Lanka (Section 2.1), trends in the disease burden of CVD and DM in terms of morbidity, mortality, complications & disability (Section 2.2), and the trends in economic burden (Section 2.3).

#### 2.1 Causes underlying the NCD surge in Sri Lanka

There is theoretical as well as empirical evidence on the major causes underlying the increase in NCDs during the last 60 years in Sri Lanka.

##### 2.1.1 Sources of information

The sources of information used for reviewing this evidence include Country Profiles of the World Bank and WHO developed based on several data sources, and all-island data routinely collected by the Registrar General's Department, Department of Census & Statistics and Medical Statistics Unit.

### 2.1.2 Current health status of Sri Lanka

Sri Lanka is well-recognized globally for its near universal health care system that is provided free to all citizens of the country. It is strategically positioned to achieve Universal Health Coverage (UHC), one of the key Sustainable Development Goals (SDGs) of the United Nations in relation to life expectancy and indicators for maternal, neonatal and under-five mortality rates.

- Sri Lanka currently assumes the lowest fertility (2.0 births per woman) as well as crude death (6.5 per 1000 population), infant & under-five mortality (7.6 and 10.1 per 1000 live births, respectively) rates in South-East Asia. Since 2000, the maternal mortality rate has been fluctuating between 20-25.7 per 100,000 live births (Ministry of Health, 2009-10). Further, the life expectancy at birth in Sri Lanka is 72 years in males and 79 years in females, which is much higher than the South Asian average of 68 years (<https://databank.worldbank.org>). While being the best in this region, health indicators of Sri Lanka are comparatively higher than in countries of similar socio-economic status and on par with those in developed countries (Table 2.1). Sustaining these interventions is vital for protecting the gains achieved.

**Table 2.1: Comparison of the health status of Sri Lanka with other countries**

Country	MMR (2015)	IMMR (2017)	TFR (2017)	Malnutrition of under 5 children (%)		Measles immunization coverage (%) (2017)	Life expectancy at birth (years)	
				Stunting (2016)	Wasting (2016)		Male (2017)	Female (2017)
Sri Lanka	30	7.6	2.0	17.3	20.5	99	72.1	78.8
India	174	32	2.3	NA	NA	88	67.3	70.4
Maldives	68	6.8	2.1	NA	NA	99	76.7	78.8
Australia	6	3	1.8	NA	NA	95	80.4	84.7
Malaysia	40	6.7	2.0	20.7	13.7	93	73.3	77.9
Singapore	10	2.2	1.2	NA	NA	95	80.7	85.2
Korea	11	2.8	1.1	NA	NA	98	79.7	85.7
Russia	25	6.5	1.8	NA	NA	98	67.1	77.4
UK	9	3.7	1.8	NA	NA	92	79.4	83.0
USA	14	5.7	1.8	NA	NA	92	76.1	81.1

MMR=maternal mortality rate per 100,000 live births; IMMR=infant mortality rate per 1000 live births; TFR=total fertility rate per woman; NA=not available

Source: World Development Indicators (WDI), World Bank (<http://wdi.worldbank.org/tables>)

- It is noteworthy that the gains in health had been achieved in Sri Lanka despite a low gross national income (GNI) per capita of current US\$ 4,060. This is in comparison with 41,330 in the UK. Total expenditure on health is also 3.9% of the gross domestic product (GDP) compared to 9.8% in the UK (Table 2.2).

**Table 2.2: Comparison of the health expenditure of Sri Lanka with other countries**

Country	GNI per capita (current US\$) (2018)	Total health expenditure as % of GDP (2016)	Government health expenditure as % of total health expenditure (2016)	Government health expenditure as % of total government expenditure (2016)	Per capita total expenditure on health current I\$ (2016)
Sri Lanka	4,060	3.9	43.1	8.6	211.8
India	2,020	3.7	25.4	3.1	61.4
Maldives	9,310	10.6	72.6	20.2	1,181.7
Australia	53,190	9.3	68.3	17.4	3,094.2
Malaysia	10,460	3.8	50.5	8.2	531.2
Singapore	58,770	4.5	54.5	13.6	2,226.7
Korea	30,600	7.3	59.2	13.5	1,604.1
Russia	10,230	5.3	57.0	8.2	757.0
UK	41,330	9.8	80.2	18.9	3,351.7
USA	62,850	17.1	81.8	39.5	8,077.9

Source: World Development Indicators (WDI), World Bank (<http://wdi.worldbank.org/tables>)

In 2017, the total expenditure on health was only 5.94%, with per capita health expenditure of only Rs. 9,615 (Central Bank of Sri Lanka, 2017; Department of National Budget, 2019; Ministry of Finance and Planning, Sri Lanka - Annual Report 2017; Department of state Accounts, General Treasury - Financial Statements for the year 2017). In the same year, the government health expenditure amounted to 1.59% of the country's gross national product (GNP). These are comparatively low as in other South-East Asian countries of similar economic development.

### 2.1.3 Causes underlying the improvement of health in Sri Lanka

Since independence, many initiatives have been taken at national level in Sri Lanka, leading the country to a steady decline in fertility as well as in crude death rate and infant & under-five mortality rates at relatively low cost.

- The gains in health have primarily resulted from social investments such as free education (1945) and free health (1951) policies, in parallel, with an island wide comprehensive

network established of health institutions belonging to the curative and public health sectors. Gains have also resulted from the programmatic initiative taken towards population reduction via the integration of family planning with the National MCH Program (1965). Another key initiative was the Expanded Program on Immunization (EPI) for achieving high immunization coverage and disease control (1978). These, backed by political commitment as means to sustainable development, enriched the skilled human resource, literacy especially among females, early care seeking practices, and social stability in the country leading to better housing, nutrition, sanitation and socio-economic status. By 2000, the health system consisted of approximately 57,000 hospital beds and a large workforce (7,963 physicians, 14,716 nurses and 5,068 field health staff) (Ministry of Health, 2009-10), while the population having access to safe drinking water was 75.4% (74.6% rural and 96-99% urban) and for latrine facilities, it was 72.6% (68.3% rural and 87% urban). In terms of health, many indicators improved drastically over the years (Table 2.3), specifically due to the intense focus of the public health system on the prevention, treatment and elimination of major infectious diseases, reduction of nutrition related issues and promotion of MCH.

**Table 2.3: Comparison of the health indicators and services in Sri Lanka, 1990-2018**

Indicator	1990	2000	2010	2018
Population, total million	17.33	18.78	20.26	21.67
GNI per capita (current international \$)	40.32	81.23	166.92	283.55
Life expectancy at birth (years)	70	71	74	75
Fertility rate (births per woman)	2.5	2.2	2.2	2.0
Contraceptive prevalence, any methods (% of women ages 15-49)	66	70	68	62
Births attended by skilled health staff (% of total)	94	96	99	99
Mortality rate, under-5 (per 1,000 live births)	21	17	12	9
Prevalence of underweight, weight for age (% of children under 5)	33.8	22.8	21.6	20.5
Immunization, measles (% of children ages 12-23 months)	80	99	99	99
Prevalence of HIV, total (% of population ages 15-49)	0.1	0.1	0.1	0.1

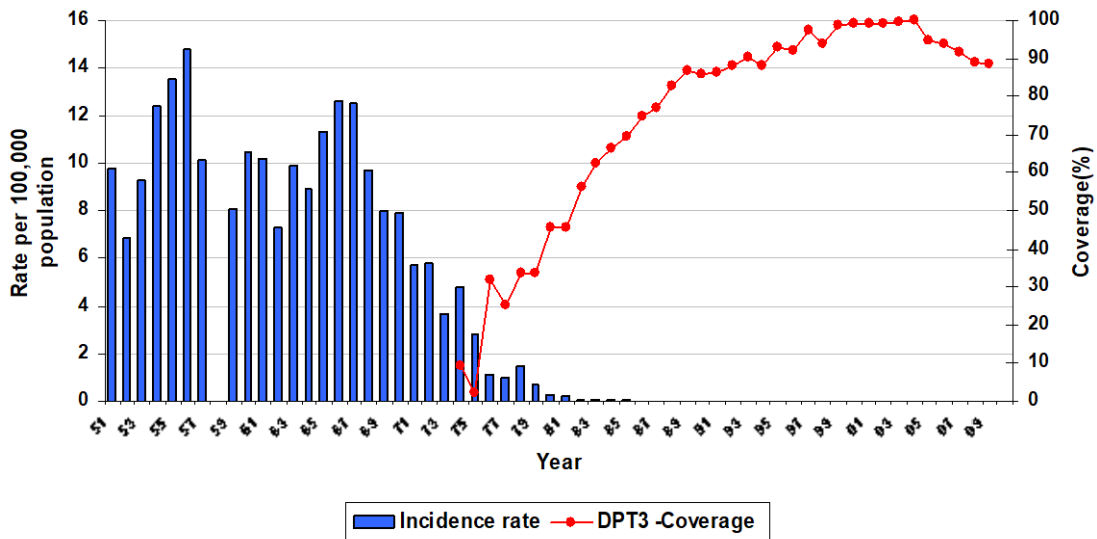
Source: World Development Indicators (WDI), World Bank (<http://wdi.worldbank.org/tables>)

- A major milestone achieved was Universal Child Immunization for six vaccine preventable diseases, giving rise to an extremely low caseload and high coverage of vaccines in some



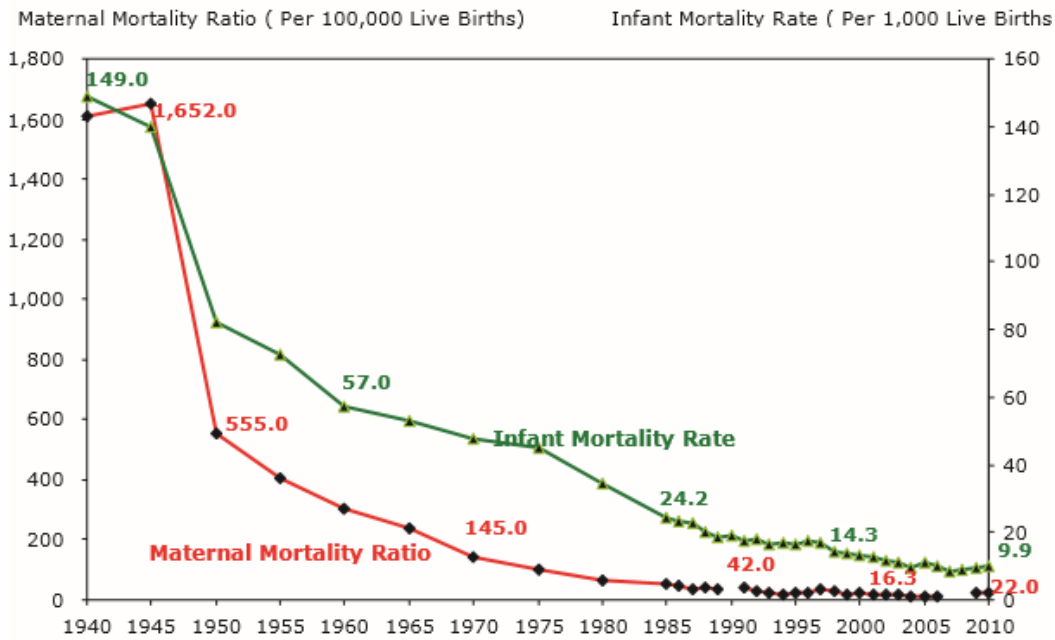
killer diseases (Figure 2.1), including the eradication of polio and recent elimination of malaria and measles from the island.

**Figure 2.1: Incidence of diphtheria and immunization coverage 1951-2010**



Source: Immunization Handbook, Epidemiology Unit, Ministry of Health, 2012

- This success in interventions enabled the deaths from major infectious diseases to gradually decline, in contrast to early 1920s where the infant and childhood mortality rates were considerably high predominantly due to the uncontrolled burden of infectious diseases (Figure 2.2). Even those who survived at the time had a shorter adult life span.

**Figure 2.2: Declining mortality trends in Sri Lanka 1940-2010**

Source: Registrar General's Department, Sri Lanka

#### 2.1.4 Change in disease pattern in Sri Lanka

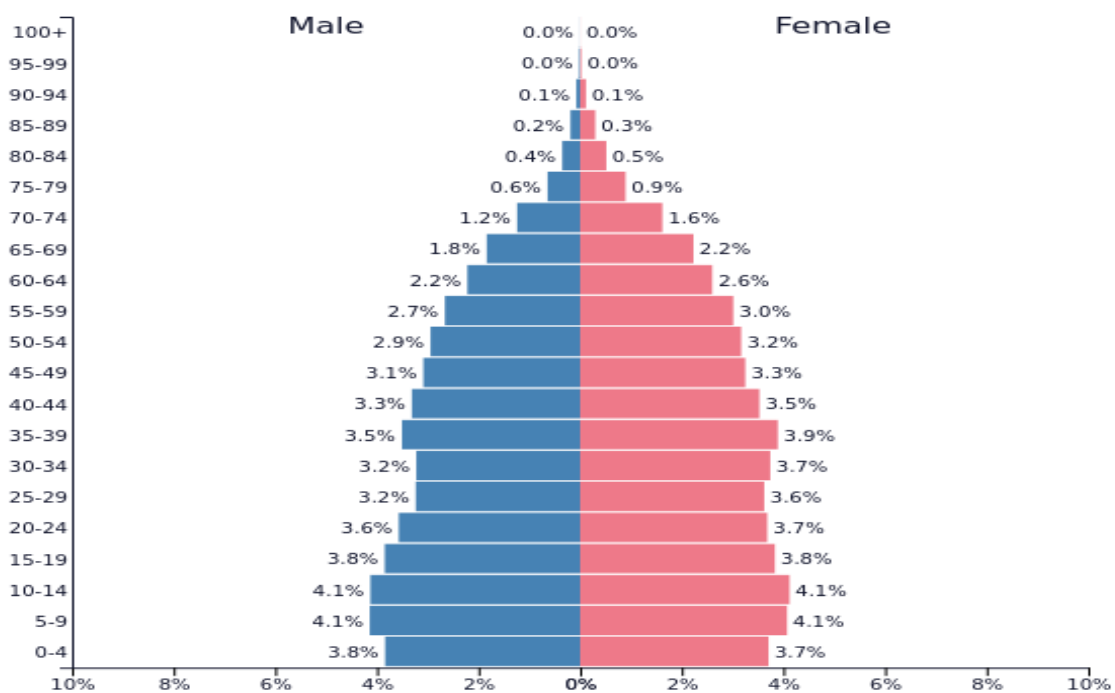
Non-communicable diseases are those without an infectious origin. The majority have a chronic onset and persist as life-long diseases, leading to mortality, morbidity and disability. Of these, four are identified as major NCDs responsible for its burden, namely CVD comprising CHD, stroke and PAD, DM, cancer and chronic respiratory diseases.

The major NCDs usually emerge during adult life most often without showing symptoms, thus leading to delayed diagnosis and complications that may be fatal or disabling. Further, these are also known as 'lifestyle diseases' mainly due to their non-infectious origin of multiple risk factors that they may accrue since childhood.

Until recent times, NCDs have been identified as a burden limited to the developed countries, but now have expanded as a public health threat to most developing and newly industrializing countries in the world (Ministry of Health, 2016a), including Sri Lanka.

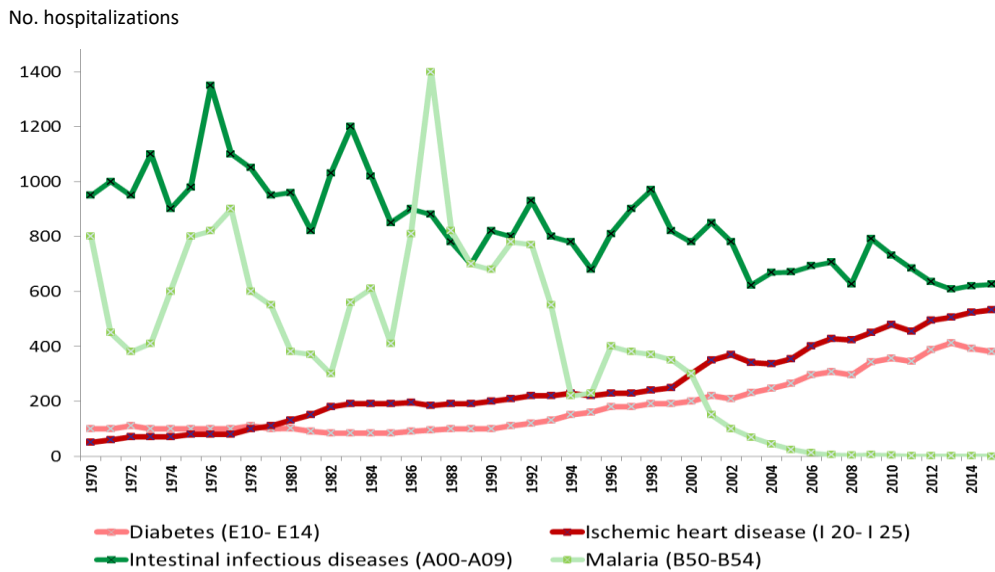
- In Sri Lanka, there are several underlying causes for this increase in NCDs. Over the last few decades, the improvement in child survival complemented by the fertility rate which had started to stagnate at 2.5 since 1995 (<https://databank.worldbank.org>). It has led to a vital change in the population structure – a demographic transition.
- The demographic transition signifies a change in the population structure towards a progressive expansion of the older segment of the population (Figure 2.3), resulting in rapid aging of the Sri Lankan population. At present, the life expectancy at birth is around 75 (<https://databank.worldbank.org>). It is projected that 20% of the Sri Lanka's population will have reached the age 60 years or over by 2020 (WHO, 2018).

**Figure 2.3: Population pyramid of Sri Lanka in 2017**



Source: Population Pyramids of the World 1950-2100 (<https://www.populationpyramid.net/sri-lanka/2019>)

- Parallel to the demographic transition, the disease pattern in Sri Lanka has taken a sharp turn – an epidemiological transition, where the NCDs, which are non-infectious in origin and of ‘adult onset’, have become more apparent.

**Figure 2.4: Trends in diseases of Sri Lanka 1970-2014**

Source: Medical Statistics Unit, Ministry of Health, Sri Lanka

As demonstrated in Figure 2.4, childhood nutritional deficiencies and infections such as malaria, tuberculosis, dengue, acute intestinal and respiratory infections are still highly prevalent, but at a gradual decline, in contrast to a sharp rise in NCDs. This transition enables NCDs to surpass the epidemiological burden of communicable diseases, compared to the past few decades.

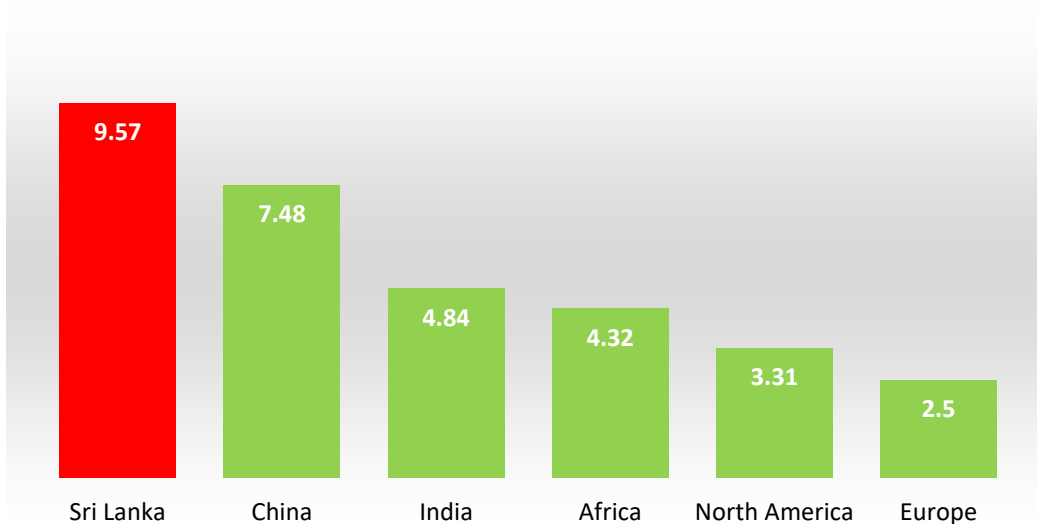
The epidemiological transition signifies, though still at a higher level, a gradual decline in communicable diseases, along with a sharp increase in major NCDs.

- Another crucial factor for this rise in NCDs is the drastic change that had taken place during the last few decades in the lifestyle of people in Sri Lanka, changing from a traditional active lifestyle to a more sedentary one in parallel with the rapid and unplanned urbanization taken place in Sri Lanka. The increasing incidence shows an exponential relationship with urbanization, improved economic status and globalization in the world, thus closely linked with sedentary lifestyle.

Preliminary analysis of a spatial survey being conducted by the UN-Habitat on urbanization across the nine provincial capitals in Sri Lanka reveals, that Sri Lanka's cities have expanded rapidly since 1990s at 9.57% growth of urban area per year during 1995-2017 (UN-Habitat, 2018). This is remarkably high by global standards, when compared

with a cross-country review of over 300 spatial case studies reporting far lower growth rates in Europe, North America, Africa, India and China during 1970-2000 (Figure 2.5).

**Figure 2.5: Average annual rates (%) of urban expansion across the globe \***



\* Sri Lanka reference period 1995-2017 for 9 provincial capitals; For others, 1970-2000

Sources: UN-Habitat State of Sri Lankan Cities Preliminary Report, 2018; For others, Seto et al., 2014

It further suggests that the urban built-up area has increased from around 41 km<sup>2</sup> in 1995 to 281 km<sup>2</sup> in 2012 in Colombo, while non-built up areas have diminished from 125 km<sup>2</sup> to 10 km<sup>2</sup> (Figure 2.6).

**Figure 2.6: Urban expansion of Colombo District \***



\* Images show the extent of area showing urban land use characteristics in UN-Habitat analysis.

Source: UN-Habitat State of Sri Lankan Cities Preliminary Report, 2018

Colombo's rapid urban expansion is mirrored across the other provincial capitals. This trend of urban expansion during this period is far greater than at any other time in the settlement's existence. Along with this trend, the diet, physical activity level and habits of people have become unhealthy, thus leading to the accumulation of the risk factors of NCD in urban settings.

Major NCDs have increased in Sri Lanka during the last few decades, on one hand due to the demographic transition towards rapid aging of the population, and on the other due to a change in the lifestyle of people from traditional active to a more sedentary lifestyle, leading to an accumulation of multiple risk factors responsible for NCDs.

## **2.2 Trends in the disease burden of major NCDs in Sri Lanka**

In this section, trends in the burden of major NCDs are assessed in relation to mortality, premature mortality and morbidity.

### **2.2.1 Sources of information**

The sources of information used for this purpose include Country Profiles of the World Bank and WHO developed based on several data sources for evidence on the trends and current status of mortality and disability on major NCDs; and all-island data routinely collected by the Registrar General's Department, Department of Census & Statistics and Medical Statistics Unit, periodically collected data in local surveys (SLDHS, STEPS Survey) and data of local epidemiological studies for evidence on the trends and current morbidity related to incidence, hospitalizations and population prevalence of CVD, DM and related complications and disability.

### **2.2.2 Mortality due to major NCDs**

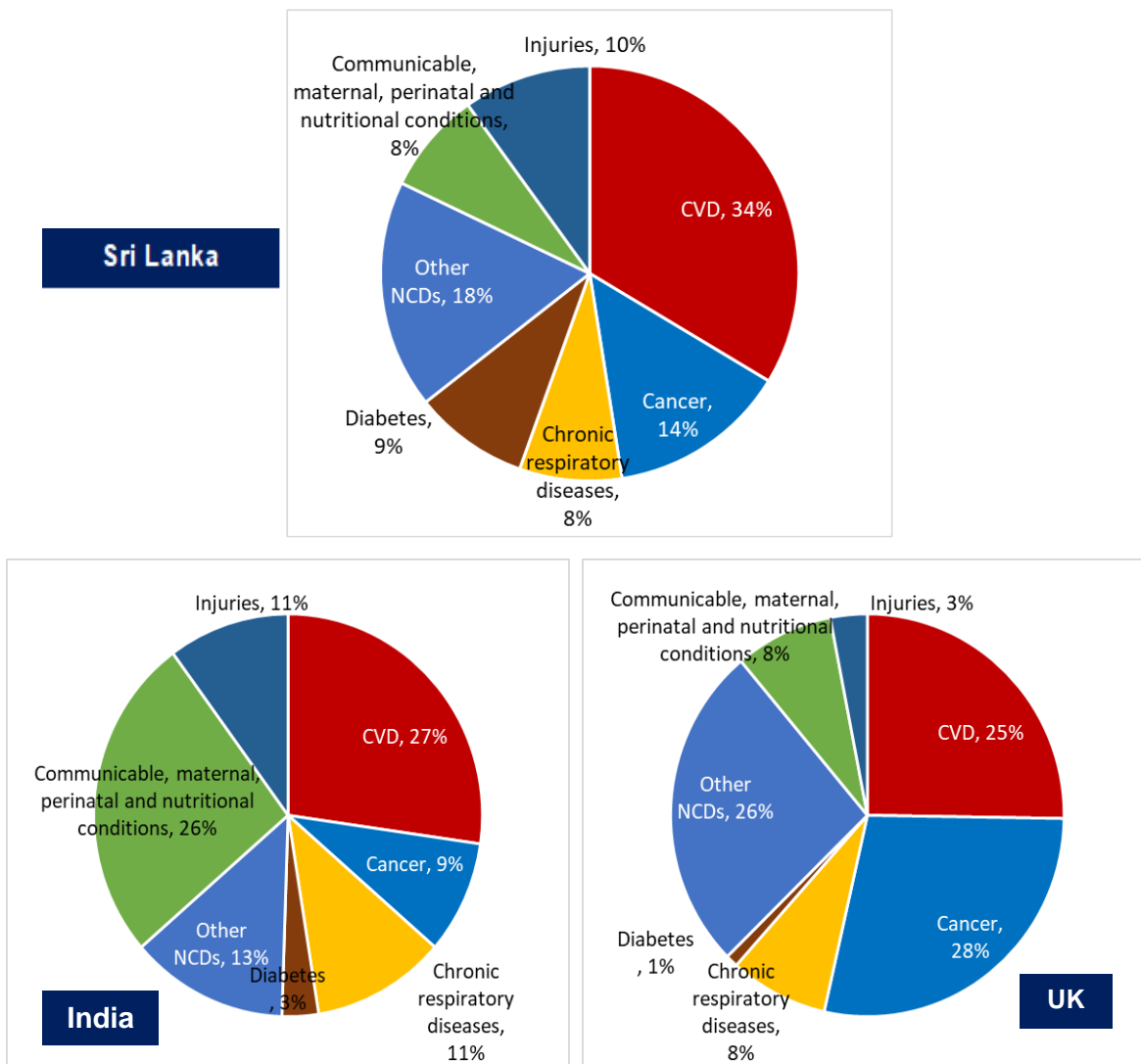
The trends in NCD burden are complex and differ between the developed and developing countries.

According to the latest WHO estimates of 2016, the four major NCDs (CVD, cancer, DM and chronic respiratory diseases) accounted for 41 million out of the total 57 million deaths in the world (72%) (WHO, 2018). Almost 80% (28 million) of these deaths occurred in LMICs. Further, unlike in high- and middle-income countries where the major NCDs are concentrated in the

poor, the burden is still higher among the rich while that due to asthma is higher among the poor in LMICs (Michael et al., 2010).

- In comparison with 72% in the world, NCDs in 2016 accounted for 83% of all deaths in Sri Lanka; 10% due to injuries; and 8% due to communicable diseases and maternal & perinatal conditions according to the WHO estimates (Figure 2.7) (WHO, 2018), highlighting higher burden of NCD mortality than the global estimate. According to the SLDHS estimates, NCDs comprised 70% of all deaths in 2016 (Department of Census & Statistics, 2016a).

**Figure 2.7: Comparison of the causes of death in Sri Lanka, UK and India, 2016**



Source: NCDs Country Profiles, WHO, 2018



- In comparison with the 83% in Sri Lanka, the contribution of NCDs to mortality was 89% in the UK and 63% in India (Figure 2.7). This reflects that Sri Lanka has a relatively higher burden due to NCD mortality in the region, and somewhat similar to that in developed countries. In further comparison, the contribution of CVD and DM to the country's NCD mortality was relatively much higher than that reported from India as well as the UK.

The substantial contribution of CVD and DM to the NCD mortality in Sri Lanka needs to be further explored in terms of genetics and environmental vulnerability of people.

- With regards to mortality trends in NCDs over the years, in comparison with 83% in 2016, NCDs have accounted for a lesser proportion of deaths in Sri Lanka in 2010 (65%); 26% due to injuries; and 9% due to communicable diseases and maternal & prenatal conditions (WHO, 2011). This is compatible with the epidemiological transition observed in the country, in which NCDs continue to rise (Ministry of Health, 2009).

In further analysis of the causes of NCD mortality, CVD is shown to be the leading cause of death in Sri Lanka, where as much as 34% was caused by CVD in 2016 (WHO, 2018). Table 2.4 indicates that during the past 40 years, circulatory disease (including heart disease and stroke) have been the leading cause of death in Sri Lanka. It has increased from 3% in 1945 to 24% by 1980 while those due to infectious diseases have decreased from 42% to 13% during the same period. In parallel, deaths from cancer and DM have also shown an increasing trend over the years, the rates almost doubling from 1960 to 1980 for cancer and from 1980 to 2000 in relation to DM.

**Table 2.4: Percentage of deaths from major causes in Sri Lanka 1945-2003**

Cause of death	Deaths (%)				
	1945	1960	1980	2000	2003
Disease of the circulatory system	2.8	8.6	24.3	21.3	23.8
Infectious diseases	41.8	24.1	12.9	18.0	19.7
Cancer	0.6	2.6	5.7	6.8	7.6
Diabetes mellitus	0.4	0.7	1.1	2.3	3.0
Maternal & child health	4.8	4.4	1.7	0.5	0.5
Injuries	2.5	5.0	6.5	14.3	9.5
Other	47.1	54.6	47.8	36.8	35.9
All causes (Total no.)	142,931	84,918	91,020	114,554	104,508

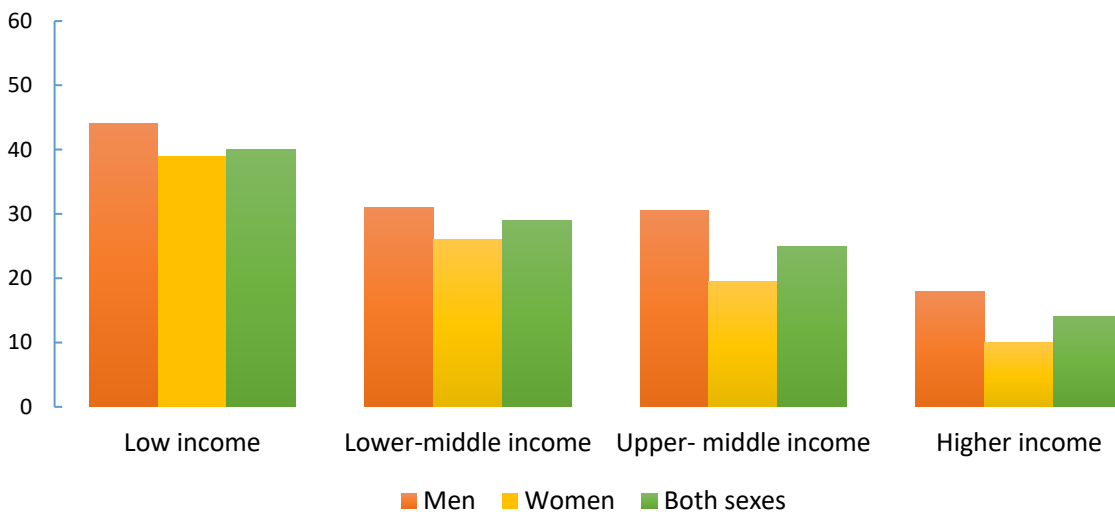
Source: Rannan Eliya et al. Institute of Health Policy Technical Report Series, 2010

More than 80% of deaths are attributed to major NCDs in Sri Lanka, highlighting a higher burden compared to the global and regional mortality estimates. Circulatory system diseases have remained as the leading cause of death since 1980s in Sri Lanka, along with a steady increase in deaths due to cancer and DM.

### 2.2.3 Premature mortality due to major NCDs

In the world, 85% of the NCD deaths occur as premature deaths before the age of 70 (age between 30-70). In 2016, this accounted for 15 million out of 57 million total global deaths. Also, as shown in Figure 2.8, the proportion of premature deaths is higher in LMICs compared to that in upper-middle income and upper-income countries.

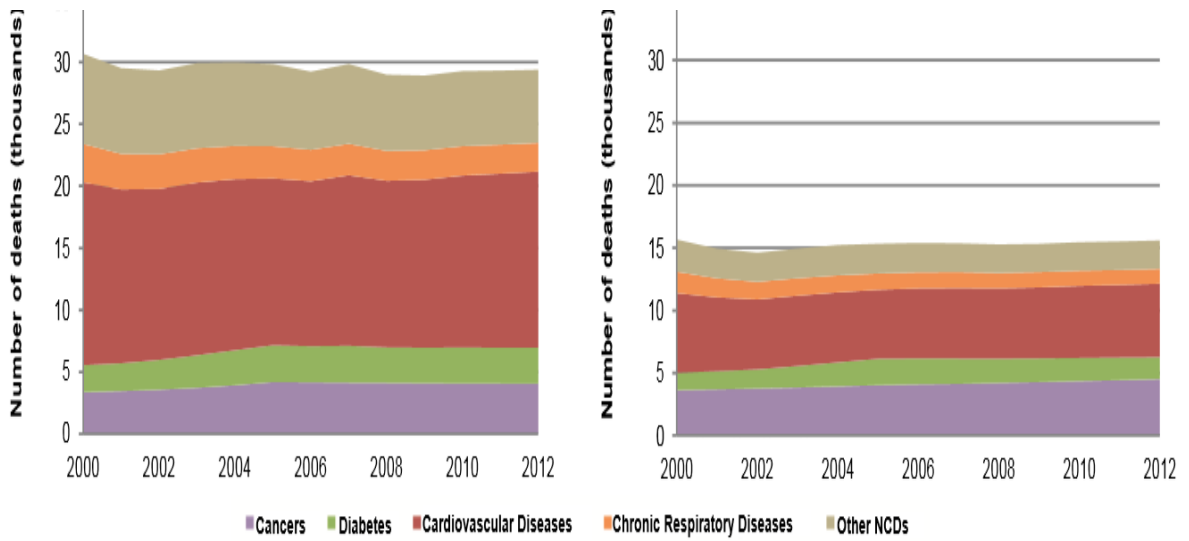
**Figure 2.8: Proportion of NCD deaths occurring among those aged 30-69 years by income groups worldwide**



Source: NCDs Country Profiles, WHO, 2018

- When the probability of dying between 30-70 from one of the four major NCDs (i.e. premature death) is considered, it is 17% in Sri Lanka (Figure 2.9) (WHO, 2018). This is in comparison with 12% in the UK and 26% in India. Further, Sri Lankan males seemed to have a greater risk (22%) than for females (13%).

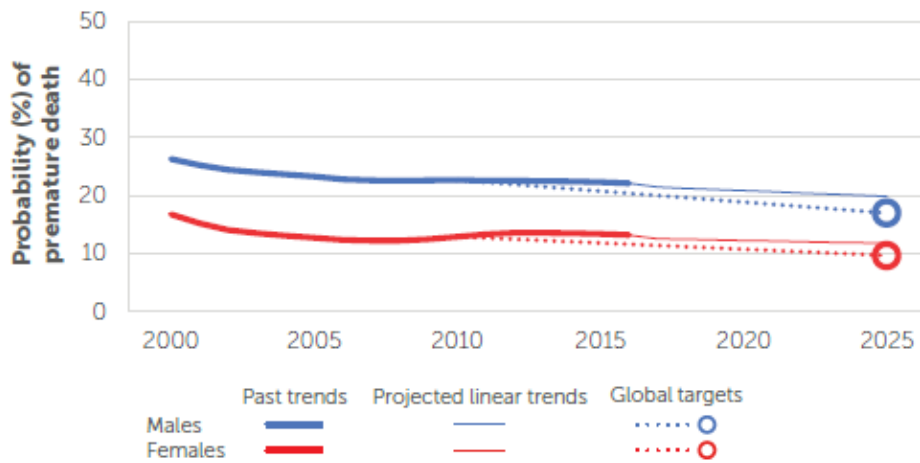
**Figure 2.9: The probability of dying from a major NCD before 70 years in Sri Lanka**



Source: NCDs Country Profiles, WHO, 2014

- Also, according to the WHO’s risk prediction, premature deaths due to NCDs are higher than the forecasted global targets in Sri Lanka from 2020-2025 (Figure 2.10).

**Figure 2.10: Risk of premature death due to NCD in Sri Lanka**



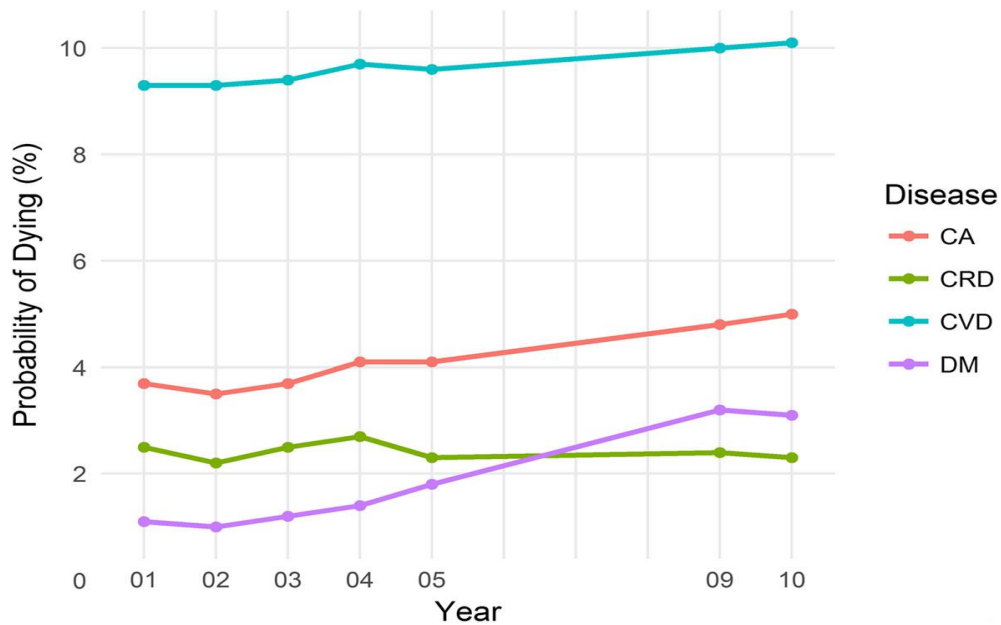
	Data year	Male	Female	Total
Total NCD deaths	2016	62600	56100	118700
Risk of premature death between 20-70 years (%)	2016	22	13	17

Source: NCDs Country Profiles, WHO, 2018

Though NCDs in Sri Lanka contribute to the total deaths in a proportion closer to that in developed countries, the premature deaths due to NCDs are much higher in Sri Lanka, reflecting a greater disease burden than in developed countries; and as in many other developing countries, the major NCDs in Sri Lanka end predominantly in premature death.

- Local studies (Karunapema et al., 2015a (abstract); Ediriweera et al., 2018) estimated the unconditional probability of dying (UPoD) between 30-70 years and age-standardized mortality rates (ASMR) due to the four major NCDs during 2010 in Sri Lanka. In this study, the life table method was used, which allows calculation of the risk of death in the absence of other causes of death. ASMRs were obtained for each NCD, by applying age-specific death rate to the WHO 2000 standard world population. Mortality data for 2010 were obtained from Registrar General Department. Results showed that the UoPD was 22%, while the ASMR was 312 per 100,000 population. The ASMRs were 163, 45, 56 and 46 for CVD, DM, cancer and chronic respiratory diseases (Figure 2.11).

**Figure 2.11: Unconditional probability of dying due to four major NCDs between 30 to 70 from 2001-2010 in Sri Lanka**



Source: Ediriweera et al. BMC Public Health 2018; 18:584

### 2.2.4 Morbidity due to major NCDs

Morbidity due to major NCDs is assessed in relation to the incidence (new cases) and prevalence (existing cases) of the diseases as well as complications leading to disabilities.

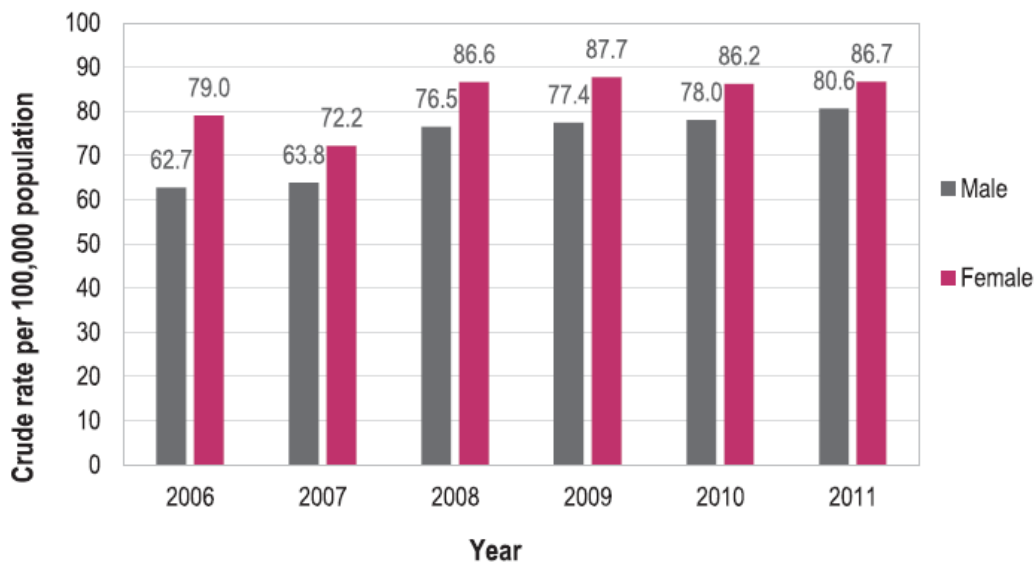
#### 2.2.4.1 Incidence and prevalence of major NCDs

##### a. Hospital-based morbidity

More reliable information on disease incidence is collected through patient registries updated annually.

- There is a registry maintained on cancer incidence data since 2001 (most updated for 2011) (Figure 2.12). The data sources include government cancer treatment centres, pathology laboratories and oral and maxilla-facial surgical units scattered in the country.

**Figure 2.12: Crude annual death rates due to cancer in Sri Lanka 2005-2011**



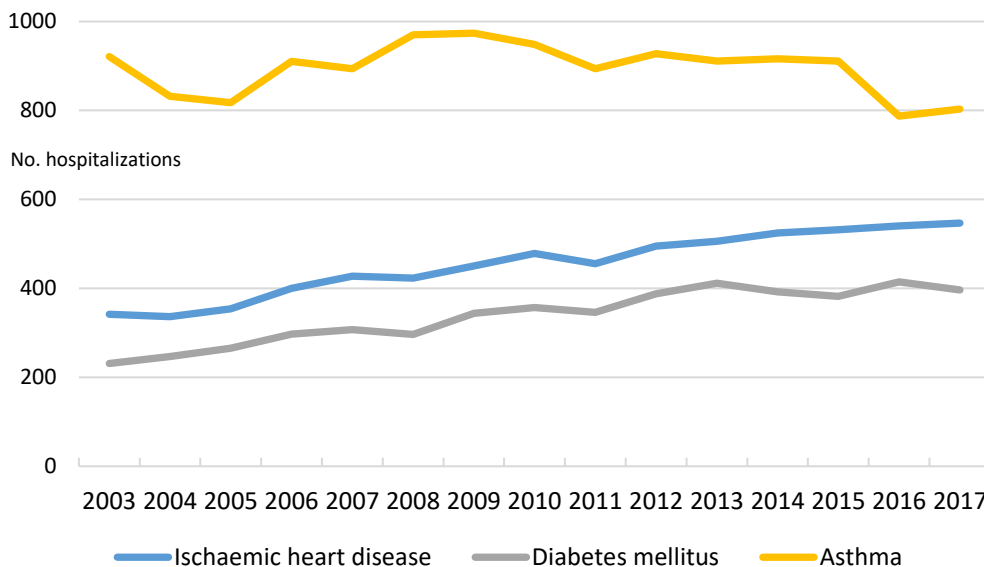
Source: Cancer Incidence Data Sri Lanka, NCCPSL, 2011

- There is another hospital-based registry established for patients diagnosed with chronic kidney disease or that of unknown origin attending the renal clinics in Medawachchi, Medirigirya, Anuradhapura and Polonnaruwa hospitals. It is planned to be converted into a national registry in future. No other registry is available for estimating the incidence of major NCDs at national level.

Indoor morbidity and mortality registers (IMMR) comprise the only source available for estimating the prevalence trends of major NCD based on hospital data.

- According to the hospitalizations recorded from 2003-2017 (Medical Statistics Unit, 2017) (Figure 2.13), though asthma shows a slight reduction, hospital admissions due to IHD and DM seem to have steadily increased over time.

**Figure 2.13: Trends in hospitalizations due to NCD in Sri Lanka 2003-2017**



Source: Medical Statistics Unit, Ministry of Health, Sri Lanka

The hospitalization trend from 2010 to 2017 shows that admissions due to IHD have steadily increased over this decade, with 547 admissions reported per 100,000 in 2017. Though hospitalizations for DM have remained at a comparatively lower level throughout, it appears to have increased parallel with IHD in the last three decades. This rise in hospital admissions due to DM also parallels with the increase in mortality due to DM during the same period in the world (WHO mortality trend 2010-2016), highlighting its increasing burden. It should however be noted that these hospitalization trends may not reflect the true prevalence, since repeated clinic visits/admissions of the same patient could add to the prevalence, which further points to the need for an efficient health information system linking patients' data through a unique identification number that could be retrieved electronically. Furthermore, though NCDs entail more outpatient than in-ward care, it is not possible to track such morbidity statistics, as such data are not routinely collected by hospitals in Sri Lanka, including in the private sector and primary health care.

The most accurate prevalence data come from population-based surveys and epidemiological studies, which are fewer in number, yet providing valuable data relevant to Sri Lanka.

### **b. Population-based surveys**

There are no surveillance data routinely collected during population-based surveys to estimate the prevalence of major NCDs in Sri Lanka.

- However, the last SLDHS conducted in 2016 collected data for the first time on heart disease and DM from 18,302 ever-married women in addition to the usually collected MCH data. Accordingly, the prevalence of heart disease was 2.2% and that of DM was 5.7%. It is noteworthy that this data is limited to a sub-group of women.
- In contrast, the STEPS Survey 2015 carried out in a nationally representative sample of 15-64 year old adults has reported a prevalence of DM of 7.4%, with a higher prevalence in females (7.6%) compared to males (7.3%). Impaired fasting glycaemia also followed a similar trend.

### **c. Epidemiological studies on DM**

The epidemiological studies conducted on DM at national level in Sri Lanka are summarised in Table 2.5. The studies varied by several characteristics, in relation to the geographical location and sample size. Further, the earlier studies have used the 1985 WHO Criteria while the newer studies have used the 1997 American Diabetic Association (ADA) Criteria for diagnosis of DM. In the absence of local cut-off values, fasting venous plasma glucose (FPG) of >126 mg/dl (>7 mmol/l) or random/post 2-hour glucose load value of >200 mg/dl (11.1 mmol/l) is currently being used for diagnosing DM in Sri Lanka, as per recommended by the ADA and WHO Criteria.

**Table 2.5: Trends in the prevalence of DM and IGT in Sri Lanka based on epidemiological studies**

Author, Year	Sample size	Target population	Study area	Sampling	Diagnosis of DM	Prevalence (%)		
						Total	M	F
Illangasekera et al., 1993	220	Above 18 years	Rural community	Not retrieved	WHO criteria	2.5 8.0*	-	-
Fernando et al., 1994	633	30-64 years	Maharagama (suburb of Colombo)	Simple random	WHO criteria	5.02 (3.6, 6.4) 5.3* (3.7, 6.8)	-	-
Mendis et al., 1994	975	35-59 years males only	Central Province in 12 GN divisions	Randomly selected	FBS; not retrieved	-	5.8	-
Malavige et al., 2002	1042	30-64 years	Maharagama (suburb of Colombo)	Simple random	FBS; ADA guidelines	6.5	-	-
Wijewardene et al., 2005 (1998-2002 Study)	6047	30-65 years	Western, North Central, Southern & Uva Provinces	Stratified cluster	WHO/ ADA definition		14.2 (11.9, 16.5) 14.2*	13.5 (6.9, 20.1) 14.1*
Illangasekera et al., 2004	220	Above 18 years	Rural area in Central Sri Lanka	Randomly selected	FBS; not retrieved	8.5	-	-
Katulanda et al., 2008a (SLDC Study 2005-06)	4485	Above 18 years	All excluding North and East Provinces	Cluster randomized model	WHO/ ADA criteria	10.9 (9.9, 11.9) 5.5*	10.3 (9.4, 11.2) 4.2*	10.9 (9.9, 11.9) 6.5*

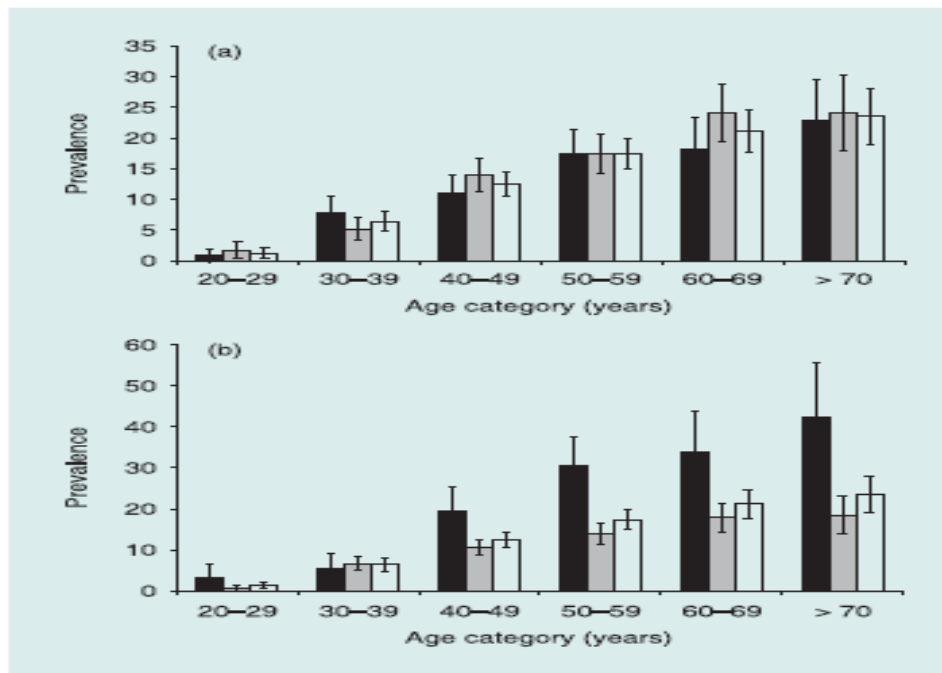


Author, Year	Sample size	Target population	Study area	Sampling	Diagnosis of DM	Prevalence (%)	Author, Year	Sample size
Mendis et al., 2011 (WHO Risk Prediction Study)	1099	40-80 years	Specific areas			9.9	-	9.9
De Silva, 2010	1234	35-64 years	Kalutara District	Stratified multistage cluster		14.7 14.3*	14.9 14.2*	16.1 16.6*
Waidyathilaka et al., 2013	2800	30-45 year old women with no known DM	Colombo Municipal Council area	Cluster from all 55 GN divisions	ADA 2012	-	-	9.7
Mayurathan et al., 2017	6335	School staff	Jaffna District	All academic and non-academic staff		6.0	8.0	6.0

\*Impaired glucose tolerance

The epidemiological studies point to characteristic features pertaining to DM in Sri Lanka.

- According to the nationally representative study on DM in Sri Lanka (SLDC Study), which has been conducted in all except North and East Provinces among 4485 adults above the age of 18 years during 2005-06 period (Katulanda et al., 2008a; Katulanda et al., 2011a), the crude prevalence of DM was 12.6%. It showed marked variation in the province- and ethnic-specific prevalence, with the highest (18.6%) reported from Western Province followed by Central (12.6%), Southern (12.2%), Sabaragamuwa (11.5%), North-Western (10.0%) and Uva (6.8%) Provinces and the lowest (6.8%) reported from Uva Province. Sri Lankan Tamils (22.1%) had the highest prevalence of DM followed by Muslims (21.4%), Sinhalese (11.9%) and Plantation Sector Tamils (3.2%). In comparison, a population-based study conducted by Wijewardene et al. (2005) almost five years before among 6047 participants representing four provinces of Sri Lanka identified the age- and sex-standardized prevalence of DM to be 13.9%, with wide variation between provinces. The highest prevalence was seen in Western Province, which was three times higher than in Southern Province.
- As shown by Wijewardene et al. (2005), the prevalence of DM is found to increase with age, with the highest in 46-65 year age group in both males and females. In concurrence, the prevalence reported in SLDC Study also seemed to increase progressively with age in both males and females, showing a significant trend ( $p < 0.001$ ) (Katulanda et al., 2008a).
- The SLDC Study further concluded that DM is significantly higher in urban areas (16.4%; 95% CI=13.8, 19.0) than in rural areas (8.7%; 95% CI=7.8, 9.6) in Sri Lanka (Figure 2.14) (Katulanda et al., 2008a).

**Figure 2.14: Age-specific prevalence of DM among Sri Lankan adults in urban & rural sectors**

**FIGURE 2** Age-specific prevalence of diabetes among adults in Sri Lanka according to (a) sex and (b) sector of residence. (a) ■, male; ■, female; □, all. (b) ■, urban; ■, rural; □, all.

Source: Katulanda et al. Diabetic Medicine 2008; 25: 1062-1069 (SLDC Study 2005-06)

Higher prevalence of DM in urban areas is supported by the SLDHS (2016) as well. Further, studies representative of urban populations have shown similar estimates, such as 16.9% in Colombo District (Arambepola, 2004); 17% in CMC area (Fernando, 2016); 17.4% in Gampaha District (Liyanapathirana, 2014); and 14.7% in Kalutara District (De Silva et al., 2011a). The latter showed further variation by residential sector (urban- 23.6%, rural- 15.5%, plantation- 8.5%).

The prevalence of DM is shown to have an increasing trend over the years; vary markedly by province; progressively increase with age and higher in urban areas. Further, as in many other developing countries, DM in Sri Lanka has an early age of onset.

- Another salient finding of the study by Katulanda et al. (2008a) was that 11.5% of the sample had pre-DM, while 21.8% had some form of dysglycaemia, indicating that one in five adults in Sri Lanka has either pre-DM or DM (Table 2.6).

**Table 2.6: Prevalence of DM, pre-DM and any form of dysglycaemia in the Sri Lankan population 2005-2006**

	Age (years)	n	Total diabetes (%; 95% CI)	IFG alone (%)	IGT alone (%)	IFG + IGT together (%)	Pre-diabetes (%; 95% CI)	Dysglycaemia (%; 95% CI)
Urban	20-29*	116	3.3 (0.0-6.6)	1.2	1.1	1.3	3.6 (0.2-7.0)	6.9 (2.2-11.6)
	30-39*	174	5.6 (2.2-9.0)	2.2	8.2	2.3	12.7 (7.7-17.7)	18.3 (12.5-24.1)
	40-49*	189	19.6 (13.9-25.3)	5.5	6.1	2.7	14.3 (9.3-19.3)	33.9 (27.1-40.7)
	50-59*	155	30.4 (23.1-37.7)	10.1	6.7	3.6	20.4 (14.0-26.8)	50.8 (42.9-58.7)
	60-69*	81	33.7 (23.4-44.0)	11.5	8.3	0.7	20.5 (11.7-29.3)	54.2 (43.3-65.1)
	≥ 70*	55	42.5 (29.5-55.5)	11.2	8.3	10.3	29.8 (17.7-41.9)	72.3 (60.4-84.2)
	≥ 20*	770	16.4 (13.8-19.0)	5.2	5.7	2.7	13.6 (11.2-16.0)	30.0 (26.7-33.3)
Rural	20-29*	527	0.7 (-0.1-1.5)	2.5	3.3	0.0	5.8 (3.8-7.8)	6.5 (4.5-8.5)
	30-39*	713	6.7 (4.8-8.6)	3.2	5.9	0.9	10.0 (7.8-12.2)	16.7 (14.0-19.4)
	40-49*	901	10.5 (8.4-12.6)	5.6	5.2	1.8	12.6 (10.4-14.8)	23.1 (20.4-25.8)
	50-59*	741	13.9 (11.4-16.4)	6.0	5.9	2.3	14.2 (11.7-16.7)	28.1 (24.9-31.3)
	60-69*	456	17.9 (14.4-21.4)	5.8	6.2	2.8	14.8 (11.5-18.1)	32.7 (28.3-37.1)
	≥ 70*	280	18.5 (13.9-23.1)	4.6	9.7	3.6	17.9 (13.4-22.4)	36.4 (30.7-42.1)
	≥ 20*	3618	8.7 (7.8-9.6)	4.2	5.4	1.4	11.0 (10.0-12.0)	19.7 (18.4-21.0)
All	20-29†	643	1.3 (0.4-2.2)	2.3	2.8	0.3	5.4 (3.6-7.2)	6.7 (4.7-8.7)
	30-39†	887	6.4 (4.7-8.1)	3.0	6.4	1.2	10.6 (8.6-12.6)	17.0 (14.5-19.5)
	40-49†	1090	12.4 (10.4-14.4)	5.6	5.4	2.0	13.0 (10.9-15.1)	25.4 (22.8-28.0)
	50-59†	896	17.4 (14.9-19.9)	6.8	6.1	2.6	15.5 (13.1-17.9)	32.9 (29.9-35.9)
	60-69†	537	21.2 (17.7-24.7)	6.9	6.7	2.4	16.0 (12.9-19.1)	37.2 (33.1-41.3)
	≥ 70†	335	23.5 (18.9-28.1)	6.0	9.4	5.0	20.4 (16.1-24.7)	43.9 (38.6-49.2)
	≥ 20†	4388	10.3 (9.4-11.2)	4.4	5.4	1.7	11.5 (10.5-12.5)	21.8 (20.5-23.1)
≥ 20 years	Male‡	1720	9.8 (8.4-11.2)	5.6	4.2	1.2	11.0 (9.5-12.5)	20.8 (18.8-22.8)
	Female‡	2668	10.9 (9.7-12.0)	3.1	6.5	2.1	11.7 (10.5-12.9)	22.6 (20.9-24.3)
	≥ 20§	4388	10.9 (9.9-11.9)	4.6	5.5	1.8	11.9 (10.9-12.9)	22.8 (21.6-24.0)

Data are % or % (95% CI—confidence intervals).  
\*Sex standardized, †sex and sector standardized, ‡age and sector standardized, §World Health Organization standard population.  
CI, confidence interval; IFG, impaired fasting glucose; IGT, impaired glucose tolerance.

Source: Katulanda et al. Diabetic Medicine 2008; 25: 1062-1069 (SLDC Study 2005-06)

- Higher proportion of raised FPG seen in relatively young high-risk populations is remarkable.

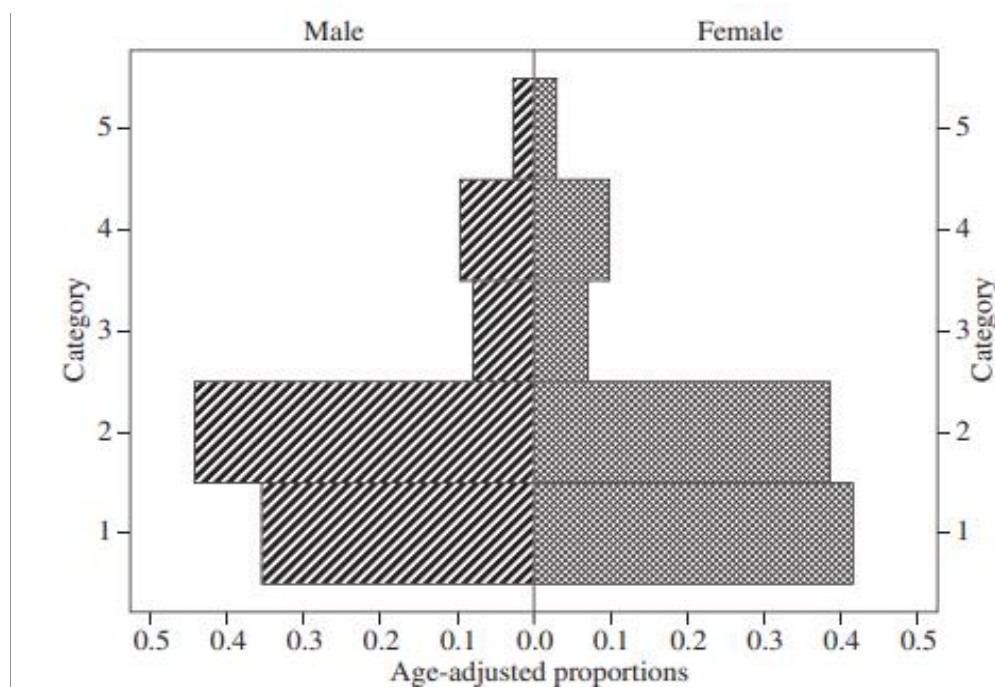
This was evident in a sample of 4532 subjects aged 10-40 years (50% below 16 years) who were having ≥ 2 risk factors (first degree family history of DM, physical inactivity, raised waist circumference (WC) and body mass index (BMI) (Wijesuriya et al, 2012), reporting an overall prevalence of impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) of 16%; DM was newly diagnosed in 106 subjects (3 cases <15 years of age; 6 between 15-19 years; and others 20-40 years). Fasting insulin level and homeostasis model assessment of insulin resistance (HOMA-IR) were not significantly different between males and females. One limitation to note is that, though it claims to represent the young urban population of Colombo District by age and sex, the sample had been drawn from 22,507 subjects residing/working/schooling within a 30 km radius of the National Diabetes Centre in Colombo Sri Lanka.

- The high prevalence of undetected DM is noteworthy.

In North & East Provinces where rapid development and urbanization had taken place following the end of civil conflict, a few recent studies have reported the prevalence of DM to be 15.7% in Point Pedro and Karaveddy MOH areas (Amarasinghe et al., 2012) (abstract); and 9.3% in 14 GN divisions of Kopay Divisional Secretariat (DS) division (Vinitharan et al., 2012) (abstract). A striking finding is that 33% and 45.9% of this prevalence was composed of previously undiagnosed DM, respectively. This was compatible with the SLDC Study, where one third of those with DM were previously undiagnosed. Prevalence among the previously undiagnosed also increased with age and peaked at  $\geq 70$  years.

When looking at the distribution of glycaemic status in an urban population (Figure 2.15), a study among 2986 adults limited to one MOH area (Ragama Health Study) showed that the age-adjusted prevalence of DM was 20.3% among males and 19.8% among females, while 35.7% of this was previously undiagnosed (Pinidiyapathirage et al., 2013). The percentage of women having impaired plasma glucose levels was less than that of men in all age groups. The prevalence increased with age in both sexes.

**Figure 2.15: Diabetic pyramid in an urban Sri Lankan population**



Category 1=Normal glycaemic category; Category 2=impaired fasting glucose; Category 3=newly detected at screening; Category 4=patients with DM without sub-optimal control; Category 5=patients with DM with optimal control

Source: Pinidiyapathirage et al. Diabetic Medicine. 2013; 30: 326-332

In concurrence, another study among 2800 women (30-45 years) recruited from all GN divisions of CMC area to represent the urban middle-aged women in Sri Lanka, women detected of dysglycaemia who were previously unaware of their glycaemic status was 272 (Waidyatilaka et al., 2019). This highlights the need for analyzing the underlying reasons for being undiagnosed, despite the primary healthcare services on DM screening provided free of charge.

The prevalence of pre-diabetes is shown to have an upward trend, with the majority remaining undetected, both in well-established urban settings and those in transition.

- Based on the UN population forecasts for the age-structure and urban-rural population distribution, Katulanda et al. (2008a) projects the age-sex standardized prevalence estimates for DM, pre-DM and overall dysglycaemia for the year 2030 to be 13.9%, 13.1% and 26.2%, respectively among Sri Lankan adults  $\geq 20$  years of age.

#### **d. Epidemiological studies on CHD**

Only a very few epidemiological studies are available on the prevalence of CHD in Sri Lanka.

- The earliest study on CHD prevalence was by Mendis et al. (1994) conducted during 1990-1991 among 975 males aged 35-59 years representative of the middle-aged Sri Lankan males. The sample was recruited from 12 GN divisions in Kandy and Matale Districts of the Central Province using simple random sampling on electoral lists. CHD was determined using a questionnaire on chest pain (developed based on the London School of Hygiene Cardiovascular Questionnaire) and 12-lead electrocardiogram. As shown in Table 2.7, the overall prevalence of CHD was identified as 10.2 per 100 males (95% CI=8.3, 12.4), with no significant difference shown in the prevalence between urban (11.5%) and rural (8%) sectors.

**Table 2.7: Prevalence of some indicators of CHD in middle-aged males in central Sri Lanka**

Diagnostic categories	No.	Prevalence (95% CI)
• Angina (definite or possible) or possible myocardial infarction by questionnaire only (without ECG changes of ischemia)	46	5.4 (4.0, 7.1)
• ECG changes of ischemia (asymptomatic)	27	3.2 (2.1, 4.6)
• Angina (definite or possible) or possible myocardial infarction, questionnaire plus ECG changes of ischemia (definitive ischemic heart disease) *	14	1.6 (0.9, 2.7)
Overall prevalence	87	10.2 (8.3, 12.4)

\*Out of 14 patients, eight had already been diagnosed as having CHD and were on treatment.

Source: Mendis & Ekanayake. International Journal of Cardiology 1994; 46: 135-142

- In 2005-06, Katulanda et al. (2010c) (abstract) in the SLDC Study revealed an age- and sex-standardized IHD prevalence of 9.3% (males- 7.2%; females- 11.3%). Risk factors present among them were HT (6%), one or more lipid abnormality (37.0%), smoking (18.4%), physical inactivity (14.1%), obesity (8.9%), DM (11.5%) and family history of IHD (22.9%).
- A more recent study by Liyanapathirana (2014) determined the prevalence of CHD among urban adults aged 30-64 years in the district of Gampaha. The prevalence based on already diagnosed cases and positive for Rose Angina Questionnaire was 6.9% (95% CI=5.4, 8.4), while the prevalence based on already diagnosed cases and ECG was 6.4% (95% CI=4.9, 7.8) (Table 2.8). Further, the prevalence of Rose positive angina differed between males (3.9%) and females (5.1%), but this difference was not significant ( $p>0.05$ ).

**Table 2.8: Prevalence of angina based on Rose Angina Questionnaire and ECG changes**

Diagnostic category	No.	Prevalence (%)
<b>Based on Rose positive angina</b>		
No history of chest pain	436	39.1
Non-exertional chest pain	452	40.5
Possible angina	177	15.9
Definite angina	50	4.5
Total	1115	100.0
<b>Based on ECG</b>		
No ECG changes suggestive of CHD	788	95.9
ECG coronary probable	6	0.7
ECG coronary possible	27	3.3
Total	821	100.0

Source: Liyanapathirana A. PGIM MD (CM) Thesis, 2014

- Another study in a semi-urban population of 1000 limited to one MOH area in Galle District (Jayawardena et al., 2017a) reported the prevalence of CAD to be 6.9% (95% CI=5.33, 0.47) and silent ischaemia to be 2.2% (95% CI=1.29, 3.11), based on the Cardiovascular Questionnaire of London School of Hygiene.

Based on limited literature, the prevalence of CHD has been around 6.4-10.2% with female predominance, and does not seem to have varied distinctly over time. However, the studies varying by sex, area and diagnostic methods used should be considered when interpreting this evidence.

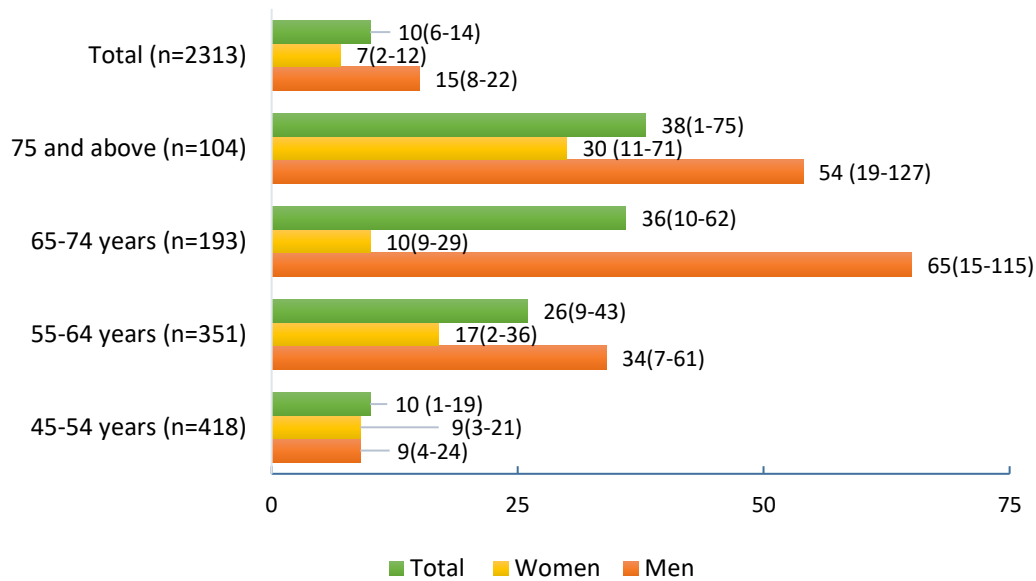
#### **e. Epidemiological studies on stroke**

Sri Lanka lacks prevalence data on stroke, except one epidemiological study conducted at national level and another at district level.

- As part of the SLDC Study, the prevalence of non-fatal stroke/ transient ischaemic attacks (TIA) in the Sri Lankan population was analyzed in a sample of 4485 adults aged  $\geq 18$  years. The diagnosis of stroke was made according to the WHO definition and through an interviewer administered questionnaire. Accordingly, 72 out of the 4473 participants had ever encountered non-fatal stroke/TIA, giving a crude prevalence of 16.09 per 1000 adults (Wijesundara et al., 2012) (abstract).
- The prevalence of stroke in a highly urban setting in Sri Lanka has been reported in a population-based study conducted by Chang et al. (2015) among 2313 adults aged  $\geq 18$  years in the district of Colombo, which was selected using a multistage sampling technique. The crude prevalence of stroke, as confirmed by medical doctors according to the WHO definition corroborated by documental evidence (medical records, brain scan reports, medication history) and interviews with participants and carers, was 14 per 1000 adults (95% CI=6.3, 14.5), with 2:1 male: female ratio. Also, 58.3% had undergone brain scan, of which 85.7% were confirmed as ischemic stroke (IS) and others as intra-cerebral haemorrhagic stroke (ICHs). The study concluded that the stroke prevalence in urban Sri Lanka lies between high-income and LMICs, with an increased prevalence among males.

In further analysis (Figure 2.16), the study showed that the compared to the least-risk group (18-44 age), the prevalence was 6-fold higher among males (62 per 1000 males; 95% CI=20, 104) and 2-fold higher among females (18 per 1000 females; 95% CI=2, 38) in the age group above 65 years.



**Figure 2.16: Prevalence of stroke in the district of Colombo per 1000 adult population**

Source: Chang et al. Stroke 2015; 46: 2965-2968

The mean age at onset of stroke victims was 58.2 years (SD=12.2 years), highlighting a relatively delayed onset. Hypertension was the commonest risk factor prevalent (62.5%) followed by smoking (45.8%), excess alcohol (41.7%), DM (33.3%) and TIA (29.2%) among the survivors. Further, 79.2% of them, mostly men, had  $\geq 2$  risk factors.

- Based on the Ragama Stroke Registry, which is the first comprehensive stroke registry in Sri Lanka capturing data of 2690 patients admitted to Colombo North Teaching Hospital (CNTH) over a seven-year period (Ranawaka et al., 2015a) (abstract), IS was observed in 81.3% and ICHS in 15.3%, with no significant difference by age and sex between the two groups. Previous history of stroke/TIA, DM, heart disease, obesity/overweight and smoking were commoner in the IS group.
- Based on the medical records collected in a retrospective study at the Teaching Hospital (TH) Batticaloa, 34 stroke patients were identified, of whom 61.8% were males, giving a male: female ratio of 1.6:1. The age group 60-69 years comprised the highest number of stroke survivors (35.3%) while 11.8% comprised the young stroke survivors (age  $\leq 50$  years) (Umakanth, 2018).

During last few decades, the prevalence of stroke has ranged around 1.61-10.2% in Sri Lanka; predominantly in males; characteristically of ischaemic type; and with delayed age of onset. Especially in urban settings, the prevalence lies between LMICs and high-income countries.

### 2.2.4.2 Complications related to CVD and DM

There is one stroke registry available in Sri Lanka (Ragama Stroke Registry), however there is no published evidence on the patient outcomes. No other long-term patient follow-up studies have been conducted in Sri Lanka to estimate the complications following DM and CVD,

#### a. Complications following DM

Several clinic-based studies are available on the prevalence of complications among DM patients (Table 2.9).

**Table 2.9: Summary of the prevalence of diabetic complications in Sri Lanka**

Study (year)	Setting and sample	Prevalence (%)			
		Retinopathy	Neuropathy	Nephropathy	
Katulanda et al., 2006a (abstract)	Clinic-based (354 DM patients)	22.0			
Katulanda et al., 2012b; Katulanda et al., 2014c	Population-based (528 DM Patients in SLDC Study)	27.4	24.0		
Katulanda et al., 2014d	Multiple-centres (684 young onset DM patients)	18.1			
Balasuriya et al., 2012	National Diabetes Centre Rajagiriya (6765 DM patients)	<1 **	6.8	11.0	18.8
		1-5	12.1	16.7	19.7
		6-10	28.3	28.6	21.2
		11-15	39.7	40.0	19.8
		16-20	52.6	54.3	23.8
		>20	57.8	65.3	25.4
Nisansala & Wimalasekera, 2015 (abstract)	CSTH clinic-based (384 DM patients)		45.6 *		
Sujanitha et al., 2015	TH Jaffna clinic-based (8401 DM patients)	12.0	34.1	39.5	

\* Neuropathy assessed by Michigan Neuropathy Screening Instrument (MNSI), Diabetic Neuropathy Index (DNI) and Monofilament Tests, and confirmed by a positive score in two of the three tests

\*\* The duration of DM (given in years)

- There is strong evidence on increased prevalence of macrovascular (CHD, stroke and PAD) and microvascular (neuropathy, retinopathy & nephropathy) complications related to DM patients in Sri Lanka (Table 2.9). It should however be noted that clinic-based findings may not reflect the true burden of complications, considering the better control that patients in clinic settings would have or the worst affected patients not attending the clinic, leading to an under- or over-estimation.

Complications related to DM are highly prevalent in clinic-based populations, highlighting the severe and extensive course of such NCDs.

- Though commonly encountered, there is evidence to suggest that complications such as neuropathy are under-diagnosed in clinic settings, as evident by only 16% of the patients identified in the study being previously diagnosed according to the recordings of clinic records, while the MNSI neuropathy score positively correlated with their postprandial blood sugar (PPBS) level (correlation coefficient=0.235;  $p=0.011$ ) (Nisansala & Wimalasekera, 2015).
- With regards to diabetic nephropathy, a study among 98 DM patients attending the Diabetic Centre at TH Jaffna suggests that with the increase in duration of DM, serum creatinine ( $r=0.1$ ), random urine albumin ( $r=0.35$ ) and urine albumin to creatinine ratio ( $r=0.43$ ) are shown to increase. Further, with longer duration, patients had macroalbuminuria rather than normo- or micro-albuminuria (Ruwanpathirana et al., 2018) (abstract).
- Based on literature, patients with DM are well known to develop CVD related complications.

In line, Arambewela et al. (2018a) reported a prevalence of CAD, stroke and PAD of 10.6%, 1.1% and 4.7% in a sample of 3000 DM patients recruited from National Hospital of Sri Lanka (NHSL) Colombo, which provides evidence that CVD is a known complications of DM. Sujanitha et al. (2015) also reports a prevalence of IHD of 21.1% and stroke of 3.9% in a large sample of DM patients attending clinics at TH Jaffna.

A study among 2422 DM patients of more than one year who were primarily managed at primary care settings (general practitioners, rural and district hospitals) over a period of four years in Galle District revealed that the control of all four major CVD risk factors (HbA1c, LDL-C, SBP, DBP) was seen only in two out of the 100 DM patients, indicating the need for improvement in target achievement in such settings (Weerathna et al., 2018a). The same study revealed that the overall prevalence of PAD was 15.3%, which was relatively high when compared with findings from other countries (Weerathna et al., 2019). Further, those with PAD were significantly different from those without PAD in SBP, DBP and estimated glomerular filtration rate (eGFR), but not with the duration of DM, HbA1c or any type of dyslipidaemia.

Underlying mechanisms of the CVD risk in relation to DM have also been explored in clinical settings.

#### **Mediating role of carotid intima thickness**

In a sample of 68 randomly selected DM patients with no history or symptoms of CVD, carotid intima medial thickness measured using B-mode ultrasonography showed a weak but significantly positive correlation with 10-year CVD risk assessed using UK Prospective Diabetes study (UKPDS) ( $r=0.26$ ;  $p<0.05$ ); positive but not significant correlation with Framingham Risk Score (FRS) ( $r=0.21$ ;  $p>0.05$ ) and a negative correlation with the WHO risk score ( $r=-0.07$ ) (Herath et al., 2016a). This highlighted the mediating effect underlying the higher risk of CVD seen among DM patients.

#### **Mediating role of body fat percentage**

Ratnayake & Hettiarachchi (2016) studying the lipid profiles of DM patients and controls based on body fat percentage, showed that groups where body fat% was  $>30$  or visceral fat levels were  $>9$  did not show any significant difference in the parameters of DM patients and controls. Therefore, it is not likely that high CVD risk is mediated through body fat levels.

- Studies on diabetic foot complications are few.

In a study on 277 patients followed-up at the DM clinic of Sri Jayewardenepura General Hospital (SJGH) for a period of three years revealed that 42.6% had evidence of PAD, 61% had peripheral neuropathy, 9.8% had foot ulcers, 1.8% had previous amputation, 10.8% had clinically abnormal (dry and fissured) foot skin, 7.7% had macerated inter-digital

spaces, 24.3% had fungal infected nails and 11.5% had callus and corn of the sole. There were significant relationships observed for the following between peripheral neuropathy and amputation; PAD and amputation; and foot ulcer and amputation (Kugaseelan, 2015).

In another hospital-based study in TH Jaffna among 188 patients, 80.3% patients did not have any deformity while others had foot related conditions, such as nail in rolling, hammer toe, charcot foot and plantar warts. Also, 46.3% of the sample had absence of vibration on their medial malleolus and 31.9% had no pain sensation, while 72.9% patients had normal ankle reflex and 69.7% had peripheral pulse (Husna et al., 2018).

When assessing the diabetic foot complications requiring surgical interventions, a cross-sectional study among 91 DM patients attending the casualty surgical unit in a tertiary care teaching hospital with foot lesions revealed that the commonest location was margins of foot (31.9%) and had callosity formation (14.3%); swollen foot (80%); painful lesions (70%); and impalpable pulses (5.5%). Lesions were of grade 1 (17.7%), grade 2 (40.6%), grade 3 (28.8%- deep ulcer with abscess) and grade 4 (13.3%- local gangrene); and none of grade 5 (extensive gangrene) according to the Meggit Wagner Wound Classification grading (Ambegoda et al., 2016).

Another study among 300 patients attending the diabetic clinic at CSTH with clinically suspected onychomycosis revealed that 85% of them were mycologically confirmed cases. *Aspergillus* species were most commonly isolated (71%) followed by dermatophytes, yeasts and other molds. Of the patients having *Aspergillus* onychomycosis, 83% were in the >50 age group. Among those with *Aspergillus* nail infection, 63% had DM for over 15 years (Wijesuriya et al., 2015).

- In the SLDC Study, among the 1109 sexually active males, 6.6% were having some form of sexual problems compared to 7.9% among the 1488 sexually active females (Katulanda et al., 2014e). Distribution of these sexual problems in relation to their diabetic status is given in Table 2.10. As shown, sexual dysfunction is significantly common in those with DM compared to those without DM in Sri Lanka.

**Table 2.10: Prevalence and type of sexual dysfunction among Sri Lankan adults according to diabetes status**

Sexual dysfunction	Men			Women		
	Non-DM (n=984)	DM (n=125)	p value	Non-DM (n=1341)	DM (n=146)	p value
Any form of sexual dysfunction	50 (5.1%)	23 (18.4%)	<0.001	98 (7.3%)	19 (13%)	<0.05
Lack of sexual desire	15 (1.5%)	8 (6.4%)	<0.001	44 (3.3%)	13 (8.9%)	<0.01
Erectile dysfunction (in men)/ lack of lubrication (in women)	36 (3.7%)	21 (16.8%)	<0.001	20 (1.5%)	6 (4.1%)	<0.05
Lack of or delay in ejaculation (in men) /orgasm (in women)	12 (1.2%)	4 (3.2%)	<0.001	15 (1.1%)	6 (4.1%)	<0.01

Source: Katulanda et al. Journal of Diabetes 2014; 6: 335-336 (SLDC Study 2005-06)

Further, in regression analysis, longer duration of the disease (OR=3.8; 95% CI=2.4, 6.1) remained significantly associated with having any form of sexual dysfunction (28.8% DM of longer duration vs. 3.8% newly diagnosed DM in males; 16% vs. 9.9% in females) among the DM patients.

Another study conducted among 253 men with DM randomly selected from a clinic in Colombo showed that 73.1% had some degree erectile dysfunction, while 33.2% had severe to complete erectile dysfunction. Reduced libido was prevalent in 25%. In the multivariate analysis, the strongest associations with erectile dysfunction were premature ejaculation (aOR=4.41); reduced libido (aOR=4.38); lower income (aOR=2.16); advancing age (aOR=2.06) and duration of diabetes (aOR=1.48) (Malavige et al., 2008; Malavige et al., 2014).

- Amarasinghe et al. (2015c) showed in their study among 186 DM patients that 13.4% had mild depression while 15.6% had moderate depression. There were no cases of severe depression. The proportion of females with depressive disorder was significantly higher than in males. The study concludes that quarter of the population of newly diagnosed patients with DM have depressive disorder. This highlights the need for screening patients with DM for depressive disorder as part of their essential basic care in clinics.

- Wasalanthanthri et al. (2014) showed in their study among 80 DM patients and 34 Non-DM controls that there was no significant relationship between decreased sweet taste sensitivity in pre-diabetics. However, this is the first study to demonstrate the sweet taste sensitivity in pre-diabetics.

Evidence suggests that clinic-based services need to focus not only on the well-established direct complications but also on the indirect consequences of the disease, and on strengthening mechanisms to prevent under-diagnosis of these complications.

Factors associated with the prevalence of complications have been studied in the SLDC Study.

- In the total sample, the prevalence of diabetic retinopathy was 27.4% (95% confidence interval (CI)=22.3, 33.1), while the majority had non-proliferative diabetic retinopathy (93.4%) in contrast to maculopathy only in 5.3% (Katulanda et al., 2014c). In the regression analysis, longer duration of DM (odds ratio (OR)=1.07), current smoking (OR=1.67) and peripheral neuropathy (OR=1.72) were significantly associated with diabetic retinopathy.

In comparison, preliminary data from the Sri Lanka Young Diabetes Study has shown that more than one in five in the young onset diabetic group was found to have retinopathy, with a gross prevalence as high as 22%. This prevalence was higher in females (72%) and the mean DM duration was 5.5 years (Katulanda et al., 2006a) (abstract).

In concurrence, a case analysis of 6765 patients attending the National Diabetes Centre, Rajagiriya (mean duration of DM=7.9 years) showed the prevalence of micro vascular complications increased with increasing duration of DM. In patients with DM of less than one year, retinopathy was 6.8% and in those of 16-20 years, it rose to 52.6%. Similarly, the prevalence of neuropathy and nephropathy was 11% and 18.8% at diagnosis, and after 16-20 years, it rose to 54.3% and 23.8%, respectively (Balasuriya et al., 2012).

- Among the DM patients identified, the prevalence of diabetic peripheral neuropathy according to the Diabetic Neuropathy Score were 48.1%, 59.1% and 28.8% among all patients, patients with already established DM and newly diagnosed patients, respectively (Katulanda et al., 2012b). The prevalence in males and female was 20.0% and 26.4%. The mean age of those with and without diabetic peripheral neuropathy was 62.1 (SD=10.8) and 55.1 (SD=10.8) years. In the regression analysis, the salient factors significantly associated with neuropathy in DM patients were female gender (OR=6.7), smoking

(OR=5.9), insulin treatment (OR=4.3), treatment with sulphonylurea (OR=1.8) and longer duration of DM (OR=1.2).

Complications are found to be relatively early in onset. To delay them, the underlying factors such as poor glycaemic control and presence of other risk factors should be addressed in clinic-settings.

### **b. Complications following CVD**

Studies on complications following CVD are fewer in number.

- In a hospital-based study, malnutrition status was assessed in 526 (61.2% males) new patients admitted to a specialist cardiology institution in Sri Lanka. 69.6% were having possible malnutrition according to Mini Nutritional Assessment tool; 47.9% were at risk of malnutrition according to Malnutrition Screening Tool; 4.2% were malnourished according to Subjective Global Assessments; and 20.4% and 19.6% subjects were at medium risk and high risk of malnutrition according to Malnutrition Universal Screening Tool, respectively. Nutritional Risk Screening detected 6.3%, 25.1% and 24.9% patients to be mildly, moderately and severely malnourished, respectively. Short Nutrition Assessment Questionnaire categorized 5.0% and 17.7% to be moderately malnourished and severely malnourished (Pathirana et al., 2014).
- With regards to cardiac complications during pregnancy, a retrospective audit conducted by Haththotuwa et al. (2009) showed that out of 145 maternal & late maternal deaths recorded in 2004, 42 were due to indirect obstetric causes, of which 25 were due to cardiac disease; and 23 had a specific cardiac cause listed, highlighting cardiac disease as the commonest cause of indirect maternal death which is second only to postpartum hemorrhage for all causes of maternal death, whereas in the UK, cardiac disease is the leading cause.

#### **2.2.4.3 Disability related to CVD and DM**

Disability-adjusted life years (DALYs) is an effective indicator to measure the burden of disease in terms of quantity and quality of life, including the number of productive years of a person spent with disability though not fatal. Living with disability due to illness can be a substantial economic loss and social burden to a country, where it is most relevant in the case of major NCDs. According to the IHME data on Sri Lanka's DALYs, the years of life lost due to NCDs is mainly due to CVD (Figures 2.17 and 2.18).



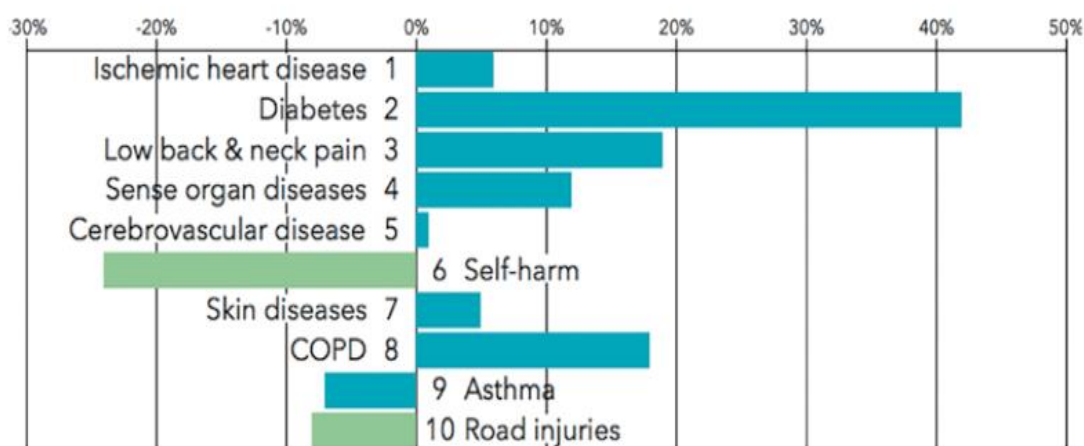
**Figure 2.17: Comparison of the top 10 cause of premature death (YLL) in Sri Lanka in 2016 with the group average for selected middle-income countries**

	Ischaemic heart disease	Diabetes	Low back and neck pain	Sense organ diseases	Cerebrovascular disease	Self-Harm	Skin diseases	COPD	Asthma	Road injuries
Sri Lanka	2,305.5	1,522.7	1,122.2	1,113.2	1,094.1	967.3	823.9	697.1	679.7	589.4
Comparison group mean (middle SDI)	2,768.0	937.5	1,005.0	1,004.2	2,267.1	404.4	755.3	1,047.2	288.2	1,113.9

Blue: significantly lower than mean; Green: statistically indistinguishable from mean; Orange: significantly higher than mean; Values given are age-standardized rate per 100,000, 2016

Source: Institute of Health Metrics and Evaluation, 2017 (<http://www.healthdata.org/sri-lanka>)

**Figure 2.18: Top 10 causes of death and disability combined (disability adjusted life years (DALYs) in 2016 and percentage change during 2005-2016), Sri Lanka**



Source: Institute of Health Metrics and Evaluation, 2017 (<http://www.healthdata.org/sri-lanka>)

Only a few follow-up studies are available that had assessed disability following CHD.

- A study was carried out by Mahesh et al. (2017a) to describe the quality of life (QOL) in patients following ST-elevation myocardial infarction (STEMI) and non-STEMI (NSTEMI). Using SF-36, the QOL was assessed at 28-day post-discharge follow-up carried out in 13 hospitals among 344 patients admitted with STEMI or NSTEMI. The follow-up QOL was gathered using a postal questionnaire (235 responded) and the pre-event QOL using an

interview. According to results, the post-event QOL was lower in seven out of the eight domains included in SF-36 than the pre-event QOL ( $p < 0.05$ ). The NSTEMI group, which had more risk factors had significantly lower pre-event QOL for seven domains ( $p < 0.05$ ), when compared to the STEMI group. For seven domains, the post-discharge QOL was not significantly different ( $p > 0.05$ ) between the STEMI and NSTEMI groups. Post-discharge general-health QOL domain score was higher than the pre-MI score ( $p = 0.03$ ) and was higher in the STEMI group compared to the NSTEMI group ( $p = 0.04$ ). Regression analysis showed a significant beta coefficient between pre- and post-QOL for five domains in STEMI and for all domains in NSTEMI groups when adjusted for the disease severity.

With regards to DM, the disabilities are mainly due to retinopathy and foot ulcers.

- Kumarasighe et al. (2015) (abstract) carried out a cross-sectional study to evaluate the HRQOL of 113 diabetic patients having leg or foot ulcer admitted to surgical wards. The Short Form-36 (SF-36) was administered to obtain the physical component score (PCS) and mental component score (MCS) for each patient. The total HRQOL score was 46.46 (SD=18.45). PCS was 41.48 (SD=19.05) and MCS was 51.53 (SD=19.9). HRQOL of females was lower than the males in total score ( $p = 0.01$ ), MCS ( $p = 0.02$ ) and PCS ( $p = 0.01$ ). Total, PCS and MCS scores were significantly lower in patients with retinopathy and poor vision ( $p = 0.02$ ) compared to normal vision; and those with hypertension ( $p < 0.0001$ ) compared to normotensives. Poor HRQOL was associated with unemployment and presence of diabetic leg ulcers. However, no association was seen with the patients' age, educational level and whether patients live on their own.

With regards to disability related to stroke, population-based evidence is scarce but many hospital-based follow-up studies of stroke survivors have been conducted, which highlight the disability incurred by the disease in acute as well as in chronic stages in Sri Lanka.

- In a population-based study, Chang et al. (2015) showed that the stroke survivors (24 out of 2313) presented at diagnosis mainly with loss of strength/numbness of face, arm or leg (91.7%) and difficulty in speech (58.3%). In the long-term, 64.3% had to either change or give up working because of stroke-related disability. Some left the job because of their physical disabilities, whereas some were asked to leave.
- One of the earliest was a follow-up study of 422 stroke patients admitted to five hospitals in Colombo District (Mallawaarachchi, 2006) to assess the quality of life of stroke survivors

along with their principal informal care givers, at one and three months after the index stroke. More than 82 % of stroke patients in all age groups were found to be disabled at the acute stage with increased disability seen with advancing age. At one and three months post stroke respectively, 48% and 22% were found to be disabled; however, only 5% and 31% were functionally independent and able to attend activities of daily living without help. Females were more disabled than males at all time points. 85% were severely handicapped and 42% were bed ridden during the acute stage, while 7% remained bed ridden even after three months. Only 38% showed no cognitive impairment at the acute stage, which declined further to 22% and 17% at one month and three months. Of the 57% showing the possibility of common mental disorders at the acute stage, 35% of the survivors were affected by it at three months.

The quality of life of stroke survivors was found to be very low (based on mean SF 36 score close to zero) at one month for all domains except bodily pain), which was found to be poor even at three months but an improvement from one month post stroke. Quality of Life was significantly lower in those who were disabled ( $p<0.05$ ), handicapped ( $p<0.05$ ) or having severe cognitive impairment ( $p<0.05$ ) at all three time points.

- Almost 10 years after, Wellapuli (2018) carried out a similar follow-up study of 363 out of the 502 first-ever stroke survivors recruited from all 11 secondary and tertiary care hospitals of Western Province. Complications and disability of the patients were assessed during six-month post stroke period. During the follow up period, 5.2% had TIA or re-stroke. In relation to the activities of daily living by end of six months, more than 70% recorded functional independence in activities related to feeding, moving, personal toilet, getting on and off toilet, bathing self, walking on level surface, controlling bladder and controlling bowel. The levels of disabilities assessed by modified Rankin Scale (mRS) revealed that 60% (95% CI=54.96, 65.04) were having slight disability or no disability, while 51.5% (95% CI=46.36, 56.64) had no or insignificant level of cognitive impairment. Depression identified among them was 17.3% (95% CI=13.03, 21.57).
- In an international multi-centre trial by Wijekoon et al. (2015) (abstract), 106 stroke patients (69% males; 84% with ISH) were assessed for post-stroke outcomes, such as disability (Barthel Index- BI); dependency (mRS); mood (Zung Depression Scale- ZDS); cognition (Mini Mental State Examination-Modified (MMSE-M) and Telephone Instrument for cognitive Status-Modified- TICS-M); and verbal fluency (animal naming). By end of three months, seven (6.6%) were dead; 2 (1.9%) suffered recurrent strokes; and

were dependent (46.5%; mRS=3-5); disabled (19.2%; BI <60); depressed (6.1%; ZDS >70); cognitively impaired (42.2%; TICS-M <20 and 37.4%; MMSE-M <14); and had inadequate verbal fluency (64.6%; word count <11). Both disability and dependency were associated with age over 65 years and stroke severity. Cognitive impairment was associated with age over 65 years (OR=3.44); pre-morbid alcohol consumption (OR=2.48); pre-existing HT (OR=2.26); and previous stroke (OR=7.33). Dependency was related to disability, and cognitive impairment was related to dependency. No significant relationships were identified for depression.

- Another hospital-based study among patients attending a tertiary care centre assessed the short-term and long-term functional outcome after stroke and factors associated with poor outcome (Ranawaka et al., 2015b) (abstract). Acutely ill patients admitted to a stroke unit over a period of 18 months were followed-up at one month and one year. The poor functional outcomes assessed were severe disability (BI of 0-60), severe handicap (mRS of 3-5) or death. Of the 187 patients with stroke, 88.8% were followed up at 1 month and 89.1% at one year. At one month, 15.5% had severe disability and 20.9% had severe handicap. The corresponding proportions at end of one year follow-up were 12.5% and 17.2%. 25% were dead at one year. On multivariate analysis, severe disability and handicap were associated with altered consciousness, bladder involvement and haemorrhagic stroke at one month, and with stroke severity at one year. Stroke severity was the only independent predictor of death at one year and one month.
- Kalyani & Dassanayake (2012) carried out a study to assess the effects of stroke on individuals' functional status and QOL. This cross-sectional study was carried out in 70 stroke patients at the Institute of Neurology of NHSL. In the study sample, 51.4% were able to feed themselves while 34.3% were highly dependent for toileting. Bladder and bowel management needed assistance in 57.2% and 51.4%, respectively. Most individuals needed total to maximum assistance for transferring and locomotion. Indicators on QOL showed better scores on the social and economic subscales (mean=3.59) compared to health and functioning subscale (mean=2.97) and psychological and spiritual subscale (mean=2.75).
- The study based on the Sri Lanka Stroke Registry showed that ICHS presented with more severe stroke (NIH Stroke Scale score >7) (67.6%) compared to IS patients (43.8%), and had more severe initial disability according to BI and mRS (Ranawaka et al., 2015a) (abstract).

- A prospective study was carried out in General Hospital (GH) Kalutara among 219 stroke patients admitted consecutively for eight months in 2001 (Wickramasinghe et al., 2003). Of them, 20.1% (n=44) died while in hospital. When compared with those who survived, they were older (73.4 vs. 63.4 years) and had significantly higher prevalence of DM (31.8% vs. 15.4%). These provided a relative risk of 1.05 (95% CI=1.01, 1.09) and 2.85 (95% CI=1.28, 6.34), respectively. The study concluded that early mortality is relatively high, which should be addressed by paying more attention to the high risk groups identified during hospital care.

As in many other developing countries, long-term outcomes related to stroke, CHD and DM are poor, suggesting that these major NCDs follow a severe course in Sri Lanka.

## 2.3 Trends in the economic burden of major NCDs in Sri Lanka

Health gains in Sri Lanka have been achieved through reliance placed on public financing in the provision of access to basic medical services and effective preventive health services.

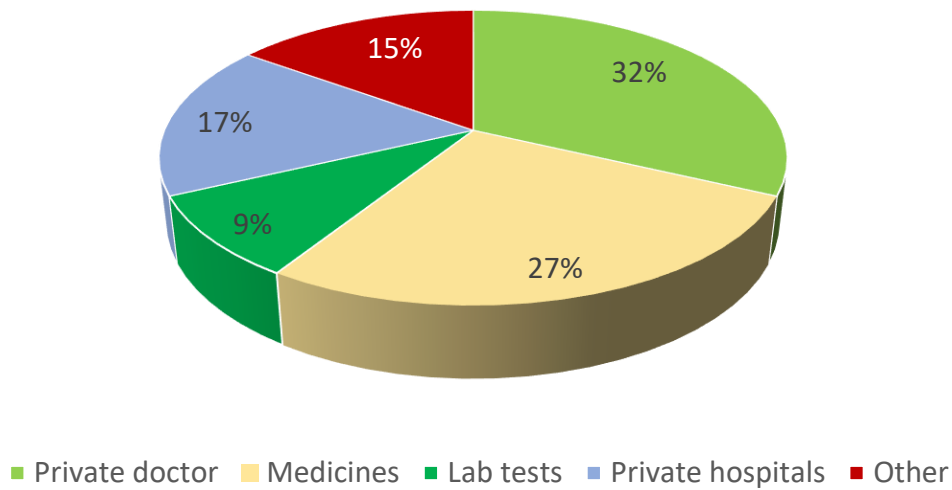
### 2.3.1 Sources of information

The sources of information used in this section include estimates made at national level by the World Bank and health economic experts in Sri Lanka on the economic impact of NCDs.

### 2.3.2 Economic impact of major NCD

The Sri Lankan government faces a 'double burden' on dealing with the country's healthcare needs. While taking measures to control the communicable diseases, ensuring that sustainable measures are also in place to reduce the burden of NCDs has been challenging. It was only in the past decade that LMICs have started focusing on health care equity and delivery through universal health coverage, however Sri Lanka's traditional financing systems have already embraced these principals in providing health care for all in the country.

- Sri Lanka has managed to achieve impressive health indicators while resorting to a historically low health expenditure, by focusing mainly on the priority areas related to MCH and eradication of communicable diseases. The Household Income and Expenditure Survey 2015-16 (Department of Census & Statistics, 2016b) shows the breakdown of out of pocket payments by households (Figure 2.19).

**Figure 2.19: Breakdown of out of pocket payments by households 2015-16**

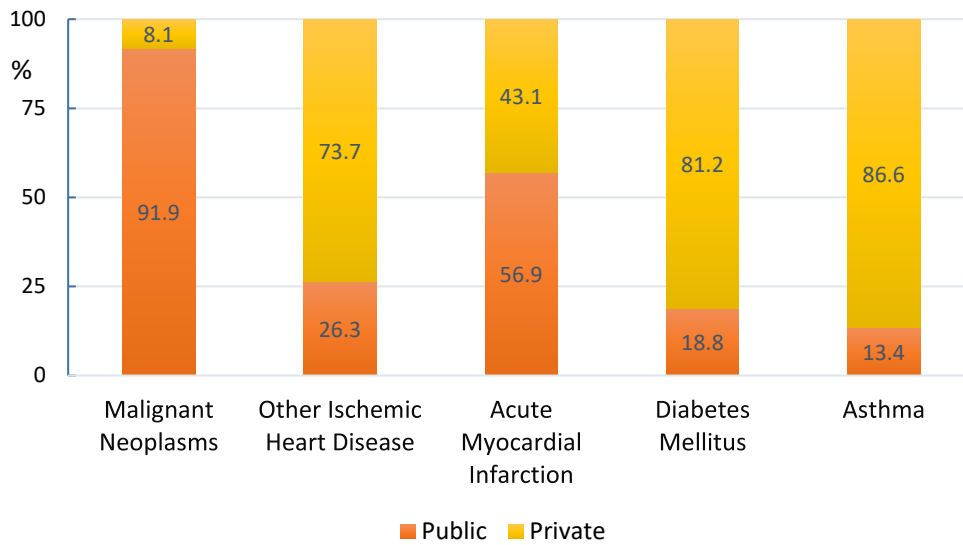
*Source:* Household Income and Expenditure Survey 2015-16, Department of Census & Statistics, Ministry of National policies & Economic Affairs, Sri Lanka

However, along with the fastest ageing population and ever-increasing prevalence of NCDs, it is crucial that the Sri Lankan Government takes cost effective, efficient and sustainable measures in the public health sector on treatment and recommendations related to NCDs.

- Sri Lankan health care is mainly financed by the government, where the domestic general government and private health expenditure as a share of the current health expenditure in 2016 has been 43% and 56% respectively, and other external minor financing sources contributing to 1% of the current health care expenditure (WHO, 2018). Around 38% of the out-of-pocket spending accounts for the total health expenditure in Sri Lanka. Other sources of private financing include expenditure by companies to provide health care and medical benefits to their employees (5-8%), contributions from private health insurance (5%) and non-profit sector contributions (2-3%).

Figure 2.20 shows that the majority of health care expenditure on NCDs is spent by the private sector. Ischemic heart disease, which is the major cause of mortality of NCDs in Sri Lanka is mainly dependent on private sector treatment (around 73.7%) followed by DM and asthma. Asthma is identified to be highly prevalent in the lower wealth quintile category and 86.6% the asthmatic population is shown to be spending out-of-pocket. This would affect the country's economy along with raised household expenditure, improvising a major financial burden to the public livelihoods.

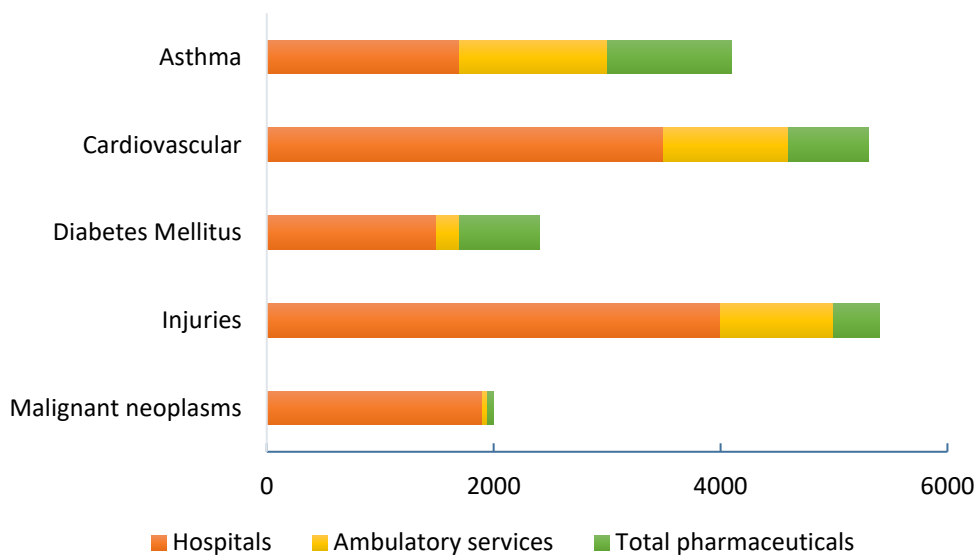
**Figure 2.20: Expenditure on major NCDs by public and private sources (%) in Sri Lanka, 2005**



Source: Michael et al. HNP Discussion Paper, World Bank, 2010

- Figure 2.21 shows the major spending areas related to NCD expenditure in Sri Lanka on 2005. It is noteworthy that there have not been any costing studies thereafter, which is a major gap in knowledge gap on the increasing expenditure on NCDs and its impact.

**Figure 2.21: Expenditure on major NCDs by major spending areas (in million rupees) in Sri Lanka, 2005**



Source: Michael et al. HNP Discussion Paper, World Bank, 2010

- Comparison of consumption levels in Sri Lanka and other countries shows that overall consumption of NCD medicines in Sri Lanka is for the most part far below the levels one would expect given its NCD disease burdens. The public sector purchases inadequate quantities of the needed medications and medical supplies for chronic NCD care. Consequently, many patients either incur large financial costs in purchasing needed tests and medicines for their treatment, or they go without.

Research evidence on the economic burden faced by patients pertaining to the management of CVD and DM is presented in Chapter 4.



“Cancer, diabetes, and heart diseases are no longer the diseases of the wealthy. Today, they hamper the people and the economies of the poorest populations even more than infectious diseases. This represents a public health emergency in slow motion.”

MR BAN KI-MOON

Former United Nations Secretary-General



# CHAPTER THREE

## Status of NCD risk factors Determinants of CVD & DM

The Global Health Observatory of the WHO identifies four key metabolic risk factors that lead to chronic NCDs. These include HT, overweight/obesity, raised blood glucose and dyslipidaemia (WHO, 2017). It further identifies four behavioural risk factors, namely physical inactivity, unhealthy diet, tobacco use and harmful use of alcohol that result in such metabolic changes, which in turn give rise to CVD and DM (WHO, 2017; Ministry of Health, 2016a). Modification of these risk factors is relevant as a primary (in apparently healthy persons) as well as secondary (in persons with CVD and DM) preventive strategy.

One of the major objectives of the National Policy for Prevention and Control of Chronic NCDs of Sri Lanka is to reduce the modifiable risk factors of NCDs and underlying social determinants, by creating health promotive environments. In line, the National Multi-sectoral Action Plan for the Prevention & Control of NCDs drawn for 2016-2020 details out a comprehensive plan specifying action that sets the stage for multi-sectoral collaboration and coordination with relevant units of the Ministry of Health and non-health ministries. It is highly commendable that this Action Plan is based on the total risk approach, so that more

emphasis is placed on multiple risk factors of major NCDs. It is therefore imperative that updated local evidence is available on the burden of these risk factors in Sri Lanka, as this knowledge is essential to plan out public health interventions as well as to measure the impact of such action.

This chapter presents evidence available on the status of NCD risk factors in both apparently healthy (Section 3.1) and diseased persons (Sections 3.2) and on the risk imparted by each for CVD and DM (Section 3.3). It also attempts to identify the gaps in knowledge as well as look into the quality of the available evidence.

### **3.1 Status of NCD risk factors in apparently healthy adults in Sri Lanka**

The status of NCD risk factors at population level was assessed in relation to their prevalence, trends across the years and factors associated with the prevalence in community-based samples.

#### **3.1.1 Sources of information**

Sources of information were data collected in national surveys and studies conducted in samples representative of regional populations.

- a. STEPS Survey at national level** - Nationally representative data collected on behavioural and metabolic risk factors of CVD/DM have been referred to (refer chapter 1.4.2.a for a detailed description including limitations).
- b. Population-based studies at national and provincial levels** - Two large-scale studies conducted in the general population on the prevalence of NCD risk factors during 1998-2002 in four major provinces (Wijewardene et al., 2005) and in 2005-06 in all except North and East Provinces (SLDC Study) have been mainly cited in this section (refer chapter 1.4.2.b for a description on the design, generalizability and precision).

As studies conducted during last 10 years, the multi-centre WHO Risk Prediction Study conducted in Sri Lanka (Mendis et al., 2011) on the population distribution of CVD risk has been referred (refer chapter 1.4.2.b). Two other studies conducted in Western Province (Subasinghe et al., 2015) and Central Province (Jayawardana et al., 2017a and 2017b) are

not generalizable as the selection of sample was not representative, however both trigger important evidence on at-risk individuals in the community.

- c. Population-based district and MOH level studies** - There were several studies conducted in samples over 1000 participants representative of the general population at district level, of which the study conducted in Colombo District has been reviewed, with reference to highly urban population of Sri Lanka (Arambepola, 2004; de Silva, 2011; Fernando, 2016); studies in Kautara & Gampaha Districts and Ragama MOH area, with reference to urban and suburban populations of Sri Lanka (Kasturirathne et al., 2008 and 2012 (abstract), Kasturirathne et al., 2013; De Silva, 2010; Liyanapathirana, 2014); and the study in Jaffna District with regards to recently urbanized districts of Sri Lanka (Amarasinghe et al, 2015a). Further, several studies on high risk groups (Pinidiyapathirage et al, 2010 (abstract); Harshani & Abeysena, 2011; Sasrubi et al, 2013 (abstract); Gamage & Seneviratne, 2016; Gamage et al., 2017; Ubeysekara, 2017; Jayaweera & Joseph, 2018) have been reviewed. Only one was a cohort study with a large sample size though limited to one MOH area (Wickremasinghe et al., 2008) (abstract). Another study conducted on multiple cardio-metabolic risk factors was limited to the most urban setting in Colombo District, which is the CMC area (Fernando, 2016).

Owing to poor generalizability, those limited to MOH settings or hospitals and done in small samples were not considered for this review.

### **3.1.2 Prevalence, trends and associations of metabolic risk factors of NCD**

High blood sugar and cholesterol, HT and overweight/obesity are identified as the major metabolic risk factors of chronic NCDs. Further, central obesity, metabolic syndrome and non-alcoholic liver disease have been recently shown to play a major role.

A summary of the studies is given in Table 3.1.

**Table 3.1: Summary of the population-based studies conducted on metabolic risk factors of NCDs**

Study, year	Sample size	Participants	Sampling method	Prevalence of risk factor (%)														
				HT			Dyslipidaemia			IGT/DM			Obesity general			Obesity central		
				M	F	B	M	F	B	M	F	B	M	F	B	M	F	B
<b>National level surveys</b>																		
MoH, HSDP & WB, 2008 (STEPS 2006)	12,500	15-64-year-old adults	Multi-stage sampling representing every district and province	22.2*	19.6*	20.9*	-	-	-	-	-	-	3.6***	5.9***	4.7***	78.9	77.3	-
MoH, 2015 (STEPS 2015)	5188	18-69-year-old adults	Multi-stage cluster sampling method representing every district and province	25.4*	26.7*	26.1*	19.1††	28.4††	23.7††	7.3#	7.6#	7.4#	3.5***	8.4***	5.9***	82.3	82.1	-
<b>Provincial or National level studies</b>																		
MoH, 2003 (STEPS 2003)	3000	15-74-year-old adults	Sample from Western Province	5.6*	8.1*	6.9*	-	-	-	-	-	-	2.0***	6.6***	4.3***	81.2	78.3	79.7
Wijewardene et al., 2005 (1998-2002)	6047	30-65-year-old adults	Stratified cluster sample from Western, North Central, Southern & Uva Provinces	18.8*	19.3*	19.0*	-	-	-	14.2#	13.5#	-	2.4***	8.8***	6.0***	-	-	-
Katulanda et al., 2008a; 2014a; 2010b & 2010a (SLDC Study 2005-06)	4485	Adults over 18 years of age	Stratified urban & rural sample with village officer unit clusters selected by PPS from all except North & East Provinces	23.4*	23.8*	23.7*	73.5++	80.7++	77.4++	9.8##	10.9##	10.3##	2.6***	4.8***	3.7***	3.1*#	18.9*#	10.8*#
Mendis et al., 2011 (WHO Risk Prediction Study 2011)	1099	40-80-year-old adults	Random cluster sample from 1000 households representing urban & rural populations	-	-	25.5 (SBP≥140)	-	-	13.8††	-	-	9.9#	-	-	6.5***	-	-	-
Subasinghe et al., 2015	495	Adults over 18 years of age	Attendees of free health camps conducted in 3 districts of Western Province	44.2‡	44.1‡	42.3‡	-	-	52.2++	28.0?	13.5?	-	35.3*†	43.7*†	-	-	-	-

Study, year	Sample size	Participants	Sampling method	Prevalence of risk factor (%)																
				HT			Dyslipidaemia			IGT/DM			Obesity general			Obesity central				
				M	F	B	M	F	B	M	F	B	M	F	B	M	F	B		
Jayawardana et al., 2017a	2462	Males (age range 16-72 years)	Males attending the routine National Transport Medical Test in Central Province in 2013/14 excluding pre-diagnosed HT/Cardiac diseases	31.7 ‡	-	-	-	-	-	-	-	-	-	-	12.3 †††	-	-	17.1 †††	-	-
<b>District level studies</b>																				
Arambepola, 2004	1400	20-64-year-old adults	Multi-stage stratified PPS cluster sampling of Colombo District (representative by age, sex and sector)	24.8 * (n=515)	20.9 * (n=515)	22.9 * (n=515)	30.5 ** (HDL) (n=515)	24.5 ** (HDL) (n=515)	27.6 ** (HDL) (n=515)	17.2 # (n=515)	16.6 # (n=515)	16.9 # (n=515)	5.8 ***	9.7 ***	7.4 ***	25.7 †††	44.7 †††	34.9 †††		
							14.1 (HDL)	18.6 (HDL)	16.3 (HDL)				26.1 * †	38.7 * †	32.2 * †					
							19.8 (TG)	10.3 (TG)	15.1 (TG)											
							27.8 (LDL) (n=515)	22.1 (LDL) (n=515)	25.0 (LDL) (n=515)											
De Silva, 2010	1300	35-64-year-old adults	Stratified multistage cluster sampling of Kalutara District	-	-	-	-	-	-	-	-	14.7 #	9.2 †††	19.2 †††	14.3 †††	17.7 †††	49.0 †††	33.6 †††		
Wijesuriya et al., 2012	4532	10-40 year-old who had ≥2 CHD risk factors (high-risk population) €	Purposive sampling within a 30 km radius of the National Diabetes Centre in Colombo Sri Lanka	33.2 †	13.4 †	23.1 †	36.6 (TG)	12.8 (TG)	24.5 (TG)	17.2 ##	8.5 ##	-			51.1 ** †	59.9 †††	67.4 †††	-		
							50.8 (HDL)	66.7 (HDL)	58.9 (HDL)	11.7 (IGT)	10.8 (IGT)	-								
Waidyathilaka et al., 2013	2800	30-45 year-old women with no known DM	Cluster sampling from all GN divisions of CMC area																	
Liyanapathirana, 2014	1143	30-64-year old adults	Cluster sampling of Gampaha District	14.8	12.5	37.5			66.5	-	-	17.4			44					

Study, year	Sample size	Participants	Sampling method	Prevalence of risk factor (%)														
				HT			Dyslipidaemia			IGT/DM			Obesity general			Obesity central		
				M	F	B	M	F	B	M	F	B	M	F	B	M	F	B
Amarasinghe et al., 2015a	544	Adults over 18 years of age	Multi-stage stratified cluster sampling of Jaffna District	45.1 †	30.0 †	36.6 †	-	-	25.0 (high TG>150 mg/dl)	-	-	23.9 ###	-	-	-	-	-	16.2 *#
Fernando, 2016	1350	35-65-year-old adults	Community based study in CMC area using multi-stage cluster sampling	-	-	32.5	-	-	49.2	-	-	17	-	-	58.9	-	-	-
<b>High risk groups/MOH level studies</b>																		
Kasturiratne et al., 2008, 2011b and 2012 (abstracts); 2011a (Ragama Health Study)	2986	Urban/sub-urban dwellers aged 35-64 years in Ragama MOH area	Community based age stratified random sampling in 2007	33.0	37.0	-	-	-	36.0 (any dyslipidaemia)	-	-	-	-	-	39.1 * †	-	-	53.4 †††
Pinidiyapathirage et al., 2010 (abstract)	401	Adults aged 35-64 years resident in 3 selected estates in the Nuwara-Eliya District	Not stated	-	-	42.0 *	-	-	49.0 (any dyslipidaemia)	-	-	10.0 #	-	-	2.0 ***	-	-	-
Harshani & Abeysena, 2011	465	Fishermen from Kalpitiya DS area (2011)	Cluster sampling	-	-	24.3 *	-	-	-	-	-	-	-	-	2.6 ***	-	-	-
Sasrubi et al., 2013 (abstract)	342	Nurses in TH Jaffna		-	-	-	-	-	-	-	-	7.6 #	5.9 ***	8.0 ***	-	50.8 †††	70.5 †††	-
Gamage, 2014	275	Senior administrative (SA) officers (275) and Managerial Assistants (MA) in administrative service in Colombo district aged 30-60 years	Stratified random sampling (stratified for institution)	-	-	32.9 *(SA) 33.0 *(MA)	-	-	-	-	-	-	-	-	-	-	-	-



Study, year	Sample size	Participants	Sampling method	Prevalence of risk factor (%)																	
				HT			Dyslipidaemia			IGT/DM			Obesity general			Obesity central					
				M	F	B	M	F	B	M	F	B	M	F	B	M	F	B			
Mayurathan et al., 2017	6335	All academic and non-academic staff	All schools in Jaffna District	20.0	15.0	17.0	-	-	-	8.0	6.0	6.0	23	25	23	†††	†††	†††			
Jayaweera & Joseph, 2018	417	Army soldiers working in dry zone, mean age of 39.5 years	All volunteer soldiers in 3 selected army camps in Anuradhapura district	-	-	1.9*	-	-	0.0**	-	-	0.1###	-	-	-	-	-	-	-	-	-

\* Defined by systolic blood pressure (SBP) ≥140 mmHg and diastolic pressure (DBP) ≥90 mmHg or on medication

† Defined by systolic blood pressure (SBP) ≥130 mmHg and diastolic pressure (DBP) ≥85 mmHg or on medication

‡ Defined by systolic blood pressure (SBP) ≥140 mmHg and diastolic pressure (DBP) ≥90 mmHg

\*\* Raised total cholesterol (TC) defined by TC >200 mg/dl or currently on medication for raised TC

†† Raised total cholesterol (TC) defined by TC >190 mg/dl or currently on medication for raised TC

‡‡ Raised total cholesterol (TC) defined by TC >232 mg/dl

++ Any dyslipidaemia

# Fasting blood glucose ≥126 mg/dl (7.0 mmol/l) or currently on medication for raised blood glucose

## Fasting blood glucose ≥126 mg/dl (7.0 mmol/l) or 2-h post-oral glucose tolerance test plasma glucose ≥200 mg/dl (11.1 mmol/l) or currently on medication for raised blood glucose

### Fasting blood glucose ≥100 mg/dl (5.5 mmol/l) or currently on medication for raised blood glucose

\*\*\* BMI >30 kgm<sup>-2</sup>

††† BMI >27.5 kgm<sup>-2</sup>

\*† BMI >25 kgm<sup>-2</sup>

\*\*† BMI >23 kgm<sup>-2</sup>

‡‡‡ WC >90 cm for men and >80cm for women

\*# WC >102 cm for men and >88cm for women

? criteria not stated

Mean waist circumference is reported

€ All values given for those above 16 years of age

SO= senior officers; MA= managerial assistants; MoH=Ministry of Health

### 3.1.2.1 HT

- The prevalence of HT in Sri Lanka is relatively low by international standards (Michael et al., 2010). According to the STEPS Survey, the overall prevalence of HT was 6.9% in 2003; 20.9% in 2006 and 26.1% in 2015, clearly showing an increasing trend. Only a slight variation has been noted in males and females.

According to the national- and provincial-level data, the age-standardized prevalence of HT was 19% in 1998-2002 (Wijewardena et al., 2005) with little difference between men and women; 27.7%, 27.4% and 27.8% in all adults, males and females in 2005-06 in SLDC Study (Katulanda et al., 2014a); and 29.8% by systolic BP (SBP) and 25.5% by diastolic BP (DBP) in both sexes in 2011 in the multi-centre WHO study (Mendis et al., 2011).

According to the large-scale studies and national surveys conducted thus far, the current prevalence of HT ranges within 25-30%, with a clear upward trend over the last 20 years.

- The prevalence of HT among high-risk populations, such as urban dwellers and occupational groups is expected to differ from that at national level.

At district level, a study comprising adults in the district of Colombo, which represents the most urban population of Sri Lanka showed a prevalence almost like that at national level (22.9%), with a slight increase in males (Arambepola, 2004). However, the prevalence according to studies done subsequently among adults representing the most urban CMC area was 32.5% (Fernando, 2016); 33% in males and 37% in females in an MOH area representing mixed populations of urban and suburban residents (Ragama Health Study) (Kasturiratne et al., 2012) (abstract); 37.5% in the district of Gampaha, which is the second most urban district in Sri Lanka (Liyanapathirana, 2014); and 37.5% in males and 36.6% in females in Jaffna District, which has recently undergone urbanization (Amarasinghe et al., 2015a), with male predominance. It should be noted that the latter study has used lower cut-off levels (SBP  $\geq$ 130 and DBP  $\geq$ 85 mmHg), however Balasubramaniam et al. (2015) studying Sri Lankan Tamils in the same district, has shown that SBP and DBP of females in the reproductive age (20-44 years) were lower than that of males ( $p < 0.05$ ).

With time, the prevalence of HT is shown to have increased in urban dwellers.

Gamage & Seneviratne (2016) compared the prevalence of HT among senior officers ('white collar') and managerial assistants ('blue collar') working in the government administrative sector, and reported a prevalence of 32.9% and 33.01% in the two categories. This study also showed that occupational stress was significantly associated with high prevalence of HT. Effort–reward imbalance (OR)=2.8; 95% CI=1.1, 7.4), high efforts (OR=2.5; 95% CI=1.2, 5.3), and over-commitment (OR=2.5; 95% CI=1.1, 5.6) were significantly associated with HT among the senior officers. Similarly, effort–reward imbalance and high efforts increased the risk of HT by two-fold (OR=2.2; 95% CI=1.1, 4.2) and by three-fold (OR=3.02; 95% CI=1.9, 4.8) in managerial assistants. In comparison, a study among the state sector university employees revealed that 4.8% were already diagnosed of HT, while 17% and 11% were newly diagnosed to have pre-HT and HT (Abrew et al., 2010) (abstract).

A cross-sectional study (Harshani & Abeysena, 2011) among fishermen from Kalpitiya has reported a prevalence of HT of 24.3% (95% CI=20.4, 28.2), which was significantly higher among those who had >10 years of work experience (OR=2.4; 95% CI=1.6, 3.9) and with duration of smoking of more than 10 years (OR=2.0; 95% CI=1.1, 3.8). In contrast, the prevalence of HT was as high as 42% in a sample of 401 Tamil tea plantation workers aged 35-64-years (Pinidiyapathirage et al., 2010) (abstract). Despite having older adults (mean age=50.3 years), this study highlights the vulnerability of lower social strata to HT in Sri Lanka. Interestingly, in a study (Jayaweera & Joseph, 2018) among 417 army soldiers working in the dry zone, the prevalence of HT was found to be only 1.9%. The mean age of this sample was 39.5 years.

Among occupational groups, the sedentary workers seem to be at higher risk for HT which is also compatible with evidence from elsewhere in the world. However, the higher prevalence noted among estate workers needs to be further explored.

- Another noteworthy finding is the relatively large number of undetected HT cases in the population.

According to screening conducted on metabolic risk factors among 495 adult attendees of free health camps in Western Province (Subasinghe et al., 2015), the prevalence of HT was 42.3%, with 37.9% composed of newly diagnosed patients. This higher prevalence could be due to voluntary participation or screening not being totally reliable, however needs further evaluation, considering the Western Province as having the largest population at risk for CVD, for any given province in Sri Lanka. Another important

implication is on the larger undetected hypertensive case load in the community. This has been further confirmed by a study conducted in the Central Province among 2462 male participants (mean age of 31 years; range: 16-72 years) (Jayawardana et al., 2017b), in which previously diagnosed patients with heart disease, DM, HT or other chronic illnesses were excluded. The prevalence rate of undiagnosed HT was 31.7%.

It is noted that undetected cases are highly prevalent even in rural settings in Sri Lanka, as shown in a community-based sample of 2289 adults representing Puttalam District, where the overall prevalence of HT was 45.9% (95% CI=43.8, 47.8), of which 16.3% were newly diagnosed (Luke et al., 2017) (abstract).

This evidence highlights that screening services for HT at primary health care need to be strengthened in all major cities.

A large proportion of patients with HT remain undiagnosed in the community. This reiterates the need for innovative screening approaches to cover the unreachable.

- An emerging issue reported among patients is the increasing prevalence of resistant HT.

A study done among the patients with HT attending cardiology clinics at the NHSL Colombo revealed that 19.1% of the patients were having resistant HT (Kumara et al., 2013). The underlying causes need to be further explored.

- With regards to low birth weight as a determinant of adulthood HT, adults born with low birth weight showed a significant association with high SBP (OR=2.89) and overall HT (OR=3.15), but not with high DBP (OR=0.75) after adjusting for other potential risk factors, based on a retrospective cohort of 217 babies delivered at Castle Street Hospital for Women (CSHW) during 1950-1966 (Ediriweera et al., 2017). The findings are of much public health importance as there is an opportunity to aim at early preventive measures among this target group.
- With regards to lifestyle correlates of HT, being male (adjusted OR (aOR)=2.36; being 50-64 years (aOR=1.93); and inadequate physical activity (aOR=1.93) have been identified in the study conducted in a representative sample of CMC sector. Being a current smoker was found to be protective (aOR=0.45) (Fernando, 2016).

### 3.1.2.2 Dyslipidaemia

It is stated that a high level of triglycerides (TG) and a low ratio of high-density lipoprotein cholesterol (HDL-C) to low-density lipoprotein cholesterol (LDL-C) are the major dyslipidaemic risk factors for CVD (Michael et al., 2010). However, most studies have measured the total cholesterol (TC) level to estimate the prevalence of dyslipidemia.

- The latest STEPS Survey Report (2015) highlights the prevalence of raised TC (>190 mg/dl or currently on medication) as 23.7% (19.1% in males; 28.4% in females) (Ministry of Health, 2015a). This was however much lower than the prevalence reported during 2005-06 in the SLDC Study (Katulanda et al., 2018), which was 77.4% for having some form of dyslipidaemia. This value was much higher than the 52.9% reported in the USA (National Center for Health Statistics., 2013) during 2003–2006, in addition to the prevalence of high LDL-C (46.0% vs. 23.0%) and low HDL-C (49.6% vs. 30.0%) being markedly higher (<https://www.cdc.gov/nchs/data/nhanes>). Low HDL-C was the commonest type (49.6%) of dyslipidemia. Women had higher mean TC, HDL-C, LDL-C and TG values compared to men across all age groups. In comparison, the WHO Study (Mendis et al., 2011) in 2011 revealed a much lower prevalence of raised TC ( $\geq 232$  mg/dl) of 13.8%. The use of different cut-off values is a likely explanation for the varying prevalence of raised TC.

National level data are not conclusive of an increase in the prevalence of dyslipidemia. The main issue in the comparison of studies is due to different parameters used and absence of a uniform cut-off level.

- Regional studies point to changes over time in dyslipidaemia in urban populations.

The prevalence of highly urban population residing in Colombo District related to high TC, LDL-C, TG and low HDL-C was 27.6%, 25.0%, 15.1% and 16.3%, respectively (Arambepola, 2004). The prevalence of low HDL-C was only higher among the females. Subsequent studies in relatively urban populations have reported higher dyslipidaemia rates, such as 36% in Ragama Health Study, with females having a higher risk (OR=1.2; 95% CI=1.1, 1.4) (Pathmeshwaran et al., 2009) (abstract); and 66.5% in Gampaha District (Liyanapathirana, 2014); and 49.2% in CMC sector (Fernando, 2016). Also, Jaffna representing a recently urbanized district revealed the prevalence of high TG ( $\geq 150$  mg/dl) to be 25.0% in contrast to low HDL-C as high as 79.3% (Amarasinghe et al., 2015b).

- With regards to dyslipidaemia among high-risk occupational groups, a voluntary sample of state sector university employees showed a prevalence of 29.6% (Abrew et al., 2010) (abstract) while in another study among nurses from TH Jaffna, it was only 6.1% (Sasrubi, 2013) (abstract). It should be noted that the latter data were obtained by self-reporting. Interestingly, in a study done among army soldiers in the dry zone, none was found to have dyslipidaemia (Jayaweera & Joseph, 2018). In contrast, dyslipidaemia was reported as 49% in a sample of 35-64-year old estate workers (Pinidiyapathirage et al., 2010) (abstract), of which the prevalence of high TG and low HDL-C was significantly higher among males. This may suggest that female estate workers are more active than their male counterparts.
- With regards to correlates of dyslipidaemia, Katulanda et al. (2018) study showed DM, obesity and HT as the leading modifiable risk factors of high TC, TG and LDL-C (Table 3.2).

**Table 3.2: Odds ratio of risk factors in predicting different types of dyslipidaemia \***

Risk factor **	High LDL-C (n=2047)	Low HDL-C (n=2208)	High TG (n=1024)	High TC (n=896)	Some dyslipidaemia (n=3445)
Advancing age	<b>1.52</b>	0.90	1.05	<b>1.36</b>	<b>1.16</b>
Female sex	<b>1.23</b>	<b>2.94</b>	<b>0.45</b>	<b>1.3</b>	<b>1.71</b>
Urban living	<b>1.58</b>	<b>1.35</b>	0.76	<b>2.75</b>	<b>1.55</b>
Body mass index	<b>2.75</b>	<b>2.42</b>	<b>4.89</b>	<b>2.85</b>	<b>4.67</b>
Waist circumference	<b>1.21</b>	<b>1.62</b>	1.23	1.06	<b>1.48</b>
Diabetes	<b>4.48</b>	<b>1.15</b>	<b>2.05</b>	0.87	<b>4.25</b>
Hypertension	<b>1.92</b>	0.82	<b>1.50</b>	<b>1.27</b>	<b>1.79</b>
Current smoking	<b>1.66</b>	1.15	<b>1.36</b>	0.91	<b>1.37</b>
Physical activity	0.96	0.99	<b>0.75</b>	1.00	<b>0.68</b>

\* p<0.05 given in bold letters

\*\* Advancing age in 10-year groups; urban living compared to rural and estate; current smoking compared to current smoking (never smoked or not smoked within last month) used for estimating OR.

Source: Katulanda et al. Journal of Clinical Lipidology 2018; 12(2): 447-454 (SLDC Study 2005-06)

The higher prevalence and significant risk seen among females for low HDL-C levels is indicative of physical inactivity increasing among them compared to males, especially in urban settings. This needs to be addressed in health promotional programs. Further, DM, HT and obesity were significant determinants of high TC, TG and LDL-C.

A more recent study (Fernando, 2016) in a representative sample of CMC area has identified being male (aOR=1.62; 95% CI=1.12, 2.36) and unsatisfactory domestic wealth (aOR=1.60; 95% CI=1.05, 2.44) as the lifestyle correlates of dyslipidaemia, while being currently unemployed was found to be protective (aOR=0.58; 95% CI=0.36, 0.99).

### 3.1.2.3 Raised blood glucose

Diabetes, as much as being a major NCD (evidence of this burden described in detail in chapter 2), it acts as an independent risk factor for CVD, along with IGT (as defined by 2hour-post-glucose load value between 140-200 mg/dl or 7.8-11.1 mmol/l) and IFG (as defined by FPG of 100-126 mg/dl or 5.6-7.0 mmol/l).

- Wijewardena et al. (2005) reported the prevalence of IFG as 14.1% (14.2% in men and 14.1% in women). Although this study used a slightly different cut-off value from the usual (6.1-7.0 mmol/l), it highlights an increasing trend for IFG, when compared with higher rates observed in Kalutara Study in 2011 (14.3%) and Jaffna study in 2015 (23.9%), which included both DM and IGT. In contrast, SLDC Study showed relatively low isolated IFG and IGT of 4.4 and 5.4% (Katulanda et al., 2008a).
- There are several determinants of DM identified in literature. Old age, physical inactivity, obesity, HT, urban living and family history were significantly associated with dysglycaemia according to the SLDC Study (Katulanda et al., 2008a).

In further review of lifestyle correlates of DM, advancing age (aOR=1.75; 95% CI=1.02, 3.03); being of Moor ethnicity (aOR=2.25; 95% CI=1.36, 3.71) and education beyond primary school (aOR= 2.5; 95% CI=1.3, 5.0) have been identified in the study conducted in a representative sample of CMC sector (Fernando, 2016).

With regards to social, cultural and economic determinants, the study conducted in Kalutara District showed that the highest DM proportions were in the highest income quintile (16.1%); those educated up to Advanced Level (AL) and above (17.3%); and as shown in Table 3.3, in the richest GN division (20.7%) with a gradient of the unsatisfactory basic needs index; and highest social status quintile (17.4%) (De Silva et al., 2012a). However, there was no definitive pattern recognized on the prevalence of DM and IFG for these indices.

**Table 3.3: Socio-economic determinants of fasting glucose levels among adults in Kalutara, Sri Lanka**

Socioeconomic determinants	Normal (n=832)		IFG (n=200)		DM (n=202)	
	No.	%	No.	%	No.	%
<b>Social status index</b>						
1 <sup>st</sup> quintile	158	66.3%	38	16.3%	47	17.4%
2 <sup>nd</sup> quintile	153	71.1%	39	14.5%	51	14.5%
3 <sup>rd</sup> quintile	158	73.2%	39	12.0%	45	14.7%
4 <sup>th</sup> quintile	163	71.7%	38	14.7%	42	13.6%
5 <sup>th</sup> quintile	182	76.1%	43	16.9%	17	7.0%
<b>Unsatisfactory basic needs index</b>						
1	80	91.0%	07	4.7%	08	4.3%
2	119	93.6%	34	1.4%	13	5.0%
3	176	70.8%	44	16.9%	28	12.3%
4	214	71.6%	46	13.6%	64	14.7%
5	243	63.3%	69	16.0%	89	20.7%

Source: De Silva et al. International Journal for Equity in Health 2012; 11: 76

- De Silva et al. (2018) further studied the health inequalities (as measured using slope index of inequality, relative index of inequality and concentration index) of DM and its risk factors in the same sample. Accordingly, the prevalence of DM showed a more consistent pro-rich distribution in females compared to males. As for the risk factors of DM, the most consistent and significant pro-rich relationship was noted with high BMI and WC in both males and females, while showing a consistent and significant pro-poor relationship with inadequate fruit intake and smoking among males.

Urban living and higher social status associated with DM and IFG indicate that Sri Lanka is still in an early stage of the epidemic of DM where the wealthy people are at a higher risk.

#### 3.1.2.4 Overweight/obesity

Generalized obesity measured using BMI is an independent risk factor for CVD and DM, while it also plays a role in developing some cancers. Based on Asian cut-off values, overweight is diagnosed by BMI  $\geq 23$  kgm<sup>-2</sup> and obesity by BMI  $\geq 25$ , 27 or 30 kgm<sup>-2</sup>, depending on the action point. Based on the European cut-off values, the diagnosis is by BMI  $\geq 25$  kgm<sup>-2</sup> and BMI  $\geq 30$  kgm<sup>-2</sup>, respectively.



- Overall obesity levels in Sri Lanka have been increasing over the past 20 years.

In 1998-2002, 46.4% of adults were overweight (BMI  $\geq 23$  kgm<sup>-2</sup>), of whom 23.6% had moderately severe obesity (BMI 25-29.9 kgm<sup>-2</sup>) and 6% severe obesity ( $\geq 30$  kgm<sup>-2</sup>), with male predominance (Wijewardene et al., 2005). This contrasted with 25.2% being overweight (BMI=23-27 kgm<sup>-2</sup>) and 9.2% being obese (BMI  $\geq 27$  kgm<sup>-2</sup>) in the SLDC Study conducted in 2005-06 (Katulanda et al., 2008f). The prevalence calculated using Europid cut-off values was even lower (3.7%), but showed a significant gender disparity. In comparison, the WHO study reported 27.3% of BMI  $\geq 25$  kgm<sup>-2</sup> and 6.5% of BMI  $\geq 30$  kgm<sup>-2</sup> in 2011 (Mendis et al., 2011); and 5.9% of BMI  $\geq 30$  kgm<sup>-2</sup> in STEPS Survey 2015.

- District level studies provide more homogenous data, indicating a strong urban-rural disparity in obesity.

A study conducted in 2004 on the epidemiology of obesity in Colombo District (Arambepola, 2004) showed a prevalence of overweight of 49% (BMI  $\geq 23$  kgm<sup>-2</sup>); and obesity of 32.2% (24.5% (BMI=25-29.9 kgm<sup>-2</sup>) and 7.7% (BMI  $\geq 30$  kgm<sup>-2</sup>), which was substantially higher among females. The study further showed a significant difference in the mean BMI between urban (23.3; 95% CI=2.8, 23.8) and rural (22.3; 95% CI=21.9, 22.7) men; as well as between urban (24.2; 95% CI=23.7, 24.7) and rural (23.2; 95% CI=22.7, 23.7) women ( $p < 0.01$ ), highlighting a strong relationship between urban living and obesity (Arambepola et al., 2008a).

In terms of clinical significance, the urban-rural difference in BMI of 1 kgm<sup>-2</sup> is equivalent to a change in weight of 2.7 kg for a man of average height (165 cm) and to a change in weight of 2.3 kg for a woman of average height (153 cm) living in the district of Colombo.

Subsequent studies conducted on obesity (BMI  $\geq 25$  kgm<sup>-2</sup>) in relatively urban districts, such as Kalutara (33.2%) (De Silva et al., 2015a) and Gampaha (44.0%) (Liyanapathirana, 2014), highlight a rapidly increasing trend in obesity over the last 20 years. In further support, the follow-up (Niriella et al., 2017a) (abstract) of a community cohort of adults reported obesity (BMI  $> 25$  kgm<sup>-2</sup>) in 39.1% in year 2007. When this cohort was followed up in 2014, of those who were initially non-obese, 14.9% had developed obesity (annual incidence of 2.13%), of whom 64% consisted of females.

- With regards to prevalence among different occupational groups, nurses in TH Jaffna (Sasrubi et al., 2013) (abstract) reported that 33.9% of the males and 28.1% of the females had BMI  $>25 \text{ kgm}^{-2}$ , while 5.9% of the males and 8.0% of the females had BMI  $>30 \text{ kgm}^{-2}$ . In another sample of 1760 Air Force personnel, the corresponding values were 37.4% (95% CI=33.7, 41.1) and 5.3% (95% CI=5.1, 5.6) (Booso, 2012). Similar rates seen between these two occupation groups is noteworthy. Unlike the soldiers, Army personnel in higher ranks appear to be less active, most likely due to the differences in the work they carry out when on duty.
- With regards to low-income occupational groups, the prevalence of overweight and obesity among fishermen was 20.6% and 2.6%, based on Caucasian Standards (Harshani & Abeysena, 2011). In another similar occupation group of estate sector workers more commonly known for their undernutrition issues reported overweight and obesity prevalence of 12% and 2%, respectively (Pinidiyapathirage et al., 2010) (abstract) in Nuwara Eliya District.

The evidence highlights the need for targeting urban dwellers, sedentary workers and especially females for obesity prevention approaches.

- The rate of overweight/ obesity is rising to epidemic proportions especially among women. In support, a household survey carried out in nine districts, each selected randomly from all nine provinces revealed overweight or obesity among 2146 non-pregnant and non-lactating females aged 15-49 years to be 29.2% (Jayatissa et al, 2012a). It increased with increasing age, most marked after 30 years. Higher level of husband's education and wealth quintiles were associated with overweight/ obesity, highlighting the need for establishing weight management clinics and promoting lifestyle behaviour among women.
- Several determinants of obesity have been identified based on well-defined samples.

The underlying factors for being overweight/obese (BMI  $\geq 23 \text{ kgm}^{-2}$ ) were female sex, physical inactivity, higher income, higher education, urban living and being middle-aged in a national sample (Katulanda et al., 2010a) (Table 3.4). The lifestyle correlates identified in a sample confined to highly urban settings (CMC sector) were almost the same, but in addition showed a positive association with being of Moor ethnicity (aOR=1.95; 95% CI=1.34, 2.82) and negative association with being 55-64 years of age (aOR=0.65; 95% CI=0.44, 0.96) and current use of alcohol (aOR=0.50; 95% CI=0.35, 0.73) (Fernando, 2016).

**Table 3.4: Correlates of obesity in Sri Lankan adults – multiple logistic regression analysis**

Covariate	OR (95% CI)	p value
Male	1	
Female	2.0 (1.8-2.3)	<0.001
Physically active*	1	
Moderately active*	1.2 (1.0-1.4)	0.005
Physically inactive*	1.4 (1.1-1.7)	0.007
Income category 1 (Rs. <6999)	1	
Income category 2 (Rs. 7000-12,999)	1.6 (1.3-1.9)	<0.001
Income category 3 (Rs. 13,000-24,999)	1.9 (1.5-2.3)	<0.001
Income category 4 (Rs. 25,000-49,999)	2.4 (1.7-3.3)	<0.001
Income category 5 (Rs. >50,000)	3.2 (1.7-6.1)	<0.001
Primary education only (<6 years of schooling)	1	
Secondary education (up to school education)	1.7 (1.4-2.0)	
Graduate or above	1.6 (1.3-2.1)	<0.001
Rural living <sup>1</sup>	1	
Urban living <sup>2</sup>	2.1 (1.8-2.5)	<0.001
Age 18-19 years	1	
Age 20-29 years	2.3 (1.2-4.5)	0.018
Age 30-39 years	5.6 (2.9-10.8)	<0.001
Age 40-49 years	7.1 (3.7-13.8)	<0.001
Age 50-59 years	6.5 (3.3-12.6)	<0.001
Age 60-70 years	4.5 (2.3-8.9)	<0.001
Age >70 years	3.6 (1.8-7.3)	<0.001

\*According to International Physical Activity Questionnaire

Source: Katulanda et al. Obesity Reviews 2010; 11(11): 751-756 (SLDC Study 2005-06)

- When taken as a continuous variable, BMI value was best predicted by the following equation for males and females (Arambepola et al., 2008a).

BMI in males = 18:22 + 0:64 (sector) + 1:74 (income) + 1:48 (marital) + 1:53 (meal size) + 1:20 (religion)

BMI in females = 23.29 + 0:95 (sector) + 2.25 (marital) + 0.87 (age) + 0.96 (physical inactivity)

As shown, males who were living in an urban area, in the highest income category, married, eating large portioned meals and were not Buddhists, had a predicted BMI of 26.56 kgm<sup>-2</sup> (equates to 23 kg extra weight) As for females, those who were married, in the 50-64 age group and having physically inactive had a predicted BMI of 28.24 kgm<sup>-2</sup> (equates to 11 kg extra).

- The bio-chemical and genetic predisposition to obesity in Sri Lankan population has been explored.

Anusha et al. (2017) reviewed the association of serum leptin levels with BMI, WC and waist to hip ratio (WHR). These associations have been well-established among Western populations and were compatible with the local study, with significant positive correlations ( $p < 0.05$ ) observed between serum leptin levels and all anthropometric parameters except height in both genders.

Further, Illangasekara et al. (2016) examined the association between FTO gene and near MC4R variants, and concluded that these genes are associated with obesity measures among Sri Lankans, while urban living accentuates the obesogenic effect of the FTO polymorphism. This evidence was based on a sample of 535 adults aged 18-70 years representative of both urban and rural areas in Kandy District, which showed that the FTO risk genotypes (AA + AT) were associated with higher BMI ( $p = 0.03$ ) and WC ( $p = 0.05$ ) measures, as well as categorical obesity ( $\text{BMI} \geq 27.5 \text{ kg m}^{-2}$ ). Further, the near MC4R risk genotypes (CC + CT) were associated with greater BMI ( $p = 0.03$ ) as well as categorical obesity. Thus, the magnitude of the risk of FTO for obesity ( $\text{BMI} > 27.5 \text{ kg m}^{-2}$ ) was 1.69-fold (95% CI=1.11, 2.56;  $p = 0.01$ ) and for near MC4R, it was 1.57-fold (95% CI=1.11, 2.22;  $p = 0.01$ ). In addition, the MC4R risk genotype carriers (CC + CT) had significantly higher FPG levels compared to the 'TT' genotype carriers independent of BMI ( $p = 0.05$ ).

The significant association of obesity seen with serum leptin, FTO gene and near MC4R variants indicate the genetic predisposition of Sri Lankans to obesity.

### 3.1.2.5 Central/ abdominal obesity

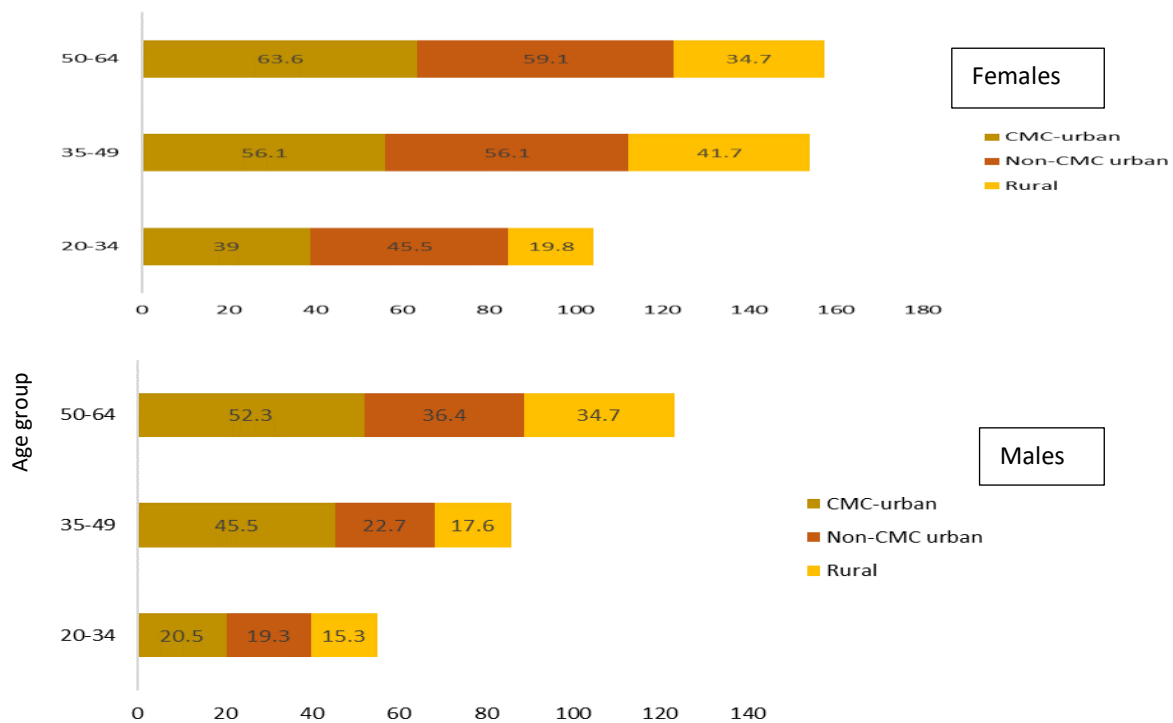
According to the WHO Classification recommended for Asian adults, abdominal obesity is defined by WC  $\geq 90$  cm among males and WC  $\geq 80$  cm among females. It has been shown that cardiovascular risk is predicted better by central/abdominal obesity than generalized obesity, thus an independent risk factor for CHD.

- Many regional studies have shown that as for the generalized obesity, the prevalence of central obesity is higher in the urban sector.

According to the epidemiological study on obesity in Colombo District, the overall prevalence of abdominal obesity was 34.9% (95% CI=32.5, 37.4) in 2004. It was shown to

co-exist with obesity, as the majority (54.4%) had their BMI in the range of 25-29.9 kgm<sup>-2</sup>. The most salient feature was a distinct gender differential (Arambepola et al., 2007), with 44.7% (95% CI=41.0, 48.5) among females compared to only 25.7% (95% CI=22.6, 29.0) among males (p<0.001). During the same period, the estimate of central obesity by SLDC Study was 26.2% (Katulanda et al., 2010a). This difference in prevalence could be due to the latter study being conducted in a mix of urban and rural districts, whereas the other in a more urban setting characterized by typical sedentary lifestyles. There was an explicit gradient in the prevalence of abdominal obesity in highly urban, urban and rural sectors, as shown in Figure 3.1.

**Figure 3.1: Distribution of abdominal obesity by age, sex and sector in Colombo District**



Source: Arambepola C. PGIM MD (CM) Thesis, 2004

Subsequent studies in relatively urban areas have reported a higher prevalence, such as 53.4% (71% in females) in Ragama Health Study (Niriella et al., 2017a) (abstract) and 33.6% (male 17.7%; female 49.0%) in Kalutara District (De Silva et al., 2015a) in contrast to 16.2% in Jaffna District (based on higher cut-off values such as WC for male ≥102 cm and female ≥88 cm). Further, in the Ragama follow-up study, among those who were initially not obese in the cohort, 21.9% (56.3% women) had developed central obesity (annual incidence of 3.12%) after 7 years.

Within the last 10 years, central obesity appears to have increased, especially in urban areas, with a distinct female tendency.

- As seen with generalized obesity, the prevalence of abdominal obesity showed variation in relation to occupational category, at alarmingly higher rates in nurses (50.8% for males and 70.5% for females) (Sasrubi et al., 2013) (abstract) in contrast to lower rates in estate workers (15% among males and 14% among females); 21.2% in university staff (Abrew et al., 2010) (abstract); and 10% in Air Force personnel, with a females predominance (Booso, 2012).
- Significant determinants of abdominal obesity are many, which vary by gender and social status.

According to Arambepola et al. (2007), the determinants of abdominal obesity showed distinct gender differentials. Those common to males (M) and females (F) were age >50 years (M: aOR=2.5; F: aOR=2.9), most urban sector (M: aOR=2.0; F: aOR=1.8) and married status (M: aOR=2.2; F: aOR=2.4). The gender-specific determinants were age 35-49 years (aOR=1.7), living in moderately urban sector (aOR=1.9) and insufficient level of physical activity (aOR=1.7) among females, which were in contrast to household income >Rs. 10,000 (aOR=6.1), increased alcohol (medium intake: aOR=1.9; high intake: aOR=2.1), low-fiber diet (aOR=1.6) and frequent large meals (aOR=1.7) among males. In concurrence, De Silva et al. (2015a) states that all three obesity categories were observed in the more educated, urban, high income and high social status segments of society.

- Niriella et al. (2017a) (abstract) further showed that low household income was significantly associated with obesity. However, these findings are contradictory to those of De Silva et al. (2015a) study in Kalutara District, where a distinct social gradient was identified in all three obesity categories, with higher prevalence observed in the more educated, urban, high income and high social status segments of society. This evidence is stronger, with social inequalities measured using validated tools.

Determinants of abdominal obesity show gender-differentials and a distinct social gradient.

- Central obesity shows significant relationships with several metabolic CHD risk factors.

Walatara et al. (2014) evaluated the association of central obesity with lipid parameters in a sample of 227 non-diabetic and non-hypertensive adults from relatively urban Sri Jayewardenepura area. The mean TG and TG/HDL-C ratio were significantly higher in obese males ( $p < 0.05$ ), and all other parameters in both obese males and females. HDL-C was lower in them. The authors conclude that even in the non-diabetic and non-hypertensive subjects, central obesity has a relationship with altered lipid profile, which could lead to obesity related metabolic abnormalities. In concurrence, Niriella et al. (2017b) has shown that raised TG, low-HDL-C, DM, HT, non-alcoholic fatty liver disease (NAFLD) are significantly associated with generalized and central obesity.

Significant relationships of abdominal obesity with other metabolic and behavioural risk factors imply relatively high obesity-related CHD risk among Sri Lankans, in line with their sedentary lifestyle.

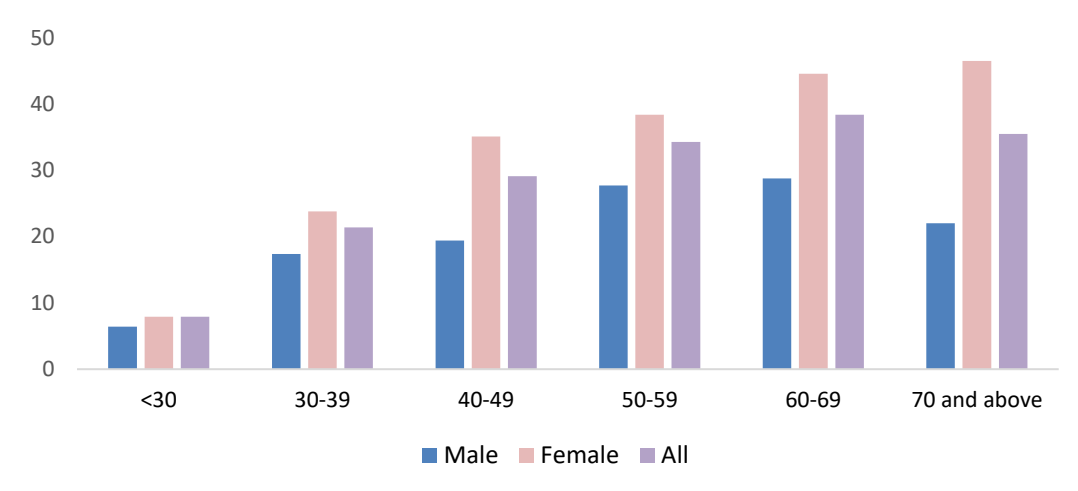
- The burden of obesity is further complicated by the misperception of body weight.

In a sub-sample of the SLDC Study, Jayawardena et al. (2014a) reported the prevalence of misperception of body weight among Sri Lankan adults. Two-thirds of the overweight males and 44.7% of the females considered themselves as 'about right weight', while 4.1% and 7.6% overweight men and women reported themselves as being 'underweight'. Over one third of both male and female obese subjects perceived themselves as 'about right weight' or 'underweight'. Nearly 32% of centrally obese men and women perceived that their WC is about right.

### 3.1.2.6 Metabolic syndrome

- The prevalence of metabolic syndrome was assessed as part of the SLDC Study (Katulanda et al., 2012a), giving an age-adjusted prevalence of 24.3% (95% CI=23.0, 25.6) (Figure 3.2). There was a significant gender difference, with 18.4% (95% CI=16.5, 20.3%) prevalence among males and 28.3% (95% CI=26.6, 30.0) prevalence among females. As per binary logistic regression result, female gender (aOR=1.7), Sri Lankan Moors by ethnicity (aOR=2.6), urban dwellers (aOR=1.7), secondary and tertiary level education (aOR=1.5 and OR=2.3), monthly income over Rs.50,000 (aOR=2.1) and physical inactivity (aOR=1.6) were significant risk factors.

**Figure 3.2: Age standardized prevalence of metabolic syndrome (%) in Sri Lanka (SLDC Study 2005-06)**



Source: Katulanda et al. Diabetology & Metabolic Syndrome 2012; 4: 24 (SLDC Study 2005-06)

- In another community-based study in Jaffna District in a sample of 544 adults, the prevalence of metabolic syndrome was reported as 24.1% (95% CI=20.4, 28); 26.8% and 21.9% among males and females respectively. Interestingly, this study showed higher prevalence among males. Urban living ( $p=0.015$ ), older age ( $p<0.001$ ) and smoking ( $p=0.005$ ) were significant risk factors for development of metabolic syndrome (Amarasinghe et al., 2015a).
- Ragama Health Study reported 38.9% prevalence of metabolic syndrome in 2007 in a cohort of 2967 adults aged 35-64 years and after seven years, it was 46.8% in the same cohort, giving an annual incidence rate of 2.13%. On logistic regression, female sex (OR=3.6), central obesity (OR=4.58), BMI  $>23 \text{ kgm}^{-2}$  (OR=4.84) and NAFLD (OR=2.44) in 2007 were independently predictive of incident metabolic syndrome in 2014 (de Silva et al., 2017) (abstract).
- On further analysis of its age distribution, in a relatively young urban population (10-40 years) from Colombo District (Wijesuriya et al., 2012) showed that the prevalence of metabolic syndrome was 13.0% among males and 8.8% among females below the age of 16 years ( $p=0.005$ ), while the corresponding percentages in those above 16 years were 29.5% and 20.0% ( $p=0.001$ ).



- A population-based twin and singleton follow-up study conducted in the district of Colombo (COTASS) revealed that approximately one third of the 2934 twins met metabolic syndrome criteria, such as International Diabetes Federation (IDF) criteria: 27.4% twins, 44.6% singletons; and the revised National Cholesterol Education Programme Adult Treatment Panel (NCEP ATP III) criteria: 30.6% twins, 48.6% singletons. The most prevalent components were central obesity (59.2% twins; 71.2% singletons) and raised fasting blood sugar (FBS) or DM (38.2% twins; 56.7% singletons) (Jayaweera et al., 2018).
- Jayatissa et al. (2014) comparing the prevalence of metabolic syndrome between males and females, where 360 adults between 30-59 years of age were selected (180 each from urban and rural sectors of three MOH areas, with equal gender distribution), has revealed an overall prevalence of 25.8% (23.9% in men and 27.4% in women;  $p=0.27$ ) as per IDF criteria. This prevalence was strongly associated with age; high BMI, WC, FPG, TG, BP, HbA1c, insulin; and low HDL-C ( $p=0.001$ ).
- Ranasinghe et al. (2009a) studying the association between height and metabolic syndrome have concluded that being short is significantly associated with high risk of the disease.

### 3.1.2.7 Non-alcoholic fatty liver disease

Non-alcoholic fatty liver disease is independently associated with constituent features of the metabolic syndrome.

- Ragama Health Study, which is a community-based follow-up study of 2155 adults has reported 33% prevalence of NAFLD at its initiation and at seven-year follow up, the prevalence had been 53.0% for men and 67.4% for women, giving an annual incidence rate of 6.6%. On multivariate analysis, increased WC (OR=1.96; 95% CI=1.3, 2.97), BMI  $>23$   $\text{kgm}^{-2}$  (OR=2.93; 95% CI=1.99, 4.3) and raised TG (OR=1.49; 95% CI=1.03, 2.13) were the independent predictors of NAFLD in this cohort. In a sub-sample of 1310 cases and 427 controls, a borderline association with NAFLD was noted at two of the 10 candidate loci: rs4240624 at PPP1R3B ( $p=0.04$ ) and rs738409 at PNPLA3 ( $p=0.03$ ) (Niriella et al., 2015) (abstract); Niriella et al., 2017b; Dassanayake et al., 2009)

- Though NAFLD is recognized as a metabolic disorder largely seen in urbanized populations, it is also prevalent in rural, physically active, low income populations, as evident in the study among 403 adults aged 35-64 years from estates in Nuwara Eliya District, which showed a prevalence of 18%. In addition, males and high BMI, WC, DBP and plasma glucose were significant predictors of NAFLD (Pinidiyapathirage et al., 2011).

### **3.1.3 Prevalence and associations of behavioural risk factors of NCD**

In this section, the status of unhealthy diet, tobacco smoking, alcohol consumption, physical inactivity and stress were considered as the main behavioural risk factors. A summary of the studies available in this regard is given below (Table 3.5).

**Table 3.5 Summary of the population-based studies conducted on behavioural risk factors of NCDs**

Study, author	Sample size	Sample	Sampling method	Prevalence of risk factor (%)														
				Tobacco smoking*			Current alcohol use			Heavy drinking			Unhealthy diet**			Physical inactivity***		
				M	F	B	M	F	B	M	F	B	M	F	B	M	F	B
<b>National level surveys</b>																		
MoH, HSDP, WB, 2008 (STEPS 2006)	12,500	15-64-year-old adults	Multi-stage sampling representing every district and province	22.8	0.30	11.5	26.0	1.2	13.5	49.9	29.7	47.8	81.4	83.3	82.4	17.9	31.9	25.0
							†	†	†	?	?	?						
MoH, 2015 (STEPS 2015)	5188	18-69-year-old adults	Multi-stage cluster sampling method representing every district and province	19.9	0.0	10.2	34.8	0.5	17.9	16.8	0.0	8.6	73.1	72.0	72.5	22.5	38.4	30.4
							†	†	†	##	##	##						
<b>Provincial or National level studies</b>																		
MoH, 2003 (STEPS 2003)	3000	15-74-year-old adults	Sample from Western Province	32.6	0.70	16.6	60.3	11.5	35.9	87.4	0.1	43.8	97.1	96.8	96.9	12.1	19.1	15.6
							††	††	††	#	#	#						
Katulanda et al., 2011b; 2014b & 2013; Jayawardena et al., 2013a (SLDC Study 2005-06)	4485	Adults over 18 years of age	Stratified urban & rural sample with village officer unit clusters selected by PPS from all except North & East Provinces	38.0	0.1	18.3	48.1	1.20	23.7	5.2	0.02	2.5	94.7	97.5	96.5	14.6	8.7	11.0
							†††	†††	†††	###	###	###						
Mendis et al., 2011 (WHO Risk Prediction Study)	1099	40-80-year-old adults	Random cluster sample from 1000 households representing urban & rural populations	-	-	6.0	-	-	-	-	-	-	-	-	-	-	-	-

Study, author	Sample size	Sample	Sampling method	Prevalence of risk factor (%)														
				Tobacco smoking*			Current alcohol use			Heavy drinking			Unhealthy diet**			Physical inactivity***		
				M	F	B	M	F	B	M	F	B	M	F	B	M	F	B
<b>District level studies</b>																		
Arambepola, 2004	1400	20-64-year-old Adults	Multi-stage stratified cluster sampling of Colombo District (representative by age, sex and sector)	-	-	-	72.9	3.4	39.1	11.7	0.0	6.0	21.2	15.9	18.6	39.1	24.7	32.4
							†	†	†	#£	#£	#£	*£	*£	*£			
De Silva, 2010	1300	35-64-year-old adults	Stratified multistage cluster sampling of Kalutara District															
de Silva, 2011	1320	20-59 year old adults	Multi-stage stratified cluster sampling of Colombo District	-	-	-	-	-	-	-	-	-	-	-	-	18.0	20.3	19.2
Wijesuriya et al., 2012	4532	10-40 year-old who had ≥2 CHD risk factors (high-risk population) €	Purposive sampling within a 30 km radius of the National Diabetes Centre in Colombo Sri Lanka															
Waidyathilaka et al., 2013	2800	30-45 year-old women with no known DM	Cluster sampling from all GN divisions of CMC area															
Chulasiri, 2014	1200	Adult males aged 20-59 yrs.	Multi-stage stratified cluster sampling of Colombo District	36.5	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Liyanapathirana, 2014	1143	30-64-year old adults	Cluster sampling of Gampaha District															

Study, author	Sample size	Sample	Sampling method	Prevalence of risk factor (%)														
				Tobacco smoking*			Current alcohol use			Heavy drinking			Unhealthy diet**			Physical inactivity***		
				M	F	B	M	F	B	M	F	B	M	F	B	M	F	B
Fernando, 2016	1350	35-65-year-old adults	Community based study in CMC area using multi-stage cluster sampling															
<b>High risk groups/MOH level studies</b>																		
Harshani & Abeysena, 2011	465	Fishermen from Kalpitiya DS area (2011)	Cluster sampling	-	-	54.6	-	-	60.2 ††	-	-	-	-	-	-	-	-	-
Ubeysekara, 2017	650	School teachers in Southern Province	Cluster sampling	-	-	1.5	-	-	12.1	-	-	-	-	-	66.7	-	-	38.7
Rambukwella & Dissanayake, 2018	368	Female estate labourers in Kotmale MOH area	Multistage probability proportionate sampling	-	-	-	-	16.8 †	-									
Jayaweera & Joseph, 2018	417	Army soldiers working in dry zone	All volunteer soldiers in 3 selected army camps in Anuradhapura district	-	-	40.3	-	-	95.9	-	-	-	-	-	-	-	-	-

\* Percentage who currently smokes daily

† Percentage of Current drinker (over past 30 days)

† † Percentage of Current drinker (over last one year)

† † † Percentage of Current drinker (over last 6 months)

# Among current drinkers, who had 5 or more drinks on any day during last week

## Among current drinkers, 6 or more drinks on any occasion in the past 30 days

### Among the total population those who consume >7 units of alcohol per week

? Criteria not stated

\*\* % who eat less than 5 combined servings of fruit & vegetables per day

\*£ % Having sub-optimal quality promoting an obesogenic diet

\*\*\* % with insufficient physical activity

### 3.1.3.1 Tobacco smoking

Tobacco is one of the major risk factors for NCD including CVD, chronic respiratory disease and cancer.

- As per the national-level data derived from STEPS Survey, the percentage who currently smoke daily has decreased over years in Sri Lanka. The overall percentages were 16.6%, 11.5% and 10.2% in years 2003, 2006 and 2015 respectively. However, as in many other South Asian countries, smoking in Sri Lanka is almost mostly confined to men, as evident by much higher estimates in males, such as 32.8%, 22.6% and 19.9%, respectively.

It is important to recognize that estimating the overall prevalence of smoking gives false re-assurance, and that it remains a crucial behavioural risk factor among one third of adult males.

- Chulasiri et al. (2016) and Chulasiri (2014) conducted a community-based study among 1200 adults in 2012-13, with a very stringent sampling process designed specifically to assess the prevalence of smoking among adult males aged 20-59 years in Colombo District. The prevalence of ever smoking was 54.1% (95% CI=51.0, 57.2), and of current smoking was 36.5% (95% CI=33.8, 39.3), which could be a special situation in Colombo district, when compared with STEPS 2015. However, Harshani & Abeysena (2011) also reported that the prevalence of ever smokers and current smokers to be as high as 56.8% (95% CI=52.3, 61.0) and 54.6% (95% CI=50.2, 59) among fishermen in Kalpitiya, which may be considered an occupational vulnerability.
- The SLDC Study reported that among the smokers, 87.0% smoked <10 cigarettes per day. The male age groups less than 20 and 20-29 years had the lowest (15.6%) and the highest (44.6%) prevalence of smoking. There was almost no difference between the urban and rural sectors in relation to current smoking (17.2% vs. 18.5%) (Katulanda et al., 2011b) (Table 3.6), but showed significant associations with lower educational level (OR=1.96), which may highlight the clustering of NCD related risky behaviour among poorly educated males.

**Table 3.6: Smoking among urban and rural adults in Sri Lanka, 2005-06**

Sector	Category	No.	Percentage (95% CI)		No. of cigarettes per bidi or cigars per day (%) among current smokers			
			Current smokers	Ex-smokers	<1	2-10	11-20	>20
Urban	Male	313	35.3 (28.9-41.8)	17.2 (12.7-21.6)	17.8	60.6	15.8	5.8
	Female	489	0.0 (0.0-0.0)	0.0	0.0	0.0	0.0	0.0
	All	802	17.2 (14.0-20.3)	8.4 (6.1-10.6)	17.8	60.6	15.8	5.8
Rural	Male	1480	38.7 (34.8-42.6)	21.6 (19.3-24.0)	29.6	59.6	9.2	1.6
	Female	2250	0.1 (0.0-0.2)	0.2 (0.0-0.4)	100	0.0	0.0	0.0
	All	3730	18.5 (16.6-20.5)	10.4 (9.2-11.7)	80.9	16.2	2.5	0.4
Overall	All	4532	18.3 (16.6-19.9)	10.0 (8.9-11.1)	27.4	59.6	10.5	2.5

Source: Katulanda et al. Asia-Pacific Journal of Public Health 2011; 23(6): 861-869 (SLDC Study 2005-06)

- In a sample of 650 schoolteachers representing Southern Province, the prevalence of current smoking was 1.5% (95% CI=0.8, 2.5) and for smokeless tobacco, it was 0.9% (Ubeysekara, 2017).

### 3.1.3.2 Alcohol intake

Excessive alcohol consumption is a well-established behavioural risk factor to a range of chronic NCDs.

- When STEPS Survey data are considered, there is an increase in the prevalence of current drinkers (drinking within past 30 days) which was 13.5% in 2006 and 17.9% in 2015. However, this trend is mainly due to the drinking pattern of males, while the female drinking prevalence remained low at 0.5%. It should be noted that there is gross inconsistency in the definition of “heavy drinking” over the years in STEPS surveys. In 2003, heavy drinking has been defined as having 5 or more drinks on any day in the last week among the current drinkers and accordingly, the prevalence was 43.8%. In 2006, among current drinkers, 47.8% had been taking more than 6 standard drinks per day. In 2015, heavy drinkers were defined as “among current drinkers 6 or more drinks on any occasion in the past 30 days” and accordingly, the reported prevalence was only 8.6%.



- The SLDC Study (Katulanda et al., 2014b) showed the overall prevalence of current drinking (23.7%; 95% CI=21.7, 25.7) to differ by urban (29.5%) and rural (22.2%) sectors ( $p=0.001$ ). Further, male sex, urban living and current smoking correlated with both current and hazardous drinking. Lower level of education, and age >70 years positively correlated with hazardous drinking. Further, the study conducted in Colombo District (Arambepola, 2004) revealed that the prevalence of abdominal obesity among the ever drinkers was seen to gradually increase with alcohol consumption up to 4-9 portions per week. Interestingly, abdominal obesity was least and showed in fact a protective effect among those who consumed 1-3 portions during past month. Despite a trend, these differences were statistically significant ( $p<0.001$ ).

The evidence is extremely inconsistent in defining hazardous drinking levels. It is recommended to follow accepted guidelines in future research.

- With regards to its prevalence in vulnerable populations, a cross-sectional study (Harshani & Abeysena, 2011) among 465 fishermen from Kalpitiya reported the prevalence of ever and current alcohol drinkers as 61% (95% CI=56.5, 65.3) and 60.2% (95% CI=55.8, 64.6). This high prevalence is anticipated in coastal regions in Sri Lanka. Another high-risk category is the tea plantation labourers. It is noteworthy that even if the female alcohol consumption remains at a very low level nationally, Rambukwella & Dissanayake (2018) studying a sample of 368 adult female estate workers from Kotmale MOH area in year 2014 has reported an ever and current drinkers of 31.25% (95% CI=26.51, 35.99) and 16.8% (95% CI=13.0, 20.6) among females.

Though prevalence of alcohol use among females is very low at national level, emphasis should be given to this issue in vulnerable settings such as estate sector.

### 3.1.3.3 Unhealthy diet

The Asian diet has been estimated to be sub-optimal in relation to some food components relevant to NCDs. This was evident in the systematic review conducted on the global, regional and national consumption of specific food groups, based on 266 country-specific nutrition surveys during 1990-2010, for which Sri Lanka too provided dietary data on salt (Powles et al., 2013), dietary fats and oils (Micha et al., 2014), sugar-sweetened beverages, fruit juices and milk (Singh et al., 2015a; Singh et al., 2015b) and major food groups (Micha et al., 2015) on behalf of the Global Burden of Diseases Nutrition and Chronic Diseases Expert Group (GBOD NutriCoDE).

Diet related to NCD is assessed quantitatively as well as qualitatively. The local researchers have looked at various aspects of diet, such as the obesogenicity of diet, adequacy of intake of fruits and vegetables, the energy level and salt intake, which are different aspects linked to NCD. Validated food frequency questionnaires are fewer in number in Sri Lanka (Arambepola, 2004; Jayawardena, 2014a).

- The STEPS survey looked at the percentage who eat less than 5 combined servings of fruit & vegetables per day. It is encouraging to note that this percentage has gone down from 96.9% in 2003 to 72.5% in 2015, indicating that people are more aware of the importance of adding fruits and vegetables in sufficient amounts to the daily diet.
- Arambepola (2004) validated a food frequency questionnaire to assess the quality of an obesogenic diet (diet rich in energy dense food and poor in micronutrients) pertaining to Sri Lanka. Using this tool, the 'usual' dietary practices during past 12 months were assessed in a representative sample drawn from Colombo District. The study findings showed a distinct pattern in the consumption of a sub-optimal diet in relation to residential area, highlighting a significant inter-sectoral difference (Table 3.7). The inadequate consumption of fruits, vegetables and whole grain products was lowest in the rural sector ( $p < 0.001$ ), while the over-consumption of deep-fried food, commercially baked food and sugar-sweetened drinks was significantly different between sectors ( $p < 0.05$ ) with the highest reported from urban non-CMC sector ( $p < 0.05$ ). A similar pattern was observed with sugar-sweetened drinks, although there was no consistent pattern (Table 3.7). Sub-optimal diet was also associated with higher prevalence of abdominal obesity.

An obesogenic diet (low fibre and energy-dense food) is apparent in urban areas, highlighting a significant inter-sectoral difference. However, this difference appears to be diminishing for sugar-sweetened drinks and processed products.

**Table 3.7: Distribution of adults in each sector by the pattern of consumption of individual food domains (N=1395)**

Food domain	Sub-optimal diet <sup>1</sup>			Significance
	CMC (n=384)	Non-CMC (n=383)	Rural (n=628)	
<b>Dietary fibre:</b>				
Vegetables	178 (46)	201 (52)	302 (48)	<b>p=0.001</b>
Fruits	180 (47)	177 (46)	197 (36)	<b>p&lt;0.001</b>
Whole grain products	176 (46)	163 (42)	226 (36)	<b>p=0.005</b>
Pulses and legumes	237 (62)	256 (67)	377 (60)	p=0.09
<b>Energy-dense food:</b>				
Milk/ dairy products	14 (4)	15 (4)	14 (2)	p=0.24
Whole eggs and products	193 (50)	173 (45)	303 (48)	p=0.36
Red and processed meat	46 (12)	56 (15)	63 (10)	p=0.09
Deep fried food	193 (50)	211 (55)	279 (44)	<b>p=0.03</b>
Commercially baked food	226 (59)	246 (64)	350 (56)	<b>p=0.03</b>
Sugars-sweetened beverages	142 (37)	176 (46)	278 (44)	<b>p=0.02</b>

<sup>1</sup> Indicates the subjects with 'inadequate' consumption of food domains related to dietary fibre and 'over' consumption of food domains related to energy-dense food

Source: Arambepola C. PGIM MD (CM) Thesis, 2004

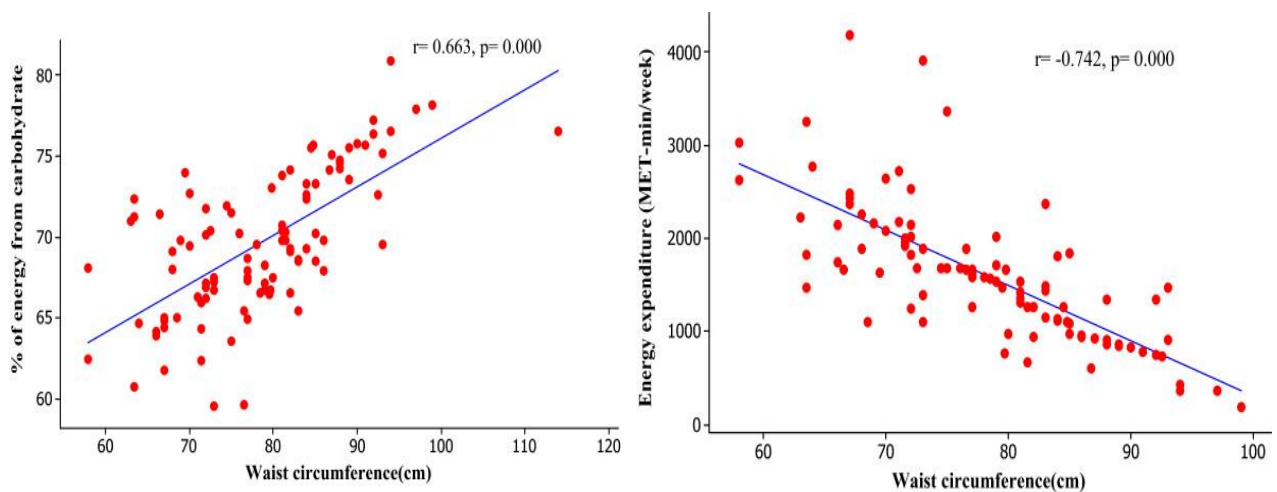
- Using another food frequency tool validated to assess the dietary energy and nutrient intake in Sri Lankan adults, the mean energy and nutrient intake were calculated in 2011 in a sub-sample of 491 participants selected from the SLDC Study 2005-05 (Jayawardena et al., 2014b). The mean energy intake of men was found to be significantly higher (1912.7 kcal/d) than that of women (1513.6 kcal/d) ( $p<0.05$ ). The total mean carbohydrate intake of Sri Lankan adults was approximately 304.4 g (71.2% of total energy from carbohydrates). The study further looked into the serving characteristics too (Jayawardena et al., 2013d) and concluded that 70% adults exceed the maximum daily recommendation of starch intake. The adults consumed over 14 portions of starch and 3-5 portions of added sugars daily. In contrast, only 3.5% of all adults (5.3% males and 2.5% females) consumed the recommended serving of  $\geq 5$  fruit and vegetables.

A high carbohydrate diet, which covers 71% of the total dietary energy exceeds the national recommendation given for starch intake.

- Females as housewives, have been identified as being at risk for central obesity, through the risk imparted by high carbohydrate diet and physical inactivity.

In a sample of 100 housewives aged 20-45 years selected randomly from two DS divisions representing urban and rural sectors showed that they consumed an average of 18 starch portions per day, which was well above the national recommendations. 70% of their total dietary energy was from carbohydrate. With regards to WC, a significant positive correlation was observed with high carbohydrate diet ( $r=0.628$ ;  $p<0.0001$ ) and a negative correlation with energy expenditure ( $r=-0.742$ ;  $p<0.0001$ ) (Figure 3.3). Further, central obesity was significantly associated with high carbohydrate diet (OR=6.26) and physical inactivity (OR=3.32) (Rathnayake et al., 2014).

**Figure 3.3: Correlation of waist circumference with dietary energy intake from carbohydrates and energy expenditure among housewives**



Source: Rathnayake et al. BMC Research Notes 2014; 7: 564

- Several high risk populations have been studied on their dietary practices.

A study conducted among 333 adult females representing Homagama MOH area, of whom 93% consisted of married women, revealed that their consumption of green leaves (92%); legumes & pulses (70%); and fruits (80%) was satisfactory. However, many resorted to unhealthy practices with regards to salt, fats and oils used for cooking, such as nearly 61% opted for deep frying or tempering as their first choice of cooking method and saturated oil as their first choice of cooking oil by 95%; 41% reused their cooking oil; and 89% added salt prior to cooking. Only 22.5% used healthy choices for snacks. However,

only 11.5% did not prepare breakfast at home on weekends and 6% on weekdays (Premajyantha & Arambepola., 2012) (abstract).

In comparison, in a more educated group of 650 sample of schoolteachers representing Southern Province, the prevalence of low fruit and vegetable consumption (<5 servings per day) was 66.7% (95% CI=63.9, 69.1) and adding salt to rice while cooking was 38.2% (95% CI=34.7, 42.2) (Ubeysekara, 2017).

Gamage et al. (2017) in her study on HT further showed that administrative officers in Colombo District had alarmingly high levels of urinary sodium, as measured by 24-hour excretion in hypertensives (202.56; SD=85.45) mmol/day as well as in non-hypertensives (176.79; SD=82.02) mmol/day, respectively. High salt intake was positively associated with HT and more prevalent in the lower socio-economic strata.

- A controversial finding reported by Jayawardena et al. (2013a) was on higher dietary diversity which was found to associate positively with obesity among Sri Lankan adults. Authors presume that though dietary diversity is considered a key element in high-quality diets, diets that offer a variety of energy-dense food could result in obesity.

Dietary messages should target particularly housewives with emphasis on improving their selection of food items, such as micronutrient rich high-fibre food.

#### **3.1.3.4 Physical inactivity**

Physical inactivity is expected to be high in parallel with urban living in many districts of Sri Lanka.

- The STEPS Survey from its inception in 2003 has captured the prevalence of low physical activity level (WHO, 2006; WHO, 2015).

In 2003, it has reported a prevalence of low physical activity of 12.1 % among males and 19.1% among females, giving an overall prevalence of 15.6%. In 2006 and 2015 surveys, the parameter used was percentage with insufficient physical activity (defined by <150 minutes of moderate-intensity activity per week, or equivalent) and in 2006, these percentages were 17.9%, 31.9% and 25% for males, females and overall respectively. In 2015, these values have gone up to 22.5%, 38.4% and 30.45%, respectively. This implies that adults have become more sedentary over time.

- Arambepola (2004) assessed the physical activity level in the sample drawn from Colombo District. It revealed 31.8% adults to be insufficiently active (38.5% males; 24.7% females;  $p < 0.05$ ); sufficiently active (60.9%); and highly active (7.3%). This tool had been validated for Sri Lankan populations using objective validation techniques by Arambepola (2004). The study also concluded that insufficient activity level was significantly associated with urban living (Arambepola, 2008a) as well as with abdominal obesity, giving a three-fold risk in males and two-fold risk in females (Arambepola, 2007).
- Analyzing data from the SLDC Study of 2005-06, Katulanda et al. (2013) reported that 60.0% were 'highly active', while only 11.0% were 'inactive' (males 14.6%, females 8.7%;  $p < 0.001$ ). Results of the logistic regression analysis indicated that female gender (aOR=2.1), age over 70 years (aOR=3.8), urban living (aOR=2.5), Muslim ethnicity (aOR=2.7), tertiary education (aOR=3.6), obesity (aOR=1.8), DM (aOR=1.6), HT (aOR=1.2) and metabolic syndrome (aOR=1.3) were significantly associated with increased odds of being physically 'inactive'.
- For understanding the patterns within each activity domain, de Silva Weliange et al. (2016) conducted a community-based study using sector specified cluster sampling in Colombo District among 1320 adults aged 20-59 years, using the IPAQ-long validated for Sri Lankan adults (Karunapema, 2007). It found that 80.8% of the adults had sufficient physical activity (82.0% (95% CI=78.5, 85.0) for males and 79.7% (95% CI=76.5, 82.6) for females). The main contributors to energy expenditure were domestic activity, followed by transportation and job-related activity, with little or no leisure time activity (Table 3.8).

**Table 3.8: Distribution of the physical activities in adults in Colombo District**

Physical activity	No.	%	Minutes spent each day			
			Mean	SD	Median	IQR
<b>Job (n=717)</b>						
Vigorous activity	142	19.8%	16.3	37.4	0.0	0.0-0.0
Moderate activity	405	56.5%	34.6	40.4	20.0	0.0-60.0
Walking	193	26.9%	14.9	31.5	0.0	0.0-10.0
Total activity	480	66.9%	65.8	70.1	60.0	0.0-120.0
<b>Transport (n=1320)</b>						
Motorised vehicle			69.7	93.6	42.5	20.0-90.0
Walking	1050	79.5%	27.1	26.1	20.0	10.0-30.0
Cycling	114	8.6%	4.0	15.5	0.0	0.0-0.0
Active travel (walking and/or cycling)	1066	80.8%	31.1	31.4	30.0	10.0-40.0
Total travel minutes			100.8	99.1	80.0	40.0-120.0
<b>Domestic (n=1320)</b>						
Vigorous-intensity work in the garden	241	18.3%	0.0	11.8	0.0	0.0-0.0
Moderate-intensity work in the garden	830	62.9%	20.0	17.3	20.0	0.0-30.0
Moderate-intensity work inside home	986	74.7%	30.0	12.7	30.0	0.0-30.0
Total activity doing household work	1080	81.8%	50.0	27.7	50.0	20.0-60.0
<b>Lesiure (n=1320)</b>						
Vigorous-intensity at leisure	52	3.9%	12.8	12.8	0.0	0.0-0.0
Moderate-intensity at leisure	136	10.3%	23.5	23.5	0.0	0.0-0.0
Walking during leisure	191	14.5%	1.6	1.6	0.0	0.0-0.0
Total leisure activity	287	21.7%	36.1	36.1	0.0	0.0-0.0

Source: de Silva Welinge et al. Asia Pacific Journal of Public Health 2016; 1-12

The study further highlighted that the correlates of sufficient activity in regression analysis were linked to their financial status (e.g. low income, living in non-CMC urban sector), work status (e.g. highly active job), travel behaviour (e.g. active transport used); and psychological characteristics (e.g. having self-efficacy for recommended activity; perceived barriers), but not with vehicular traffic safety, aesthetics and facilities for cycling, low residential density and perceived physical environmental factors. Several social environment correlates were identified in the qualitative assessment, while physical environment correlates such as residential density and street connectivity were identified as significant through GIS mapping.

While encouraging to maintain physical activity through household and transport related activities as per the current trend, more emphasis should be placed to enhancing leisure time activity. Also, understanding the activity pattern within each domain helps in planning well-targeted programs.

- McNiven et al. (2012) conducting a review on population-based studies on physical activity levels of adults in Asia-Pacific region reported 2003 STEPS Survey data (based on GPAQ) and World Health Survey data (based on IPAQ-2003), where the prevalence of inactivity was reported as 10%. Citing more updated data sources from Sri Lanka, a recent systematic review (Ranasinghe et al., 2013a) on physical activity in South Asia concluded that the prevalence of inactivity vary widely from 11.0% to 31.8%.

Physical inactivity varies widely in Sri Lanka; thus, research should focus on vulnerable population sub-groups and settings for health promotion programs.

- Occupation-related physical inactivity is more prevalent in Sri Lanka, as shown by many studies.

In concurrence, the prevalence of physical inactivity in a 650 sample of schoolteachers representing Southern Province was 38.7% (95% CI=34.9, 44.2). Age  $\geq 40$  years (OR=3.18; 95% CI=1.44, 6.9), using inactive modes of transportation (OR=5.61; 95% CI=1.87, 16.8), non-availability of facilities for sports and physical activities in workplace (OR=2.09; 95% CI=1.06, 4.15) and not being involved in exercises or sports training sessions at school (OR=2.07; 95% CI=1.1, 3.9) were identified as independent risk factors for physical inactivity by multivariate regression analysis (Ubeysekara, 2017). Another study sample representing relatively young adults in sedentary vocation reported that the overall physical activity level among 421 medical undergraduates of a Sri Lankan university was 41% (Medagama et al., 2017), with total mean weekly metabolic equivalent of task (MET)-minutes of 1468.2 (SD=1873). Females (47%) were more inactive than males (34%), and demonstrated significantly lesser MET-minutes (1676.2 in males vs. 1319) ( $p=0.05$ ). Interestingly, 88% owned a portable internet device such as a smartphone or tablet, and those using health-related apps on their devices had significantly higher level of physical activity ( $p=0.01$ ) and lower BMI ( $p=0.04$ ) than those who did not. In addition to this, the regression analysis showed that physical inactivity was significantly associated with gender ( $p=0.01$ ) and the year of study ( $p=0.03$ ).



### 3.1.3.5 Stress

There was only one study conducted on the prevalence of chronic stress in Sri Lanka (Senanayake, 2016) which was conducted in a community-based sample of 2408 adults aged over 18 years in the district of Colombo. This study validated the Chronic Stress Measurement Scale (CSMS) for Sri Lankan adults, and accordingly reports a prevalence of high level of chronic stress among males, females and the overall of 18.4%, 16.4% and 17.4%, respectively.

### 3.1.3.6 Clustering of the cardio-metabolic risk factors in population

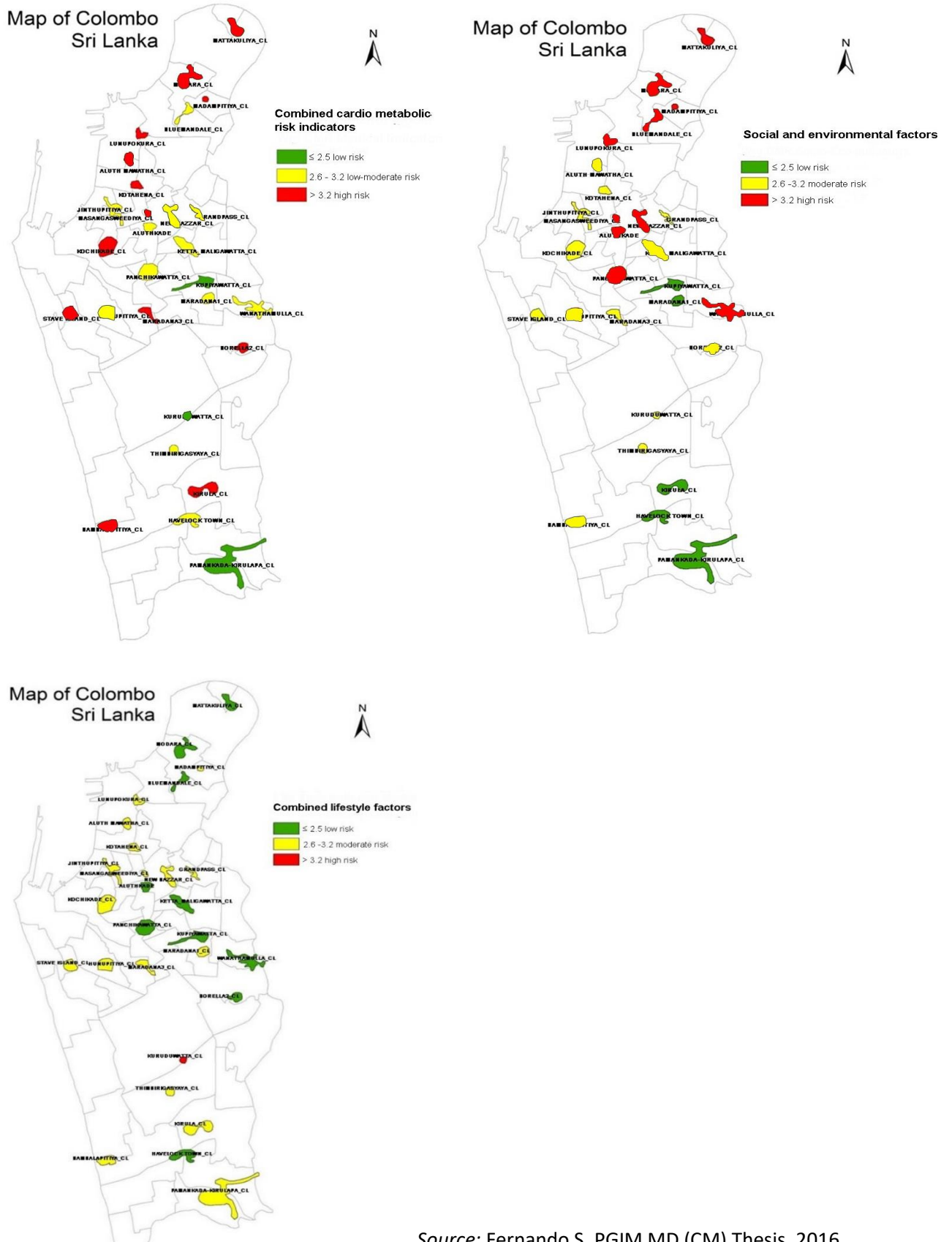
With the risk of NCDs being multifactorial in nature, it is no longer useful to study the independent effect of each risk factor on disease outcomes. A shift in focus towards studying the clustering of risk factors using pattern analysis, would lead to a greater understanding of the true multi-factorial nature of risk. Such clustering effect of CVD risk has been studied in relation to geo-referencing as well as using statistical techniques in Sri Lanka.

#### a. Spatial distribution of cardio-metabolic risk factors

An attempt has been made to characterize the area level distribution of the significant cardio-metabolic risk indicators and the social, environmental and lifestyle correlates using geographical information system (GIS) mapping (risk weighted based on accepted classifications) (Fernando, 2016).

- As shown (Figure 3.4), Modara, Mattakkuliya, Madampitiya and Lunupokuna had the highest risk weighted distribution of overall cardio-metabolic risk in the CMC sector. In further analysis, Kurunduwatta, Bambalapitiya and Masangasweediya had the highest risk weighted distribution for cardio-metabolic risk indicators; Kotahena, Aluthkade, Lunupokuna and New Bazaar for social and environmental correlates; and Khetarama-Maligawatta and Panchikawatta for lifestyle correlates.

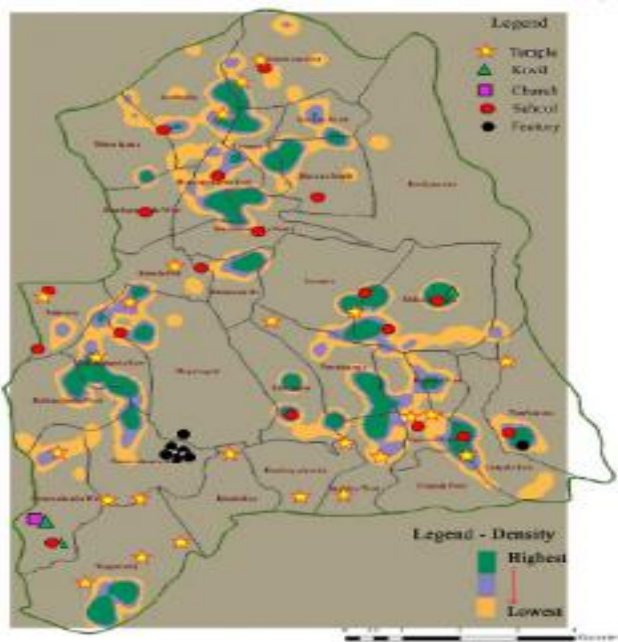
Figure 3.4: Geospatial distribution of cardio-metabolic risk factors and correlates in CMC area



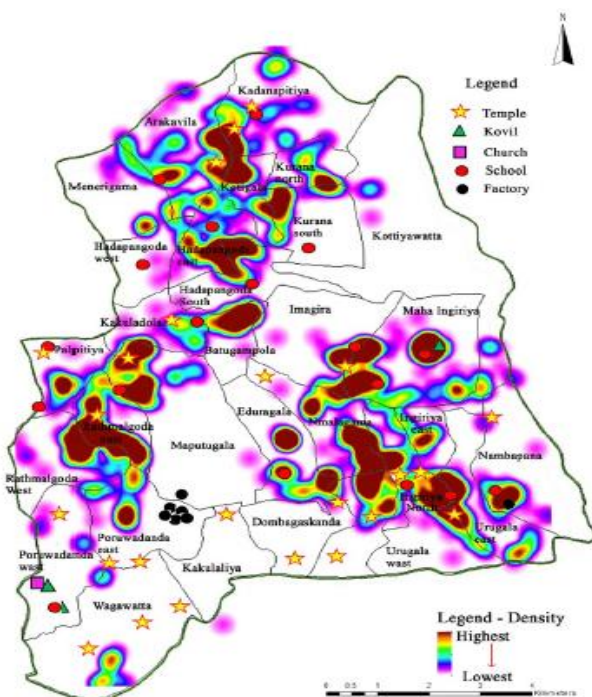
Source: Fernando S. PGIM MD (CM) Thesis, 2016

- Focusing exclusively on males, another GIS study (Silva, 2016) has been conducted to map unhealthy lifestyle related behaviour of all men aged 35-50 years in an MOH area in Western Province (Figure 3.5 a-b). Clustering of such behaviour was identified visually and statistically in relation to locations such as schools, places of religious worship and factories in the area, and the clustering mostly seen in areas with less population density. Smoking and alcohol were clustering in estate areas occupied by Tamils.

**Figure 3.5a: Kernel density of current alcohol use and important places in Ingiriya**



**Figure 3.5b: Kernel density of current smoking and important places in Ingiriya**



Source: Silva JP. Asia-Pacific Journal of Public Health 2016; 28(1S): 10S–16S

### b. Lifestyle patterns of high risk population

The observation that foods and food groups cluster within different cultures such as Mediterranean, Western and Asian cultures has led to the development of dietary pattern analysis, which affords a much better opportunity to study the synergistic effects of diet than that provided by a single-nutrient or -food approach.

- For the first time, Waidyathilaka et al. (2014) derived lifestyle patterns incorporating dietary and physical activity parameters, among middle-aged urban women unknown of their DM status. For this purpose, Principal Component Analysis (PCA) was used for the extraction of factors related to the frequency consumption of each of the ten food groups studied and physical activity, in a sample of 617 apparently healthy (with no previously known DM) women representing the CMC area. The parameters with factor loadings >0.3 and communality >0.3 were retained in the lifestyle patterns identified.

**Table 3.9: Factor loadings and communalities estimated for the dietary patterns of urban Sri Lankan women aged 30–45 years (N=617)**

Food and physical activity domains	Factor loadings		
	Lifestyle Pattern 1	Lifestyle Pattern 2	Lifestyle Pattern 3
Rice and rice flour-based products	0.524	-0.304	0.467
Pulses	0.579		
Seafood	0.613		
Fruits	0.513	0.451	
Vegetables and DGLV	0.792		
Dairy products			0.602
Snacks			0.671
Processed meat		0.621	
What products and potato		0.719	
Red meat		0.683	
Physical activity			-0.658
Eigenvalues	2.583	1.539	1.145
% of variance explained	23.48	13.99	10.41
% of accumulated explained variance	23.48	37.47	47.87

Source: Waidyathilaka et al. British Journal of Nutrition 2014; 112(6): 952-957

As shown above (Table 3.9), three lifestyle patterns were identified, each explaining 23.5%, 14% and 10.4% of the model variance, respectively. Pattern 1 was characterized by rice and rice flour-based products, pulses, seafood, fruits, vegetables and dark green leafy vegetables; Pattern 2 by wheat, wheat-based products and tubers, red meat and processed meat; and Pattern 3 by snacks, dairy products and poultry along with a negative factor loading for physical activity. Together, these patterns explained 47.9% of the model variance.

### **3.1.4 Prevalence and associations of non-modifiable NCD risk factors**

In this section, the status of age, sex, family history and genetics were considered.

- Katulanda et al. (2008c) studied the clinical characteristics of maternally inherited DM and deafness caused by mt3243A >G-mutation in young adult diabetic subjects in Sri Lanka. The prevalence was found to be 0.9%. It further demonstrated that a maternal family history of DM and either a personal and/or family history of deafness only distinguished half of the patients with maternally inherited DM from Sri Lankan subjects with young-onset DM.
- Akiyama et al. (2014), conducting a multi-country study where Sri Lankan participants also represented one arm, has attempted to explore the causal genetic variants associated with high BMI and DM. They were able to fine map the association of FTO locus by this multiethnic study, further strengthening the evidence available on the possible associations.
- Ranasinghe et al. (2015a) studying the influence of family history on the prevalence of HT found that presence of a family history significantly increased the risk of HT (OR=1.29; 95% CI=1.13, 1.47), obesity (OR=1.36; 95% CI=1.27, 1.45), central obesity (OR=1.30; 95% CI=1.22,1.40) and metabolic syndrome (OR=1.19; 95% CI=1.08,1.30). In all adults, the presence of family history in parents (OR=1.28; 95% CI=1.12, 1.48), grandparents (OR=1.34; 95% CI=1.20, 1.50) and siblings (OR=1.27; 95% CI=1.21, 1.33) were all associated with significantly with increased risk of developing HT.

## 3.2 Status of the NCD risk factors in patients having CVD and DM

The status of NCD risk factors in patients was assessed in relation to their prevalence, trends over the years and factors associated with the prevalence in those having CVD or DM in clinic-based samples.

### 3.2.1 Sources of information

There are many studies providing evidence on NCD risk factors among clinic patients, but most of these studies were of small size; not selected using probability sampling; not representative of the diabetic patient population; and data mostly derived from clinic records. Only a few studies have been conducted in large samples using good quality data. The other main issue is, since most of the studies have used a cross-sectional design, the temporality of diseases and risk factors cannot be readily established.

This section mainly refers to the studies conducted in diabetic clinics among patients with DM, such as in a sample of 2432 representing Southern Sri Lanka by Herath et al. (2015); at TH Jaffna in a sample of 8401 by Sujanitha et al. (2015), in 300 by Jasliya et al. (2018) (abstract) and by Senthuran (2018); at NHSL in a 3000 sample by Arambewela et al. (2018a and 2018b) and in a 430 sample by Abhayaratne et al. (2015); at GH Kalutara by Rupasinghe et al. (2014) (abstract); at TH Peradeniya in a 128 sample by Medagama et al. (2015a) and Medagama & Widanapathiranan (2015); and at a family practice centre in Colombo District in a 100 sample by Senadheera et al. (2016).

### 3.2.2 Prevalence, trends and associations of NCD risk factors among DM patients

In this section, the status of metabolic as well as behavioural risk factors among patients with DM is described.

#### 3.2.2.1 HT among DM patients

Cardiac risk assessments have been done in patients attending the diabetic clinics in hospitals.

- The results reveal a prevalence of HT in 69.2% with isolated elevated DBP, accounting for a prevalence of 48.1% among 2432 patients in Southern Sri Lanka (Herath et al., 2015); 65.7% among 300 DM patients at TH Jaffna (Jasliya et al., 2018) (abstract); and 34.9% & 40.8% in males and females in a sample of 430 DM patients at NHSL (Abhayaratne et al. 2015). A recent study in a larger sample of DM patients (n=3000) in the same location (Arambewela et al., 2018a) revealed a prevalence of HT of 77.6%. Such variation in the

prevalence could be due to differences in the health seeking behaviour of patients in different districts, despite all being tertiary care hospitals.

### 3.2.2.2 Dyslipidaemia among DM patients

The prevalence of dyslipidemia differed in DM patients based on the district.

- Patients attending the diabetic clinic at GH Kalutara has shown that 75% of them were having high LDL-C levels (Rupasinghe et al., 2014) (abstract), while the overall prevalence of dyslipidemia with at least one abnormal lipid parameter in a similar setting in Southern Sri Lanka among patients who had been on statin treatment for at least three months was 89% (Weerarathna et al., 2017; Herath et al., 2016b). Raised LDL-C was the commonest lipid abnormality affecting 84% of the subjects. Hypertriglyceridemia and low HDL-C were comparatively less common, accounting for only 19.1% and 17.6% respectively. In comparison, Abhayaratne et al. (2015) reported that among DM patients at NHSL, 31.2% of the males and 61.0% of the females were having low HDL-C; and 31.2% of the males and 32.6% of the females having high TG levels. Arambewela et al. (2018a) also reported 76.7% of dyslipidaemia in a sample of 3000 DM patients from NHSL. In concurrence, Jasliya et al. (2018) (abstract) reported a prevalence of dyslipidaemia of 72.3% from TH Jaffna.
- Though these studies suggest that the prevalence of dyslipidaemia among DM patients is higher than that of general population, a small set of DM patients (n=24) and controls in the North Central Province has concluded that there was no significant difference in the lipid parameters of the two groups (Rathnayake et al., 2016a).

### 3.2.2.3 Obesity among DM patients

Several clinic-based studies have been conducted on obesity in patients attending the diabetic clinic.

- Overall, 18.2% of the subjects studied were obese and its prevalence in females was 22.2% in comparison to 15.8% in males, according to a study representing Southern Sri Lanka (Herath et al., 2015). With regards to studies conducted in diabetic clinics in TH Jaffna, the prevalence of overweight and obesity was 20.5% and 33.8% among 8401 DM patients from years 2009-2013 (Sujanitha et al., 2015); and 43.3% and 23% (Jasliya et al., 2018) (abstract); and 39.2% & 26.7% (Senthuran et al., 2018) (abstract) according to the most recent publications from Jaffna. In comparison, 44% (females 50%; males 36%) of the

sample of 100 DM patients from a family practice clinic in Colombo District were either overweight or obese. However, only 60% of those patients accepted that they were either overweight or obese (Senadheera et al., 2016).

- With regards to central obesity among DM patient attending the NHSL, the prevalence of central obesity was 51.4% among males and 81.6% among females compared to generalized obesity rates of 37.6% and 52.1% for males and females (Abhayaratne et al., 2015) while combined overweight/obesity prevalence was 80% (Arambewela, 2018a). Both studies were among DM patients from NHSL and used Asian Standards for determining obesity.

Obesity among DM patients is very much in line with higher prevalence of generalized and central obesity than that seen in the general population.

#### **3.2.2.4 Metabolic syndrome among DM patients**

- A study conducted on metabolic syndrome among DM patients gave a crude prevalence of 63.7% according to the IDF Criteria (Abhayaratne et al., 2015). A significantly higher number of females had metabolic syndrome when compared to males (72% vs. 42.2%).
- Another study done in TH Peradeniya with newly diagnosed DM patients revealed a prevalence of metabolic syndrome of 66.3% with NCEP-ATP III Criteria and 62.9% with IDF Criteria. With both criteria, females were more affected than males (Wijesinghe et al., 2012) (abstract).

#### **3.2.2.5 Dietary practices among DM patients**

Clinic-based studies have assessed the practices of DM patients in relation to the prescribed dietary guidelines.

- Diabetic patients in Sri Lanka are shown to consume an energy restricted, high-carbohydrate, low-fat diet compared to those in Western countries. Though consuming less starch and more fruits and vegetables compared to their non-diabetic counterparts, a substantial proportion of these patients in Sri Lanka still fail to meet the recommendations with regards to dietary guidelines.

This was evident in the study evaluating the diet following nutrition counseling among 123 DM patients at TH Peradeniya (Medagama et al., 2015a). The participants' mean daily



intake was estimated to be 1438.47 kcal for energy; 33.05 g for fat; 18.13 g for dietary fibre; and 249.7 g for carbohydrate. Except for energy intake, there was no significant difference between males and females. Carbohydrates accounted for 68.1% of the total daily energy intake. 50% of carbohydrate was consumed as rice, while pulses, vegetables, wheat-based products and fruits contributed 44.7%. Animal proteins contributed to 36% of the total protein intake. This study provides valuable evidence on the energy and macronutrient intake of a semi-urban diabetic population, where there is no previous data available. Calculating the nutrient content of most food using the United States Department of Agriculture (USDA) nutrient database is commendable, however the use of a single 24-hour dietary recall may have introduced potential recall bias.

- Senadheera et al. (2016) in the study among 100 DM patients attending a family practice center in a semi-urban setting in Colombo District also showed that although vegetables, fatty foods and poultry consumption of DM patients was in accordance with the guidelines, a significant percentage (45.5%) consumed rice-mixed meal for all three meals which was higher than that of the normal population. 67% consumed fruits daily. The daily green leafy vegetable intake and the quantity consumed were also inadequate to obtain beneficial effects. Majority (71%) consumed full cream milk; and sugar intake (77%) was in accordance with the guidelines. Non-caloric sweetener usage was nonexistent.

### **3.2.2.6 Physical activity levels among DM patients**

- The SLDC Study 2005-06 highlights that the prevalence of physical inactivity among the 528 DM adults identified in the general population was 13.9%. The MET minutes of the inactive, moderately active and highly active groups, as per IPAQ-short were 597 (SD=538), 1648 (SD=883) and 4790 (SD=1633) Those physically active (moderate and highly active) were significantly younger; had earlier onset of DM; and had lower WC and WHR. No such relationship was noted with their current glycaemic control, lipid levels or BP (Ranasinghe et al., 2014c).
- Diabetic patients attending a family practice centre in a semi-urban setting in Colombo District showed that only 14% exercised daily while 69% never exercised (Senadheera et al., 2016).
- In contrast, Jasliya et al. (2018) (abstract) reports that among DM patients attending the diabetic clinic at TH Jaffna, 26.3% are having low physical activity levels. Overall prevalence of physical inactivity was 13.9%. Females (3091; SD=2119) had a significantly

higher mean weekly total MET minutes than males (2506; SD=2084) ( $p<0.01$ ). Inactivity of those residing in urban (17.2%) areas was higher than rural (12.6%) in all adults. A noteworthy finding was that participants from Moor ethnicity were more inactive compared to others. Adults who were physically active had significantly low waist and hip circumferences, BMI and SBP.

### 3.2.2.7 Alcohol & tobacco among DM patients

- Jasliya et al. (2018) (abstract) reports that among DM patients attending TH Jaffna diabetic clinics, 5.7% are consuming alcohol, 19.7% are having habit of tobacco and betel chewing. Senthuran (2018) also reports that 14.6% males smoked among the sample of DM patients they studied from TH Jaffna. Arambewela et al. (2018a) reports a smoking prevalence of 11%, however it should be noted that this sample composed of only 27.3% of males.

### 3.2.3 Prevalence, trends and associations of NCD risk factors among CVD patients

In this section, the status of metabolic as well as lifestyle related risk factors among patients with CVD were considered. This evidence was limited to a few studies.

- Katulanda et al. (2010c) (abstract) based on their SLDC Study 2005-06 reports on the following risk factors among the identified IHD patients: HT in 12.6%, one or more lipid abnormality 37.0%, smoking 18.4%, physical inactivity 14.1%, obesity 8.9%, DM 11.5% and family history in 22.9%. About one fifth of males with known IHD or its risk factors continued to smoke compared with those without: IHD (17.6% vs. 39.2%;  $p=0.003$ ), DM (26.0% vs. 39.0%;  $p=0.01$ ), HT (15.1% vs. 41.4%;  $p<0.001$ ), and hyperlipidemia (12.9% vs. 39.6%;  $p=0.001$ ).
- In comparison, several studies have highlighted the incidental finding of DM in a large proportion of hospital patients admitted with CAD (Nanayakkara et al., 2015; Bandara et al., 2016a).

A study among 102 CAD patients awaiting coronary artery bypass grafting (CABG) has revealed that 70.6%, 53.9% and 87.3% had a history of HT, DM and dyslipidemia, respectively (Bandara et al., 2016a). Family history of CHD was a risk in 54% of the sample, with females having a higher frequency (77%).

Another study conducted in Colombo South Teaching Hospital (CSTH), in which 504 patients with CAD admitted to the University Unit of CSTH with acute coronary syndrome (ACS) revealed pre-existing IHD to be present in 46.8%; DM in 39.3%; HT in 50.4%; and dyslipidemia in 21.6% (Matthias et al., 2018). 24.4% were current smokers while 21.2% were former smokers. Further, participants completed the International Physical Activity Questionnaire (IPAQ), and accordingly 25.1% were highly active; 17.1% moderately active; and 56.7% low active, with no differences seen between males and females ( $p=0.06$ ). When considering METs per week, 26.3% patients spent less than 1000 METs/week, while 26.3% of the patients did not meet the recommended minimum 1000 METs/week energy expenditure for cardiovascular benefit.

- Another study done among patients presenting with acute myocardial infarcts at TH Karapitiya reported 57.3% to be smokers; 13.6% to have DM; 19.4% to have HT; 97.1% to have dyslipidaemia; 51.5% to have metabolic syndrome; and 1.9% to be obese (Wickramatillake, 2015) (abstract). Bandara et al. (2014a) (abstract) studying 46 in-ward patients at SJGH awaiting CABG reports a prevalence of hyperlipidaemia prior to admission of 62%.

As per the available evidence from Sri Lanka, lack of physical activity and central obesity stands out as two major modifiable risk factors for DM and impaired glucose tolerance.

### 3.3 Determinants of CVD and DM

The magnitude of risk imparted by each NCD risk factor in the occurrence of CVD and DM varies according to the population-specific disease epidemiology. Such risk associations among Sri Lankans was studied as determinants of CVD and DM.

#### 3.3.1 Sources of information

A limited number of studies provided conclusive evidence on the risk imparted for CVD and DM, which are predominantly case control studies or cross sectional analytical studies providing odds ratio.

#### 3.3.2 Determinants of DM

Table 3.10 summarizes the available evidence from Sri Lanka on the strength of association of different risk factors in the occurrence of DM.

**Table 3.10: Magnitude of the risk of metabolic & behavioural factors for DM**

Risk factor	Source	Strength of association	Remarks
Ethnicity	Jayatilake et al., 2014	aOR=2.54 (1.42, 4.52)	Sri Lankan Tamils were at higher risk
Family history	Jayatilake et al., 2014	aOR=3.49 (3.45, 3.5)	
	Waidyathilake et al., 2013	No association	
	Ranasinghe et al., 2014a	aOR=3.35 (2.78, 4.03)	
	Jayawardena et al., 2012b **	aOR=2.75 (2.11, 3.58)	
Gender	Jayatilake et al., 2014	No significant association	
	Jayawardena et al., 2012b **	No significant association	
Urban living	Allender et al., 2011	aOR=2.44 (1.66, 3.57) Males	
		aOR=2.29 (1.64, 3.21) Females	
Lack of physical activity	Jayatilake et al., 2014	aOR=1.57 (1.19, 2.59)	
	Waidyathilake et al., 2013	aOR=4.56 (2.37, 8.77) *	Reference group=>1435.5 MET-minutes/week on walking
Central obesity	Waidyathilake et al., 2013	aOR=7.34 (3.06, 17.62) *	Reference group <80 cm waist circumference
	Jayawardena et al., 2012a **	aOR=1.36 (1.26, 1.52)	Waist to hip ratio was considered
NAFLD	Kasturiratne et al., 2013	OR=2.15 (1.80, 2.57)	
Gestational DM	Sudasinghe et al., 2018	aOR=4.1 (1.1, 15.7)	DM at one year postpartum
	Herath et al., 2015	aOR=10.42 (6.01, 19.12)	Retrospective cohort with 10-year follow-up

\*Risk for dysglycaemia

\*\* Findings relevant to South Asia

**NOTE:** Though specific risk ratios have not been reported, the SLDC Study (Katulanda et al., 2008a) reports that older age, obesity, positive family history, urban living and physical inactivity are significantly associated with DM and pre-DM ( $p < 0.01$ ) in Sri Lankan adults. Further, a follow-up study of adults in a relatively urban population reports that WC, SBP, TG and LDL-C levels are significantly higher in DM patients compared to those without DM in both males and females (Pinidiyapathirage et al., 2013). Excess maternal transmission and familial aggregation of DM have also been demonstrated in Sri Lanka (De Silva et al., 2002).

- The trends on determinants of DM (Table 3.10) are in line with other South Asian countries, as evident in a systematic review on the trends of DM in South Asia, where increasing age, SBP, family history, urban residency, sedentary lifestyle and higher BMI & WHR have been shown to be associated with higher risk of DM among South Asians (Jayawardena et al., 2012b). A systematic review conducted on DM in Sri Lanka however points out that there is relative lack of evidence with regards to diet related risk of DM in Sri Lankan setting (Ranasinghe et al., 2015b).
- Particularly males of South Asian origin are known to be at increased risk of developing insulin resistance and DM. In this regard, ethnic variation in CAG repeats in the androgen receptor (AR) has been reported, which is shown to associate significantly with body fat content, leptin and insulin.

For exploring this relationship further, a case control study of 21-65 aged 100 males each with DM (cases) and no DM (controls) recruited from NHSL was conducted (Malavige et al., 2017). The study concludes that AR CAG repeat polymorphism is not associated with insulin resistance and diabetes among Sri Lankan males.

- Sleep loss and disturbance have an effect in overall metabolic profile. Interestingly, Walatara et al. (2016) reports on reduced sleep duration at night as a potential risk factor for DM in the study conducted among 227 apparently healthy non-diabetic subjects from a suburban area, in which those sleeping <6 hours at night/day showed significantly higher FPG ( $p=0.003$ ).
- HIV and drug therapy are shown to lead to an increase in metabolic dysfunction. A study provides evidence based on a sample of 268 HIV patients, in which 6.7% were diabetics and 18.3% had IFG (Weerakkody et al., 2013). The study further confirmed metabolic abnormalities (20%- high TC; 24.4%- optimal LDL-C; 15.3% high TG) among them.

### 3.3.3 Determinants of CVD

Determinants of CVD have been assessed in relation to overall CVD and stroke, and to CHD and PAD individually.

### 3.3.3.1 Risk for CHD

- There were three extensive studies conducted during the review period that have assessed the strength of the metabolic and behavioural risk factors for CAD. Among those, two were multi-centre studies, in which Sri Lankan patients were also included. Table 3.11 summarizes the findings of the three studies.

**Table 3.11: Strength of association of risk factors with CAD as described by different sources**

Risk factor	Source	Strength of association	Remarks
Current smoking	Sonnadara, 2012	OR=1.12	Data from a multi- country study (ÍTERHEART) including Sri Lanka Reference group was never smoked; a common risk measure calculated for Bangladesh, Nepal and Sri Lanka
	Teo et al., 2006	OR=2.87 (2.58, 3.19)	
	Joshi et al., 2007	OR=2.61 (1.99, 3.41)	
Abdominal obesity	Sonnadara et al., 2012	OR=1.15	Data from a multi- country study (ÍTERHEART) including Sri Lanka
	Joshi et al., 2007	OR=1.78 (1.32, 2.41)	
	Yusuf et al., 2004	OR=1.12	
Hypertension	Joshi et al., 2007	OR=4.07 (2.94, 5.62)	
	Yusuf et al., 2004	OR=1.91	
Diabetes	Joshi et al., 2007	OR=3.92 (2.5, 6.14)	
	Yusuf et al., 2004	OR=2.37	
Alcohol consumption	Joshi et al., 2007	OR=0.97 (0.67, 1.37)	≥once a week
	Yusuf et al., 2004	OR=0.91	Regular consumption
Moderate or high-density exercise	Joshi et al., 2007	OR=0.81 (0.51, 1.59)	Regular physical activity
	Yusuf et al., 2004	OR=0.86	
Psychological factors	Joshi et al., 2007	OR=3.87 (1.76, 8.52)	
	Yusuf et al., 2004	OR=2.67	
Daily consumption of fruits and vegetables	Yusuf et al., 2004	OR= 0.70	
Apolipoprotein B/ Apolipoprotein A-I Ratio	Joshi et al., 2007	OR=2.35 (1.60, 3.44)	
	Yusuf et al., 2004	OR=3.25	

NOTE: Though exact risk estimates are not available, the SLDC Study reports on higher risk estimates for IHD with HT, DM, physical inactivity and multiple risk factors in both males and females (Katulanda et al., 2010c) (abstract). In a study of 115 patients, the correlation coefficient between Framingham risk score (FFRS) and hsCRP was 0.006, thus showing no relationship (Jesuthasan et al., 2014) (abstract).

One was INTERHEART Study conducted in 52 countries including Sri Lanka (Yousuf et al., 2004; Teo et al., 2006), which calculated the common odds ratios for the entire sample. The other was conducted in South Asian countries (Joshi et al., 2007) and the risk ratios were calculated taking Sri Lanka, Bangladesh and Nepal together probably due to inadequate sample size. The only study reported from Sri Lanka during this period was a case control study by Sonnadara (2012), carried out among 150 patients admitted with non-fatal myocardial infarcts to the Cardiology Units of NHSL and 150 controls.

- A case control study was conducted among 164 CVD patients from the cardiology clinic at TH Kandy (cases) and 667 non-CVD patients from the diabetic clinic at TH Peradeniya (controls) (Illangasekera & Dissanayake, 2012). CVD was diagnosed on symptoms and signs of IHD, being treated for such disease and investigations such as ECG, echocardiography and coronary angiography. The study revealed positive correlations of CVD with family history ( $r=0.77$ ), dyslipidaemic ( $r=0.29$ ), smoking ( $r=0.28$ ), HT ( $r=0.18$ ) and high WC in males ( $r=0.1$ ) and negative correlation with DM ( $r=-0.24$ ) and ironically no correlation with metabolic syndrome.
- Kurotoni et al. (2018) compared the circulating fatty acid compositions and its association with arterial stiffness among Sri Lankan and Japanese populations. The study revealed that odd chain saturated fatty acids might be inversely associated with atherosclerosis in Sri Lankans.
- Further, Bandara et al. (2014a) (abstract), studying the lipoprotein (a) levels of CAD patients awaiting CABG revealed that it could be a potential marker for assessing the susceptibility for CAD, especially in those with other risk factors but considered as non-hyperlipidaemic.

Most of the metabolic as well as lifestyle risk factors of NCD are proven to be associated with a higher risk of CHD in Sri Lanka. However, more evidence is needed on the role of dyslipidaemia.

### 3.3.3.2 Risk for stroke

- In an epidemiological study among adults aged >18 years in Colombo District (Chang et al., 2015), stroke was prevalent in 2:1 ratio between men (15 per 1000 men; 95% CI=7.8, 22.2) and women (7 per 1000 women; 95% CI=2.3, 11.7). Further, significant differences were noted further between these men and women for the presence of  $\geq 2$  risk factors and individually for smoking, alcohol, and past stroke/transient ischemic attack ( $p < 0.01$ ).
- A study on 190 newly diagnosed patients with ischaemic stroke admitted to the NHSL assessed the risk of anaemia as imparting a risk for functional disability in stroke. Of them, 58.4% had anaemia and they showed significantly higher functional disability (measured by mRS) compared to the non-anemic stroke patients (77.3% vs. 55.7%) (OR=2.17; 95% CI=1.13, 4.17). (Chang et al., 2014) (abstract).
- Conducting a hospital registry-based study in CSTH in the years of 2012-13, Perera et al. (2015a) found that lacunar stroke subtype to be common (56.8% vs. 43.2% non-lacunar stroke) among this sample of patients which is in line with evidence from other Asian countries. Lacunar strokes were commoner among males (aOR=2.1; 95% CI=1.08, 4.29).

### 3.3.3.3 Risk for PAD

- Weragoda et al. (2016) studied about the specific risk factors for PAD in the Sri Lankan population by conducting a case control study. Having a history of DM more than 10 years (OR=5.8; 95% CI=2.2, 14.2), history of dyslipidemia for more than 10 years (OR=4.9; 95% CI=2.1, 16.2), history of HT for more than 10 years (OR=3.8; 95% CI=1.8, 12.7), smoking (OR=2.9; 95% CI=1.2, 6.9), elevated high-sensitivity C Reactive Protein (HsCRP) (OR=3.7; 95% CI=1.2, 12.0) and hyperhomocysteinaemia (OR=3.0; 95% CI=1.1, 8.1) were identified as the country-specific significant risk factor of PAD.

### 3.3.3.4 Diet related risk for CVD

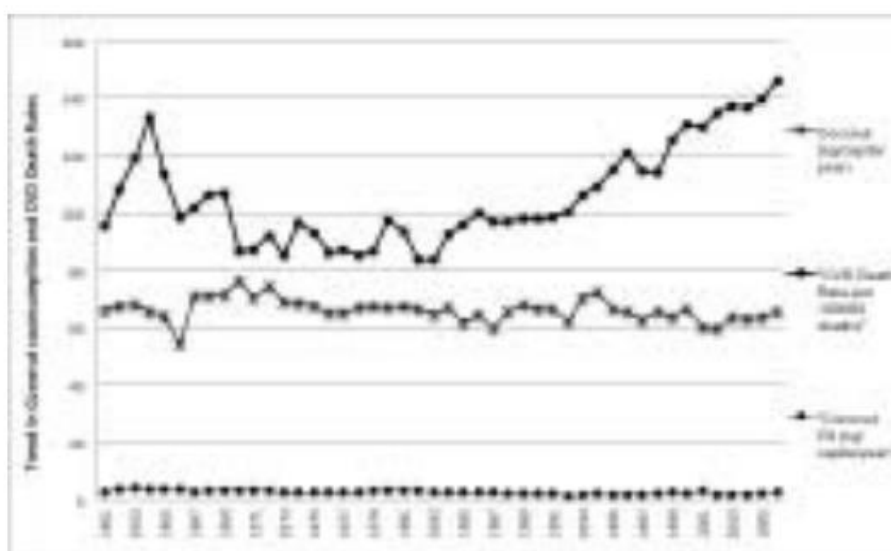
Diet related CVD risk is estimated to be substantial, as evident in the Global Burden of Disease Study 2010 (GBOD, 2010), which was a collaborative project of nearly 500 researchers in 50 countries. It has further revealed the dietary risk to be the leading risk factor accounting to cardio and circulatory diseases in Sri Lanka.

In the Sri Lankan setting, there are many concerns with regards to the commonly consumed constituents in the diet that may impart a substantial protective effect or risk for CVD.



- Coconut is one such food. Athauda et al. (2015), studying the population level per capita consumption over the years from 1961 to 2006 has concluded that there is no association between increasing CVD death rates and per capita coconut consumption (Figure 3.6).

**Figure 3.6: Trends of coconut and coconut oil consumption and cardiovascular death rates in Sri Lanka 1961-2006**



Source: Athauda et al. Ceylon Medical Journal 2015; 60: 97-99

The authors also concluded that the CVD death rates correlated more with per capita GDP, percentage of urban population and elderly dependency ratio in the multiple linear regression analyses rather than with consumption of coconut and coconut oil, and life expectancy at birth (Table 3.12).

**Table 3.12: Results of regression analysis using CVD death rates (per 100,000 population) as the dependent variable**

Variable	Regression coefficient	95% CI	p value
Per capita coconut consumption	0.33	-0.29, 0.95	0.29
Per capita coconut oil consumption	2.97	-1.92, 7.85	0.23
Per capita GDP	0.04	0.02, 0.06	<0.001
% urban population	-16.13	-23.66, -8.59	<0.001
Elderly Dependency Ratio	-13.51	-23.29, -3.74	0.008
Life expectancy	-0.34	-1.57, 0.9	0.59

Source: Athauda et al. Ceylon Medical Journal 2015; 60: 97-99

- Further, Kurotani et al. (2018) studying about the difference in morbidity and mortality patterns in CVD patients in Sri Lanka and Japan concluded that circulating odd-chain saturated fatty acids; which are commonly seen in dairy products and fish, may have a protective effect against arteriosclerosis among patients in Sri Lanka. However, there are no studies that have assessed the strength of association of CVD with different Sri Lankan diet styles.
- Other than the contribution made by each food domain, the synergistic effect of diet and physical activity (i.e. lifestyle) on the cardio-metabolic risk in urban women has been explored by Waidyathilaka et al. (2014).

In the same sample that identified lifestyle patterns of urban women (refer Table 3.5), the mean factor scores differed significantly between the 272 dysglycaemic women and 345 normoglycaemic women in relation to lifestyle Patterns 2 and 3. Further, it revealed that women who were predominantly physically inactive and consumed snacks and dairy products (Pattern 3) had the greatest cardio-metabolic risk, with a higher likelihood of having unfavourable obesity indices (e.g. increased WC, fat mass % and BMI, and decreased fat-free mass %); glycaemic indices (e.g. HbA1c and FPG); lipid profile (e.g. increased TC/TG and decreased HDL-C); and increased C-reactive protein concentrations.

Studying lifestyle patterns as opposed to individual food domains or physical activity alone provides a greater opportunity to understand the high-risk behaviours within real-life complexities in Sri Lanka. Intervention strategies that reduce physical inactivity and snacking comprise a pragmatic approach to take.

### 3.3.3.5 Hormonal risk for CVD

The cardio-protective effect of oestrogen in pre-menopausal women is shown to be attenuated by increased androgenicity after menopause, contributing to a higher CVD risk. This was evident in a study conducted in a hospital-based NCD screening clinic to compare the pre-menopausal and post-menopausal women in relation to their CVD risk factors (Atapattu et al., 2017), which showed that overweight/obesity, LDL-C, DM and IHD were significantly higher in the pre-menopausal women and TC and dyslipidaemia in post-menopausal women ( $p < 0.05$ ). The study concluded that the first contact care providers have a vital role to play in identifying women at risk at an early age before they reach menopause.

As for assessing the role of testosterone in males, a study was conducted among 31 males aged 45 years and below with CAD (cases) and 31 males without CAD. Total testosterone levels of cases were significantly lower than those of controls (11.1 vs. 27.1 nmol/L) ( $p=0.001$ ), which remained significant after adjustment, highlighting that low level of testosterone may be related to the development of premature CAD (Wickramatilake et al., 2014).

### 3.4 Overall risk prediction for CVD and DM

Early detection of CVD/DM will ensure adequate control of the disease, so that the complications and disability could be delayed as much as possible. In this regard, the biggest challenge the low-resource settings would face is the cost and sophistication of the screening tools. As a pragmatic solution, risk-prediction tools have been developed in Sri Lanka, which are low cost and simple to identify the CVD risk early in the general population.

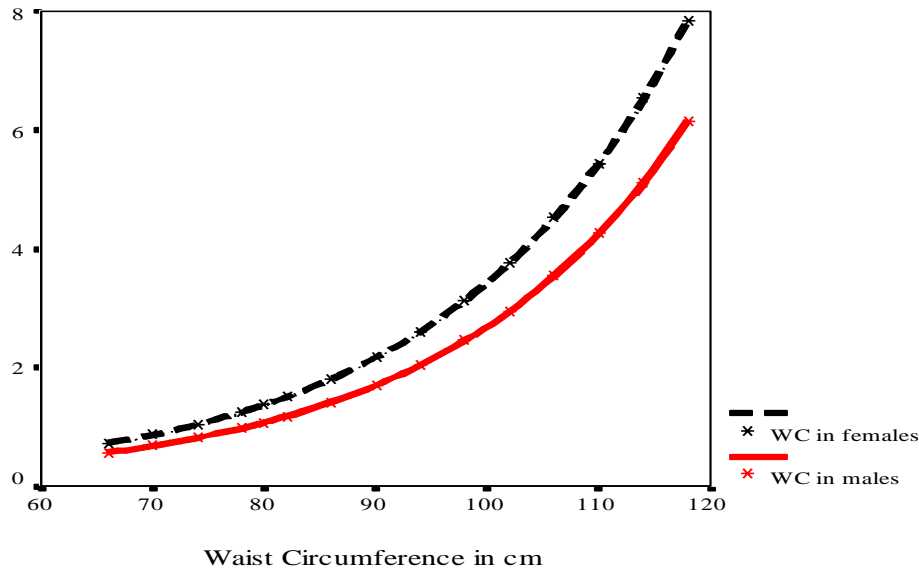
- Mendis et al. (2011), in the Risk Prediction Study using the WHO/International. Society of Hypertension (WHO/ISH) Charts have reported 94.9% of the general population in Sri Lanka to be having <10% risk for CVD mortality and 1.4% to have >30% risk.
- Ranawaka et al. (2016a) quantifying the risk of CVD among 35-64-year old adults in an urban area in Sri Lanka, the 10-year CHD risk, total CVD risk and CVD mortality risk were calculated using three risk prediction tools, namely NCEP-ATP III, SCORE and WHO/ISH Criteria respectively. Of the 10-year CHD risk, 25.4% (95% CI=23.6, 27.2) were categorized as 'high risk'; of the total CVD risk, 8.2% (95% CI=7.3, 9.2) were 'high risk'; and of the CVD mortality risk, 11.8% (95% CI=10.5, 13.1) belonged to 'high risk' category. The study concluded that risk estimates were relatively high in urban communities and varied with the different prediction tools; comparatively higher estimates by NCEP-ATP III charts.
- Herath et al. (2015) carried out cardiac risk assessments in 2432 patients with DM attending a diabetic clinic in Southern Sri Lanka using the two risk assessment tools, WHO/ISH Charts and UK Prospective Diabetes Study (UKPDS) risk engine. WHO/ISH Charts identified 78.4% of subjects as having low cardiac risk, whereas the UKPDS risk engine categorized 52.3% as having low cardiac risk ( $p<0.001$ ), while 1.9% had >30% risk as per WHO/ISH and 2.1% as per UKPDS. However, the agreement between the two tools was found to be poor ( $Kappa=0.144$ ;  $p=0.01$ ) in this population.

- Niriella et al. (2016) (abstract) in an attempt to find out the anthropometric correlates of visceral adiposity and cardio-metabolic risk in an urban community cohort in Sri Lanka found that simple anthropometric measurements such as BMI, WC, waist to height ratio (WHtR) correlated well with visceral fat percentage and equally good enough in predicting cardiovascular risk factors.
- Arambepola et al. (2008b) attempted to predict the risk of having  $\geq 1$  obesity-related-CHD risk factors (BP, DM, high TC, TG or LDL-C, low HDL-C) using anthropometry (WC and BMI) in a sub-sample of 515 adults obtained from the epidemiological study in Colombo District. The WC correlated better with most of the parameters, compared to BMI in both males and females ( $p < 0.001$ ). Further, in the regression models, WC was proven to be a significant predictor of the risk of an individual having at least one obesity-related-CHD risk in both males and females, whereas BMI was significant only in males, demonstrating gender differentials in the role of anthropometry in CHD risk.

Application of WC is a simple and valid tool to predict the obesity-related CHD risk in apparently health both males and females, and therefore to be incorporated into routine clinic practice along with BMI.

The study further showed that the risk of having  $\geq 1$  obesity-related-CHD risk factors at a WC of 80, 90 and 94 cm in males was 1.07, 1.7 and 2.04-fold, compared to one with no such risk. The corresponding risk in females was 1.37, 2.17 and 2.6-fold, respectively (Figure 3.7). This highlights that the current anthropometric cut-offs denoting the cardiovascular risk may not be accurate for Sri Lankan populations as they are derived from Caucasian based populations.

**Figure 3.7: Relationship of WC with odds ratios for the presence of  $\geq 1$  obesity-related-CHD risk factors in males and females**



Note: Exponential curve fitted to odds ratio (OR) of WC for males and females; the risk of having  $\geq 1$  obesity-related-CHD risk factors corresponding to different values of WC were derived by calculating OR with BMI at the 25<sup>th</sup> percentile in the sample taken as the reference point.

Source: Arambepola et al. Prevention and Control 2008; 3: 11-19

The optimal cut-off values of WC as a screening tool in identifying obesity-related-CHD risk, were identified as 88.5 cm in males and 82 cm in females, while that of BMI in males was 23  $\text{kgm}^{-2}$ . These cut-offs were derived using ROC curves to obtain the optimal combined sensitivity and specificity. The study concluded that WC with its sex-specific cut-off values can serve as a better screening tool than BMI in identifying individuals at risk of obesity-related CHD in low-resource settings.

- Katulanda et al. (2011c) also attempted deriving anthropometric cut-off levels for BMI, WC & WHR to identify high CVD risk for Sri Lankan adults. The risk factors considered were an improvement from those considered by Arambepola et al., 2007 (triglycerol and oral glucose tolerance test (OGTT) testing included). Accordingly, the cut-off values of BMI, WC & WHR for males were 20.7  $\text{kgm}^{-2}$ , 76.5 cm and 0.89 respectively. The same for females were 22.0  $\text{kgm}^{-2}$ , 76.3 cm and 0.87.
- A few other parameters have also been assessed subsequently and have been proven on its predictive value, such as the distance between lower edge of the xiphisternum and the center of the umbilicus as an indicator of CVD risk (Katulanda et al., 2010d); and WHtR as

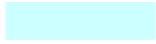
a simple and effective anthropometric index to identify obesity-associated metabolic risks among Sri Lankan adults (Jayawardena et al., 2013c).

- In addition, using the SLDC Study sample, several parameters have been tested for their accuracy in determining obesity, such as proposing BMI of  $20.5 \text{ kgm}^{-2}$  (sensitivity 0.80%, specificity 0.80%), WC of 77 cm (sensitivity 0.75%, specificity 0.82%) and WHR of 0.88 (sensitivity 0.58%, specificity 0.59%) as the cut-off values for predicting obesity (defined by 25% of adiposity measured using isotope dilution technique based 2C body composition model) in Sri Lankan adults (Jayawardena et al., 2013d) (abstract).

“You need to be skillful in identifying and increasing awareness about the presence of evidence based and cost-effective interventions that could save millions of lives and be implemented in low resource countries.”

PROFESSOR RIFAT ATUN

Professor of Global Health Systems, Harvard University





# CHAPTER FOUR

## Interventions of CVD and DM

Having undergone an epidemiological and demographic transition, Sri Lanka is now faced with the challenge of managing an immense caseload of major NCDs, that the health care system is not fully geared to deal with. This chapter is on evidence of the health system response in Sri Lanka for controlling CVD and DM.

There are many management options available for DM and CVD, which occur at three levels of prevention, namely primary (in apparently healthy people), secondary (in diseased populations) and tertiary (in those with disability and complications). This chapter presents evidence available on the interventions at all three levels of prevention (Sections 4.1, 4.2 and 4.3), their effectiveness in terms of disease outcomes and the response of the health system, recipients and health care providers in Sri Lanka.



## 4.1 Primary prevention of CVD and DM

It is imperative that population-wide primary preventive strategies are adopted urgently, which are effective, simple and essential, especially in populations at risk for developing CVD and DM. These strategies broadly comprise screening for CVD & DM risk factors, lifestyle modifications and health education for improving knowledge, attitudes and preventive practices in apparently healthy people.

### 4.1.1 Sources of information

The sources of information included are both descriptive studies and trials which have been carried out on interventions that prevent CVD and DM among apparently healthy populations. Secondary data obtained on programs carried out at national level for the prevention of NCDs were also included. Owing to poor generalizability, evidence based on single centres (one MOH setting or hospital) and done in small samples (<100) selected using non-probability sampling were not considered for this review.

### 4.1.2 Screening for early detection of CVD risk factors

Screening for early detection of CVD risk factors has been identified as one of the key strategies under primary prevention.

- A structured NCD screening program has been introduced since 2011 by the NCD Unit, Ministry of Health, by initiating healthy lifestyle centres (HLCs) at primary health care settings. Healthy lifestyle centres have been established through the lowest level of primary health-care institutions, which are the MOHs. The main service objective of HLCs is to reduce the CVD risk of adults aged 40–65 years, through early detection of CVD risk factors and facilitation of access to specialized care. After screening, those detected with more than 30% of 10-year CVD risk are referred to specialized medical clinics, while others are followed-up with lifestyle modifications and re-screening, based on their level of CVD risk and presence of risk factors.
- The HLCs were established after obtaining evidence from three pilot projects, namely the WHO Package of Essential NCD Prevention Interventions for primary health care in low-resource settings (WHO-PEN); the NCD Prevention Project (NPP) under the Japan International Cooperation Agency (JICA) (NPP-JICA); and the community-based health promotion component of the National Initiative to Reinforce and Organize General

Diabetes Care in Sri Lanka (NIROGI Lanka) of the Sri Lanka Medical Association (Mallawaarachchi et al., 2016a).

- The key features of the three pilot projects are compared in Table 4.1.

**Table 4.1: Key features of pilot projects on screening and managing NCDs through primary healthcare conducted in Sri Lanka in the healthy lifestyle centre model**

Pilot model	WHO-PEN <sup>6</sup>	NPP-JICA <sup>8</sup>	NIROGI LANKA - Sri Lanka Medical Association <sup>9</sup>
Duration	2009-2011	2008-2013	2009-2015
Location of pilot	1 district	2 districts	1 district
No. of facilities	3 MOH areas	3 MOH areas	1 MOH area
Key features relevant to development of the HLC model	WHO/ISH chart for CVD risk prediction <sup>10</sup> Guideline for management of NCDs in primary health care, developed by the Ministry of Health, based on a total-risk approach, is being used to manage persons screened at HLCs <sup>11</sup> List of essential medicines proposed is being adapted and made available at primary health-care institutions to manage the screened persons being referred	Health check-up model used to recruit clients for the HLCs Health Guidance model is being used in managing the persons screened at HLCs Information system (registrant and returnees) is being used to document services provided at HLCs Health-education material developed in the social marketing model is being used in health-promotional education at HLCs	Approaches used to address the risk behaviour of communities and families

Source: Mallawaarachchi et al. WHO South-East Asia Journal of Public Health 2016; 5(2): 89-95

The key interventions of NPP Project include developing intervention guidelines for health check-ups, guidance and promotion, and intervention tools and activities pilot tested in Kurunegala and Polonnaruwa, representing a mixed population predominantly of rural origin. The WHO PEN Project includes an action-oriented set of cost-effective tools and resources developed to enable early detection and management of major NCDs, including CVD and DM; and prevent life threatening complications, which have been pilot tested

specifically in low resource settings. Interventions in The NIROGI Lanka project include establishing a low cost and locally relevant health promotional model to empower at-risk populations for CVD and DM, which was pilot tested in both urban and suburban populations in Colombo District.

The screening program to detect NCD risk factors, which is initiated in healthy lifestyle centres is based on local evidence of three pilot projects conducted in urban and rural settings in Sri Lanka.

- Since its inception, services at HLCs have improved, but face major challenges in terms of under-utilization.

The proportions of screened population with risk factors are given in Table 4.2 from 2013-2015 (Mallawaarachchi et al., 2016a). Overweight followed by raised BP had been the most commonly detected CVD risk factors. Yet, the proportions of CVD risk factors do not appear to have increased with time.

**Table 4.2: Number and proportions of targeted population screened in Sri Lanka with behavioural or intermediate risk factors, 2013-2015**

Risk factor	No. (%) of screened population with risk factor		
	2013 <sup>a</sup>	2014 <sup>b</sup>	2015 <sup>c</sup>
FBS >126 mg/dl	37 980 (11.58)	48 853 (12.75)	41 372 (10.57)
SBP ≥140 and/or DBP ≥90 mmHg	69 400 (21.16)	91 805 (23.96)	89 862 (22.97)
Overweight (BMI ≥25 kgm <sup>-2</sup> )	90 686 (27.65)	100 618 (26.26)	99 873 (25.53)
Obese (BMI ≥30 kgm <sup>-2</sup> )	29 255 (8.92)	29 043 (7.58)	32 300 (8.28)
Current tobacco smoker	18 170 (5.54)	25 557 (6.67)	26 826 (6.86)
Current drinker	40 604 (12.38)	28 775 (7.51)	29 836 (7.63)
Smokeless tobacco user	21 089 (6.43)	53 604 (13.99)	53 651 (13.71)
With 10-year CVD risk ≥30%	1 836 (0.56)	1 724 (0.45)	2 268 (0.58)

BMI: body mass index; CVD: cardiovascular disease

<sup>a</sup>88 554 men screened; 239 425 women screened; total population screened: 327 979.

<sup>b</sup>110 469 men screened; 272 692 women screened; total population screened: 383 161.

<sup>c</sup>108 399 men screened; 282 861 women screened; total population screened: 391 260 (weighted data).

Source: Mallawaarachchi et al. WHO South-East Asia Journal of Public Health 2016a; 5(2): 89-95

- Many challenges have been identified to persist in HLCs (Mallawaarachchi et al., 2016a). As shown in Table 4.3, despite the percentage of MOH areas having  $\geq 2$  HLCs has been increased over the years, the cumulative % of the target population being screened has not increased in parallel.

**Table 4.3: Number and services of HLCs in Sri Lanka, 2011-2016**

	2011	2012	2013	2014	2015	2016 (1 <sup>st</sup> quarter)
Total no. of HLCs	126	420	672	760	814	826
% of MOH areas in a district with two or more healthy lifestyle centres <sup>a</sup>	–	–	56.0	69.5	77.8	79.6
Cumulative % of the target population (aged 40-65 years) screened <sup>b</sup>	2.5	3.8	12.7	19.9	23.1	25.5
Ratio of men: women screened <sup>a</sup>	–	–	2.6:7.3	2.9:7.1	2.8:7.2	2.9:7.1

HLC=Healthy Lifestyle Centre; MOH=medical officer of health

<sup>a</sup> Data not available for 2011 and 2012

<sup>b</sup> Target population is nearly 25% of the country population

Source: Mallawaarachchi et al. WHO South-East Asia Journal of Public Health 2016; 5(2): 89-95

Mallawaarachchi et al. (2016a) has identified several drawbacks in running the HLCs, such as under-utilization of the services provided especially by men; weak staff adherence to protocols; lack of integration into pre-existing NCD-screening services; non-inclusion of screening for all the major NCDs; and human resources. The government plans to address this under-utilization of screening services, within the context of the National Multisectoral Action Plan for the Prevention and Control of NCDs in Sri Lanka 2016–2020. Key interventions include extended opening hours for HLCs as well as outreach activities in workplaces and integration with well woman clinics. Costs related to actions have been realistically estimated. Some actions have already been initiated, while others are being designed with identified funds.

- In addressing the drawbacks identified in HLCs, there is evidence on locally relevant pragmatic interventions implemented as pilot projects.

Over a period of six months, a wellmen clinic (WMC) service was pilot-tested in 2006 in Arachchikattuwa MOH area with the support of public health staff, as an entry point to screen for NCD and risk factors among men aged 35 years or above (De Silva et al., 2008a). The services provided were health education, medical examination and appropriate

referral. There were 14 clinic sessions in five PHI areas and 301 attendees during the study period. The average time per clinic session was about 4 hours with 20-25 attendees per session. 34% of them were referred to the curative sector. During the same period, attendance to the well woman clinics was much less.

In 2009, the NIROGI Lanka project (Wijeyaratne et al., 2016; Sagner et al., 2016) provided evidence on successful capacity building and establishment of a new cadre 'DM Educator Nursing Officers' (DENOs) of nurses in diabetic clinics and primary health care settings in the state as well as private sector, with the aim of improving the knowledge, skills and attitudes in the control and prevention of DM of hospital attendees. This is the first-ever training of nurses for this purpose in Sri Lankan hospitals.

In 2012, the project provided evidence through its 'NIROGI Maatha' component on gestational DM on the capacity building of field-based public health nursing sisters and midwives to initiate national-level universal screening for DM in pregnancy and to support pregnant women with DM and their families to adopt healthy lifestyles. This component also attempted in developing a population-specific cut-off value for detecting gestational DM in pregnant women (Hemachandra & Wijeyaratne, 2014).

Though effective in identifying the at-risk population for CVD, HLCs face challenges, some of which are addressed based on evidence on novel approaches, such as introducing DENOs in hospitals and universal screening for gestational DM at MOH level.

#### **4.1.3 Lifestyle modification in the prevention of CVD and DM**

The 'best buy model' in primary prevention is to implement the most cost-effective interventions, which however thus by far appears to be complex requiring multiple health and non-health sectors at various levels of governance to collaborate to implement a model as cohesive as possible. Further, the applicability of 'best buys' proven elsewhere needs to be strengthened by local evidence, as it could pose many challenges and threats to the cost effectiveness of the interventions in local settings. Therefore, it is crucial that these 'best buys' are assessed for their effectiveness.

- In the context of Sri Lanka, the most feasible approaches have been identified for promoting healthy diet by Somasundaram & Kalupahana (2016), such as restrictions on advertisement of unhealthy food, taxation of unhealthy foods, subsidies for production of healthy foods and laws on nutrition labelling that introduces colour-coding of packaged

foods. A summary of evidence-based population approaches to promote healthy diets is given (Table 4.4).

**Table 4.4: Population-based approaches to promoting healthy diets**

Area	Population approach
Media and education	<ul style="list-style-type: none"> <li>• Media and educational campaigns to increase consumption of healthy foods or to reduce consumption of unhealthy foods or beverages</li> </ul>
Labelling and information	<ul style="list-style-type: none"> <li>• Mandated nutrition facts panels or front-of-pack labels/icons, as a means to influence industry behaviour and product formulations</li> </ul>
Economic incentives	<ul style="list-style-type: none"> <li>• Subsidy strategies to lower the prices of healthy foods and beverages</li> <li>• Tax strategies to increase the prices of unhealthy foods and beverages</li> <li>• Changes in agricultural subsidies to facilitate production, transportation and marketing of healthier foods</li> </ul>
Schools	<ul style="list-style-type: none"> <li>• Specialized educational curricula, trained teachers, supportive school policies, healthy food and beverage options</li> <li>• School garden programs</li> <li>• Fresh fruit and vegetable programs that provide free/ affordable fruits and vegetables to students</li> </ul>
Workplaces	<ul style="list-style-type: none"> <li>• Comprehensive worksite wellness programs</li> <li>• Increased availability of healthier food/beverage options</li> </ul>
Restrictions and mandates	<ul style="list-style-type: none"> <li>• Restrictions on television advertisements for unhealthy foods or beverages advertised to children</li> <li>• Restrictions on advertising and marketing of unhealthy foods or beverages near schools and public frequented by youth</li> <li>• General nutrition standards for foods and beverages marketed and advertised to children</li> <li>• Regulatory policies to reduce specific nutrients in foods (e.g. trans fats, salt, sugar)</li> </ul>

*Source:* Somasundaram & Kalupahana. WHO South-East Asia Journal of Public Health 2016; 5(1): 22-26

In Sri Lanka, mass media especially the electronic media plays an influential role on shaping the attitudes and response of the public to the current issues faced in relation to major NCDs; and mobilizing the public towards non-risky behaviour. In this context, media campaigns for promoting healthy lifestyles, including their compliance shown to

restrictions imposed on advertisements of unhealthy food, would be of paramount importance.

Somasundaram & Kalupahana (2016) propose that restrictions be applied not just for food containing calorie sweeteners but for all food items that are calorie dense. Although not popular, taxation of food rich in high fat, salt and sugar (HFSS) has shown to be effective in decreasing the consumption of unhealthy food in other countries. Sugar taxation has been recently introduced to Sri Lanka, but no research evidence is available on its effectiveness in the Sri Lankan context.

Prathapan et al. (2016) (abstract) recommends that the Ministry of Health should follow-up all food and beverage-focused advertisements for policy formulation and implementation. This was based on a study comparing the strategies used in television advertisements for promotion of food and beverages targeting children and adults, for which nearly 50% of the 16 analog television channels available in Sri Lanka were selected randomly, stratified by language; and 95 food & beverage advertisements recorded during the weekdays and weekends were analyzed on their contents. 78% of these advertisements were child-focused, of which 74% had claimed health benefits. A significant difference was noted in terms of the implications related to nutrition or health ( $p < 0.05$ ). None of the advertisements contained disclaimers.



- A summary of the evidence-based population approaches to improve physical activity is also given in Table 4.5.

**Table 4.5: Population-based approaches to promoting physical activity**

Area	Population approach
Labelling and information	<ul style="list-style-type: none"> <li>• Point of decision prompts to encourage use of stairs</li> </ul>
Schools	<ul style="list-style-type: none"> <li>• Increased availability and types of school playground spaces and equipment</li> <li>• Increased number of physical education (PE) classes and trained PE teachers at schools</li> <li>• Regular classroom physical activity breaks during academic lessons</li> </ul>
Workplaces	<ul style="list-style-type: none"> <li>• Worksite wellness programs</li> <li>• Structured worksite programs that encourage activity and also provide a set time for physical activity during work hours</li> <li>• Adding new or updating worksite fitness centres</li> </ul>
Local environment	<ul style="list-style-type: none"> <li>• Improved accessibility of recreation and exercise spaces and facilities (e.g. building of parks and playgrounds, increasing operating hours, use of school facilities during non-school hours)</li> <li>• Improved land-use design</li> <li>• Improved pavement and street design to increase active commuting (walking and cycling) to school by children</li> <li>• Improved traffic safety</li> <li>• Improved neighbourhood aesthetics (to increase activity in adults)</li> <li>• Improved walkability</li> </ul>

Source: Somasundaram & Kalupahana. WHO South-East Asia Journal of Public Health 2016; 5(1): 22-26

#### 4.1.3.1 Health promotional models to prevent CVD and DM

There have been several health promotional models, which had been assessed on their effectiveness in reducing the burden in populations highly vulnerable to CVD and DM.

- One such pilot intervention is NIROGI Diviya. Since 2009, 'NIROGI Diviya'- a component of the NIROGI Lanka Project has been carrying out action-oriented health promotional programs to empower vulnerable populations in schools, communities and workplaces (Samarasinghe et al., 2013; Wijeyaratne et al., 2016; Sagner et al., 2016). The number of health promotional groups formed, and the activities undertaken are shown in Tables 4.6 and 4.7.

**Table 4.6: Numbers of health promotional groups initiated during 2009-2015**

Health-promotion groups by type	2009	2010	2011	2012	2013	2014	2015
Schools in highly urban settings	–	–	–	–	8	5	5
Workplaces in highly urban settings	–	–	–	–	5	5	4
Schools in semi-urban settings	8	10	9	7	6	6	6
Workplaces in semi-urban settings	6	7	11	16	14	13	13
Community settings in both highly urban and semi-urban settings	17	37	46	62	54	35	35
Total	31	54	66	85	87	64	63

**Table 4.7: Health promotional activities in cumulative numbers for project indicators**

Activity (2012-2015)	Targeted population	Cumulative no.
Provided training in primary prevention	Teachers	413
	Primary and secondary school children	2135
	Parents (via schools)	85
Providing training of trainers	Health promotion facilities	195
	Employees in work settings	1810
	Schoolchildren (as “health messengers”)	205
	Community group participants	1052
Sensitized and diabetes control and prevention	Schoolchildren and their families	3948
	Members of the general public	9398

Source: Wijeyaratne et al. WHO South-East Asia Journal of Public Health 2016; 5(1): 34-39

The project had several unique features. It provides evidence on the effectiveness of initiating HP through already existing networks of people (e.g. workplaces, community organizations and schools); feasibility of training non-health volunteer personnel as ‘health promotional facilitators’ to take the lead in each setting; their ability to transfer leadership and skills to others in the group; empowering populations by initiating the HP process in each setting, than focus on its outcomes; and successful introduction of a new cadre called ‘HP Officers’ who are graduates in HP, Rajarata University for coordinating the HP activities at field level. The project provides strong evidence on its expansion of settings through ripple effect; physical activity as the most effective interventions followed by dietary changes, which were varied (Samarasinghe et al., 2013; Wijeyaratne et al., 2016; Sagner et al., 2016).

- Community-oriented primary care is another health promotional model involving the primary health care delivery system in the Nallur MOH area. Though done in a relatively small area, it provides evidence on the feasibility of a model that engages in lifestyle modification, screening for risk factors among healthy populations and community-based education while providing palliative care and rehabilitation services (Kumaran et al., 2016) (abstract).

#### **4.1.3.2 Workplace-based interventions to prevent CVD and DM**

Programs targeting workplaces are pragmatic as a strategy to reduce NCDs in Sri Lanka. These programs aim to transform a workplace into a health promotional setting, where lifestyle changes in workers lead to a modification of risk factors for NCDs.

- A health promotion program was conducted in a divisional administrative office in a semi-urban office in Southern Sri Lanka. An office-based health promotion committee was established, and an action plan was prepared with participation of the workers. Prior to the intervention, workers were screened for BMI, BP, FPG and TC. Information gathered during assessments were used for individual counseling of at-risk people. The WHO Risk Assessment Model was used to plan referrals and follow up to HLCs. Behavioural change and communication (BCC) programs were conducted to improve physical activity and dietary modifications (Chandrasiri et al., 2016). The program resulted in identifying new patients with NCDs (Table 4.8).

**Table 4.8: Distribution of the newly diagnosed disease conditions by characteristics of the participants**

Characteristic	FBS $\geq$ 121 mg/dl		BP $\geq$ 140/90 mmHg		Cholesterol $\geq$ 241 mg/dl)	
	High	Normal	High	Normal	High	Normal
<b>Age</b>						
<40 years	1 (2.4%)	40 (97.6%)	2 (4.9%)	39 (95.1%)	5 (12.2%)	36 (87.8%)
$\geq$ 40 years	4 (10%)	36 (90%)	6 (15%)	34 (85%)	5 (12.5%)	35 (87.5%)
		p=0.34		p=0.24		p=0.76
<b>Sex</b>						
Male	3 (9.4%)	29 (91.6%)	4 (4.9%)	28 (95.1%)	4 (4.9%)	28 (95.1%)
Female	2 (4.1%)	47 (95.9%)	4 (8.1%)	45 (91.9%)	6 (7.4%)	43 (92.6%)
		p=0.62		p=0.79		p=0.75
<b>Job category</b>						
Administrative	0 (0.0%)	6 (100%)	1 (16.7%)	5 (83.3%)	0 (0.0%)	6 (100%)
Clerical	4 (9.1%)	40 (90.1%)	4 (9.1%)	40 (90.1%)	7 (15.9%)	37 (84.1%)
Field	1 (4.2%)	23 (95.8%)	2 (8.3%)	22 (91.7%)	2 (8.3%)	22 (91.7%)
Minor	0 (0.0%)	7 (100%)	1 (14.3%)	6 (85.7%)	1 (14.3%)	6 (85.7%)
		p=0.69		p=0.73		p=0.82
<b>BMI value</b>						
<24.9 kgm <sup>-2</sup>	3 (4.8%)	59 (95.2%)	5 (8.1%)	57 (91.9%)	7 (11.3%)	55 (88.7%)
$\geq$ 25 kgm <sup>-2</sup>	2 (10.5%)	17 (89.5%)	3 (15.8%)	16 (84.2%)	3 (15.8%)	16 (84.2%)
		p=0.72		p=0.58		p=0.90

Source: Chandrasiri et al. Work 2016; 55(2): 281-284

The study further identified that the intervention dropped the smoking rate by 75% and physical inactivity by 14%. On the other hand, consumption of fresh fruits and vegetables was increased by 19%. It should however be noted that the true benefit of risk factor modification through BCC programs will only become apparent in longitudinal assessments. Nevertheless, the study recommended the programs targeting workplaces with workers as owners be promoted as a new strategy for reducing NCDs in Sri Lanka (Chandrasiri et al., 2016).

#### 4.1.3.3 School-based interventions to prevent CVD and DM

Lifestyle interventions through health promotion approach can also be used to improve nutritional practices in schools.

- An interventional study was carried out among 72 teachers attached to Type 1C schools in Colombo District. A lifestyle intervention was delivered throughout six months, targeting healthy eating and physical activities with continuous follow-ups. Healthy nutritional practices were discussed through role play models. The mean BMI, which was 24.0 kgm<sup>-2</sup> before the intervention was reduced to 23.7 kgm<sup>-2</sup> by end of six months. The corresponding drop in weight was from 60.74 kg (SD=8.5) to 60 kg (SD=7.97) (p=0.001).

Promoting healthy lifestyle among teachers would be useful in turn, to promote healthy practices among schoolchildren. Although this study assessed the effectiveness by pre and post intervention levels, it was not purely interventional as in a randomized control type. However, the findings are effective in stimulating further programs targeted towards healthy populations (Senavirathne et al., 2014a) (abstract).

#### 4.1.3.4 Community-based interventions to prevent CVD and DM

Community-based interventions are expected to be the most effective in prevention, as these cover a larger target population.

- A randomized controlled trial has been conducted by the National Diabetes Centre, Rajagiriya (Wijesuriya et al., 2014 (abstract); Wijesuriya et al., 2017) to evaluate the effectiveness of an intensive lifestyle modification program to reduce the incidence of primary cardiometabolic composite endpoints among relatively young persons. A total of 4606 participants aged 5-40 years who were at risk of DM (having two or more risk factors, namely raised BMI and WC, first degree family history of DM and physical inactivity) were randomized into, either tri-monthly intensive (pragmatic) or 12-monthly less-intensive (control) lifestyle modification programs, using cluster randomization method. Both groups received individualized peer educator advice aimed at reducing weight, improving diet, reducing psychological stress and increasing physical activity over four years. Results obtained are given in Table 4.9.

**Tale 4.9: Effect of pragmatic lifestyle modification as compared to control lifestyle modification on the incidence of cardio-metabolic endpoints in 3539 healthy participants**

Component of primary composite endpoint	Pragmatic lifestyle modification n=1726	Control lifestyle modification n=1813	Incident rate ratio (95% CI)	p value
Composite	479	561	0.89 (0.83, 0.96)	0.002
New onset diabetes	58	72	0.8 (0.65, 1.02)	0.08
New onset IGT	143	168	0.89 (0.79, 1.01)	0.08
New onset IFG	146	166	0.93 (0.82, 1.06)	0.27
New onset dysglycaemia <sup>a</sup>	347	406	0.9 (0.83, 0.97)	0.01
Hypertension	115	152	0.79 (0.68, 0.9)	0.01
Statin therapy	41	46	0.92 (0.72, 1.18)	0.5
Renal disease events	2	8	0.26 (0.1, 0.63)	0.003
Cardiovascular events	1	0		N/A
Deaths	2	0		N/A

<sup>a</sup> composite of DM=IFG and IGT; DM=diabetes mellitus, IGT=impaired glucose tolerance; IFG=impaired fasting glycaemia' N/A=not applicable

Source: Wijesuriya et al. BMC Medicine 2017; 15: 146

This study concluded that the intensive (tri-monthly) lifestyle modification program would significantly reduce the incidence of predictors of cardio-metabolic diseases in high risk populations. This highlights the importance of early intervention in those at risk in South Asia.

In further analysis, Poisson regression resulted in a significant relative risk reduction (RRR) of 26% for new DM (95% CI=2, 44) ( $p=0.04$ ) and 18% for IGT (95% CI=7, 28) ( $p=0.002$ ). The RRR for cumulative incidence of the primary end point after 4 years was 9% (95% CI=1.0, 16), which was independent of the baseline age and gender ( $p=0.02$ ). Although 59% regressed from IFG to normoglycaemia in the intervention group, this difference was not significant compared to 49% in the control group ( $p=0.16$ ). The corresponding values for regression of IGT to normoglycaemia were 52.4% and 52% ( $p=0.9$ ). Nevertheless, regression of both IGT and IFG together of approximately 50% to normoglycaemia provides evidence on the effectiveness of the intervention, thus the study concluded that intensive lifestyle modification significantly reduces the development of DM, IGT and primary composite cardio-metabolic end point.

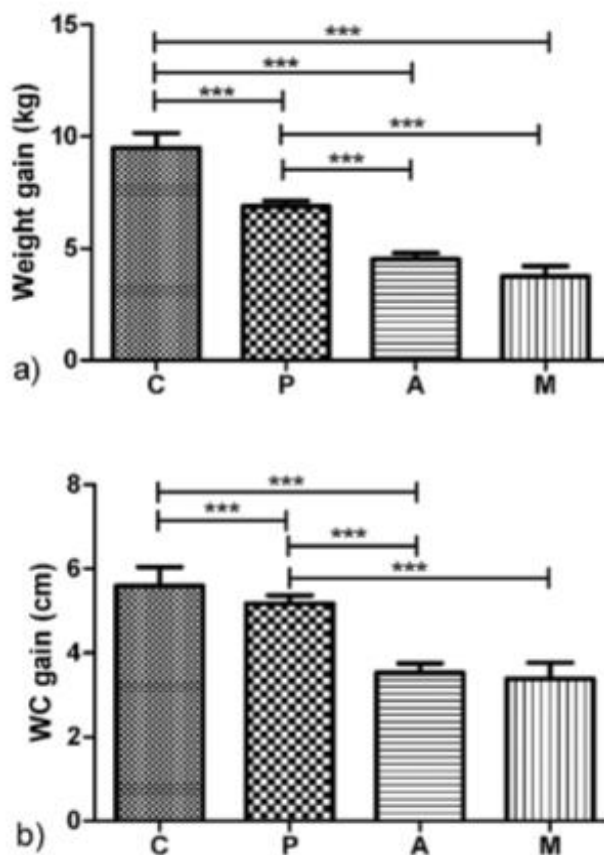
Locally relevant, culturally appropriate, and low-cost health promotional models have been tested in communities, schools and workplaces, which provide mixed results.

#### 4.1.3.5 Trials on specific lifestyle changes related to CVD and DM

A few trials have been carried out targeting outcomes following specific lifestyle modifications in the prevention of CVD and DM.

- The same trial conducted by the National Diabetes Centre, Rajagiriya (refer Section 4.1.3.4), examined progression through the stages of change and how readiness to change relates to healthful dietary changes in an intensive lifestyle modification group (visits every 3 months) and less intensive control group (visits annually) of 5-40 year old persons at high risk for metabolic syndrome (Guess, et. al., 2016). Principles of the lifestyle change program, which included changes in diet and physical activity, were based upon the Indian DM Prevention Program. The mean differences in weight and WC are given in Figure 4.1.

**Figure 4.1: Mean changes in weight and waist circumference from baseline to year 4 by stage of change in the entire cohort**



Note: p values were adjusted for multiple comparisons and reflect differences between stage of change. C=contemplation; P=preparation; A=action; M=maintenance. The study took place from 2007 to 2012 in Colombo, Sri Lanka. \* $p \leq 0.05$ ; \*\* $p \leq 0.01$ ; \*\*\* $p \leq 0.001$ .

Source: Guess et al. Preventive Medicine 2016; 90: 193-200

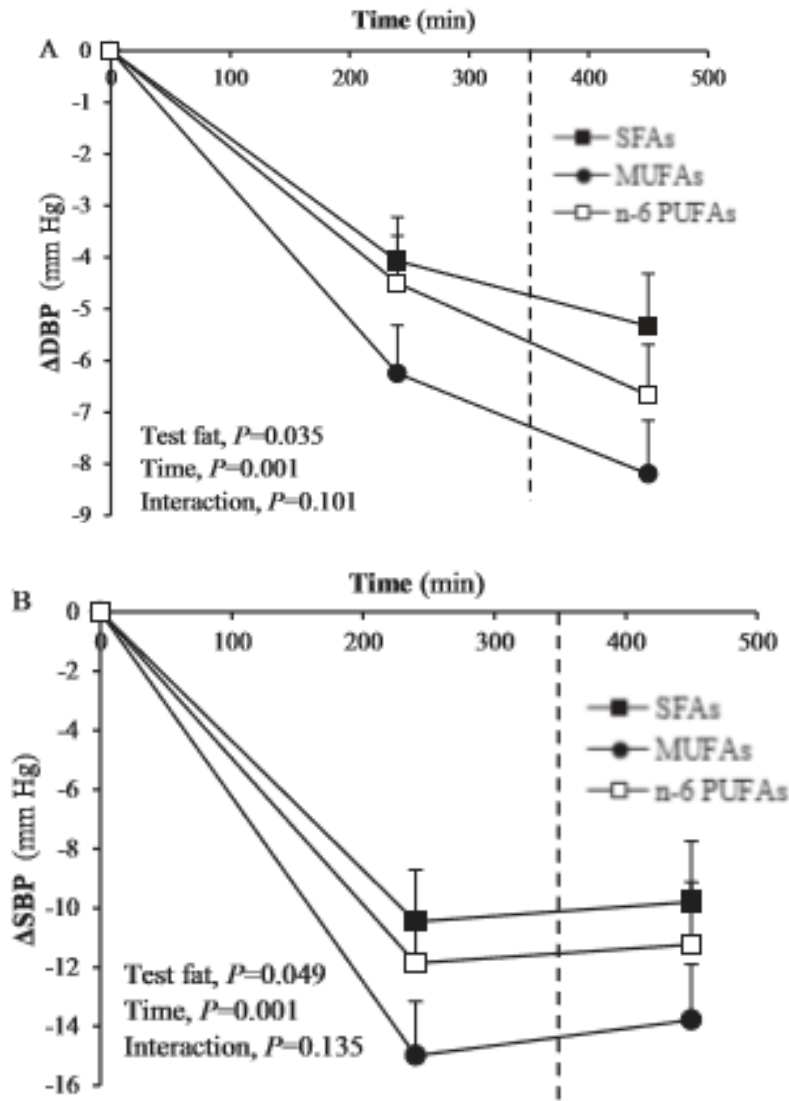
The study demonstrated that individuals in both groups continued to progress through stages of change over the study period, and that measures of dietary behaviour improved from baseline to final follow-up. They also demonstrated that the stage of change positively correlates with dietary behaviour including the ratio of recommended: not recommended items, unpolished: polished starches and low fat: high fat food items throughout each year of the study. Finally, participants in the later stages of change at year 2, year 3 and year 4, had a significantly attenuated increase in weight and WC at the final visit in both groups. Thus, the usefulness of stage-matched approach in modifying complex dietary behaviour was well- demonstrated, including stage of change as a valid measure of dietary behaviour over time.

- A double-blind randomized cross-over trial was conducted in 32 postmenopausal women to investigate the impact of sequential meals rich in saturated fatty acids (SFA), mono-unsaturated fatty acids (MUFA) and n-6 poly-unsaturated fatty acids (n-6 PUFA) on the postprandial flow-mediated dilatation (FMD) (primary outcome measure) and on vascular function and CVD risk biomarkers (secondary outcome measures) (Rathnayake et al., 2018).

Results showed that the postprandial FMD, laser Doppler imaging and digital volume pulse responses were not different after consuming the test fats. The incremental area under the curve (iAUC) for DBP was lower after the MUFA-rich meal than after the SFA-rich meal (mean=-2.3; SD=0.3 compared to mean=-1.5; SD=0.3 mmHg × 450 min × 103) (p=0.009). A similar trend was noted for SBP (p=0.012). This corresponded to a lower iAUC for plasma nitrite response after the SFA-rich meal than after the MUFA-rich meal (mean=-1.23; SD=0.7 compared to mean=-0.17; SD=0.4 µmol/L × 420 min) (p=0.01). The soluble inter-cellular adhesion molecule 1 (sICAM-1) time-course profile, AUC and iAUC were lower after the n-6 PUFA-rich meal than after the SFA- and MUFA-rich meals (p<0.001). Lipids, glucose and markers of insulin sensitivity did not differ between the test fats. The results showed therefore a differential impact of meal fat composition on BP, plasma nitrite, and sICAM-1, but no effect on lipaemia in postmenopausal women. Hence, the study concluded that MUFA-rich meals had favourable effects on postprandial DBP as well as for maintaining a higher plasma nitrite response than sequential SFA-rich meals. Some of these findings are presented in Figures 4.2 and 4.3.



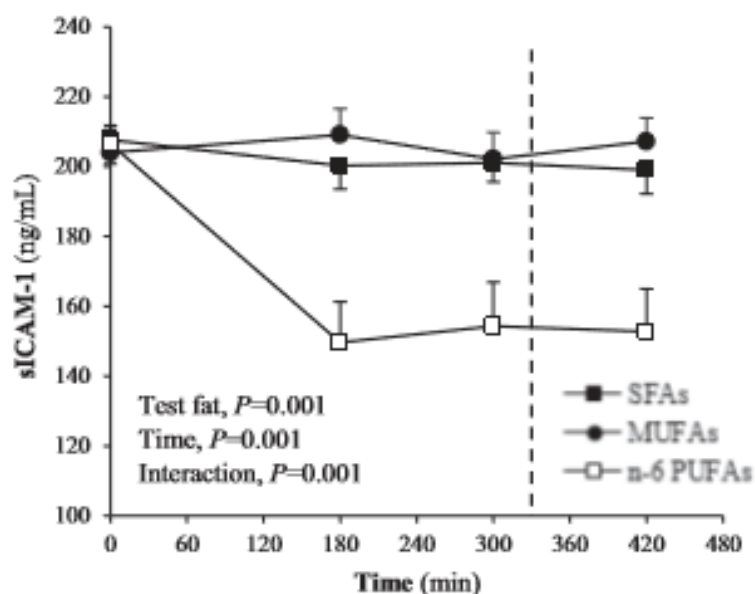
**Figure 4.2: Incremental DBP (A) and SBP (B) responses after sequential meals (0 min and 330 min) enriched in SFAs, MUFAs and n-6 PUFAs in postmenopausal women**



Note: Values are means + SEM (n=32). The timing of the second meal (330 minutes) is denoted by dashed lines. Differences in the incremental responses between test fats were analyzed by repeated measures ANOVA. DBP=diastolic blood pressure; SBP=systolic blood pressure;  $\Delta$ =change from 0 min

Source: Rathnayake et al. Nutrition Research Review 2018; 31(2): 193-203

**Figure 4.3: Postprandial plasma sICAM-1 in postmenopausal women after sequential meals (0 min and 330 min) enriched in SFAs, MUFAs and n-6 PUFAs**



*Note:* Values are means  $\pm$  SEM (n=27). The timing of the second meal (330 minutes) is denoted by dashed lines. The plasma sICAM-1 responses after the test fats were analyzed by 2-factor repeated-measures ANOVA. sICAM-1=soluble intercellular adhesion molecule 1

*Source:* Rathnayake et al. Nutrition Research Review 2018; 31(2): 193-203

- In a systematic review on Zinc (Zn) supplementation on DM, Jayawardene et al. (2012c) (abstract) showed that it has beneficial effects on the glycaemic control and promotion of healthy lipid parameters. Another systematic review carried out by Ranasinghe et al. (2015c) showed that Zn supplementation significantly reduces TC, LDL-C and TG.

Following these reviews, Ranasinghe et al. (2018a) carried out a randomized double-blind placebo-controlled Phase II trial among 200 subjects with pre-DM to evaluate the effect of Zn supplementation on glycaemic control and other cardio metabolic/anthropometric parameters and progression of disease. The treatment group received Zn (20 mg daily). Evaluations were done at baseline, 1, 3, 6 and 12 months. Primary outcome was defined as change in the glycaemic control from baseline.

During the follow-up period, a significantly higher percentage in the placebo group (25.0%) developed DM compared to the treatment group (11.0%) (p=0.016). The FPG and OGTT were significantly reduced in the treatment group, with significant improvements in  $\beta$ -cell function. In all four regression models, the best predictor of all dependent variables was Zn treatment. The study concluded that Zn supplementation reduces blood

glucose and insulin resistance, while improving  $\beta$ -cell function. Furthermore, the disease progression to DM was reduced and the beneficial effects of supplementation noted on TC and LDL-C. Zn supplementation was shown to be beneficial not only in the prevention of DM, but also in CVD.

According to trial, Zn supplementation is beneficial in the prevention of both DM and CVD, by reducing blood glucose, insulin resistance, certain lipids and progression to DM.

#### **4.1.4 Health education to improve the knowledge and attitudes on preventive measures related to CVD and DM**

It is important to identify the level of knowledge and attitudes of the general public and high-risk groups for designing effective preventive programs for CVD and DM. In this regard, several studies have been carried out on healthy populations, of which the following point to important findings.

- Several studies provide evidence on the level of knowledge on DM and risk factors in apparently healthy people. Its association with their level of education appears to be inconclusive.

A community-based study conducted in three MOH areas in Galle District among 277 previously healthy literate individuals who have not attended any DM education program in the last two years (Herath et al., 2017a), has shown that the majority (77%) had either moderate (39%) or above moderate (38%) knowledge on DM. However, despite having adequate knowledge, their attitudes towards DM were poor in the majority (88%) and with regards to preventive practices, more than half never had their blood sugar checked; about 65% used to take refined sugar liberally; and 80% had no regular exercise. Both knowledge and attitudes were significantly and positively associated with educational level ( $p=0.001$ ). It appeared that having knowledge on DM does not translate well into healthy practices or positive attitudes towards prevention in the general public. Further, it showed that educational level plays a minimal role in this regard.

In contrast, a study carried out to describe the knowledge possessed by 379 non-DM patients attending the out-patient-department (OPD) and clinics at the GH Ampara (Widisinghe et al., 2014) (abstract) found that the majority (70.7%) had good knowledge on DM, which was significantly associated with their level of education. However, their

awareness was inadequate with regards to non-curability and complications of the disease.

The education level as a determinant of knowledge, practices and attitudes relevant to CVD and DM is not conclusive.

- Knowledge on healthy dietary practices has been an important focus during health education, especially in high risk populations.

With regards to salt consumption, the level of knowledge among 384 apparently healthy adults aged 18-70 years from Gampaha District on the maximum daily recommended amount of salt was found to be poor, but showed positive attitudes through their willingness shown to cut down on salt, provided they receive correct messages (Karunapema et al., 2014) (abstract).

Housewives is an important target group for health education as they are directly involved in decision making at household level especially on diet. A study conducted predominantly among housewives in a suburban setting (refer Section 3.1.2.3) revealed that only 18% had adequate knowledge on diet related to chronic NCDs, in contrast to the majority of women resorting to unhealthy household practices related to the oils used, salt added and unhealthy choices for snacks, except on eating out (only 11.5% did not prepare breakfast at home on weekends and 6% on weekdays) (Premajayantha & Arambepola, 2012) (abstract).

- Having adequate knowledge on the causes, warning symptoms and outcomes of stroke and CHD would ensure timely health seeking behaviour.

A study was conducted among apparently healthy relatives of non-stroke patients admitted to medical wards of NHSL without a personal or first degree family history of stroke/TIA. The sample was recruited using systematic sampling from all wards, to represent the general public who were likely to seek state healthcare in the event of an acute episode (Chang et al., 2012a) (abstract). The study included 840 individuals from 21 districts. Of them, 53.2% did not know that the brain was affected in stroke. Only one third knew that occlusion or rupture of a brain blood vessel could cause stroke. However, over 90% correctly identified the three stroke warnings and the three stroke risk factors. Most said that they would seek Western medicine (84.6%) following stroke warning symptoms, 52.9% believed that indigenous medicine was the best treatment for stroke. Nearly 44.2%

were not sure whether stroke was preventable while the large majority (80.1%) did not know that aspirin could prevent stroke. With regards to acquiring information, 56.7% had got information from friends or relatives, 45.3% got information from the television, and only 7.8% had got information from the medical staff.

In comparison, another study with similar methodology conducted in a sample of 502 from medical and surgical wards of the District General Hospital (DGH) Matale using a self-administered questionnaire revealed that only 52% identified brain as the affected organ in stroke; 72% were aware of  $\geq 3$  stroke symptoms; 62% knew  $\geq 3$  preventative lifestyle measures; only 26.8% could correctly identify  $\geq 3$  stroke risk factors; and 79.3% were unaware that aspirin could prevent a stroke. Higher level of education was associated with better awareness on symptoms, aetiology, organ affected, preventive drug and lifestyle changes ( $p < 0.05$ ), while those with higher income knew the organ affected ( $p < 0.02$ ), stroke symptoms ( $p < 0.05$ ) and lifestyle measures ( $p < 0.006$ ) (Galhenage, 2014) (abstract).

Ranawaka et al. (2016b) carried out a community survey on stroke related knowledge among 711 adults and 155 schoolchildren in grade 6 and above in Kelaniya MOH area. Only 36.8% were able to recognize brain as the organ involved in stroke, however unilateral weakness (93.9%) or sensory symptoms (88%) and speech difficulty (88%) were identified as the main presenting symptoms. HT (74.3%) was most commonly recognized as a risk factor for stroke, however their awareness was inadequate regarding DM (60.5%), heart disease (60.9%), hypercholesterolaemia (62.5%) and smoking (61.3%). With regards to stroke, 60.1% considered that it is preventable; 74% that stroke could recur; 91.3% that early treatment would improve outcome; and 88.8% that it is an emergency. The majority were graded as having 'average' (46.8%), 'poor' (5.9%) or 'very poor' (3.4%) overall knowledge, with no significant difference between adults and schoolchildren. The study was deficient in evaluating their knowledge on TIA and their response to early warning signs/symptoms.

The general public, despite knowing its seriousness, lacks preventive knowledge on stroke warning signs and risk factors relevant to Sri Lanka, which is to be addressed in stroke awareness programs.

- Knowledge and practices with regards to screening for CVD and DM are effective for reducing the morbidity of CVD and DM.

A study carried out in a sample of 350 bankers aged 35 years and above in four private commercial banks revealed that the majority had been screened for HT (81.4%), DM (71.4%) and dyslipidemia (61.7%). Among the non-hypertensives, 66% had undergone BP screening annually. The screening was carried out at the general practitioner (53.4%); 9.4% in private hospital; 29.2% during medical checkup; 4.5% at HLC; and 3.8% at traditional doctor. Most had been screened for blood sugar (29.4%) and dyslipidaemia (31.1%) as well at the general practitioner (Niyas & Senarath, 2016) (abstract).

Inadequate knowledge, unhealthy practices and negative attitudes with respect to prevention are apparent in some adult target groups. This calls for improving education among them.

## 4.2 Secondary prevention of CVD and DM

Secondary prevention exclusively covers the clinical management of a disease. With regards to CVD and DM, the secondary preventive strategies broadly comprise early detection of the disease and adequate treatment & follow-up., which encompass both pharmacological and non-pharmacological interventions. It is also well-known that pharmacological management needs to be supplemented by lifestyle modification, if the maximum potential of the treatment is to be obtained and the maximum quality of life for the patient is to be achieved.

In line, this section provides evidence available on the following aspects:

- Clinical interventions carried out for early detection of CVD & DM related conditions (Section 4.2.2)
- Interventions for adequate treatment and follow-up of patients with CVD & DM (Section 4.2.3)
- Effectiveness of specific treatment in CVD & DM (Section 4.2.4)

#### 4.2.1 Sources of data

Studies included in this section are on CVD or DM patients, which focus on assessing the effectiveness of novel investigations, screening procedures and technological advances in the management of DM and CVD. Further, studies pertaining to the economic burden incurred by patients as well as by the state have been included. Owing to poor generalizability, those limited to a single MOH setting or small hospital and done in small samples (<100) selected with non-probability sampling were not considered.

#### 4.2.2 Clinical interventions for early detection of CVD & DM and related conditions

Early identification of CVD, DM and related conditions would enable the proper control of disease status, so that complications which are life threatening could be prevented or delayed as much as possible. Research studies have attempted to evaluate diagnostic tests or procedures, which may be simpler and more cost effective and valid compared to those routinely practised in Sri Lanka.

In line, evidence on the following aspects is given in this section.

- Evaluation of diagnostic tests/screening procedures related to CVD (Section 4.2.2.1)
- Evaluation of diagnostic tests/procedures related to DM (Section 4.2.2.2)
  - Accuracy of tests in the diagnosis of DM (a)
  - Accuracy of tests in the monitoring of DM control (b)
  - Applicability of tests in disease conditions to screen for DM (c)
- Evaluation of tests to screen for complications in DM (Section 4.2.2.3)
- Applicability of electronic- or web-based applications related to CVD & DM management (Section 4.2.2.4)

##### 4.2.2.1 Evaluation of diagnostic tests/screening procedures related to CVD

A few technology-enabled techniques have been tested on their diagnostic ability.

- Endothelial dysfunction is a well-known indication of the early stages of CVD. Non-invasive methods have grown with popularity in determining the dysfunction, considering the safety issues when applied on patients repeatedly over time.

A study was carried out among 11 DM and 21 non-DM participants to evaluate a combined non-invasive endothelial function assessment method, which acquires a Peripheral Arterial Tonometry (PAT) signal and a Digital Thermal Monitoring (DTM) signal from

fingertip. In participants, the endothelium was stimulated to induce reactive hyperemia by occluding the upper arm using a BP cuff. Results indicated that the Reflection Index, TEMPAUC, TMP-fall and Rise/Fall parameters are significant in differentiating the non-DM from DM persons. It further identified that when the parameters are considered together, it has a significant effect in differentiating DM patients from non-DM. Along with findings of other research on this aspect, it suggests that the system can be trained to a level which could assess the level of endothelial function, so that it could be used as a screening system for determining the likelihood of having vascular diseases (Maduwantha et al., 2017).

- Electrocardiogram (ECG) reports have a great CVD predicting potential, thus the demand for real-time analysis is becoming increasingly high. Although algorithms are present to perform analysis, most countries still use analogue acquisition systems that can only output a printed trace. It is necessary to extract the signal from these printouts to perform analysis. With time, this task becomes increasingly difficult.

A study proposed a method, which is specifically focusing on extracting signals from the faded traces, while maintaining a minimum user involvement requirement. Due to fading of reports, a single method could not fully extract the signal without user assistance. The proposed method was tested on 550 trace snippets, and the resultant comparative analysis showed an average accuracy of 96%. Extraction of ECG signals from scanned reports is clearly a requirement in clinical practice. Due to the fading of reports, a single method could not fully extract the signal without user assistance. Instead, the set of presented tools provided an excellent extraction accuracy. With the scanning resolutions clearly showing a correlation with the extraction accuracy, the study recommended that all ECGs be scanned at 600DPI resolutions. The 3-window time-based feature extraction method showed higher levels of accuracy than the 2-window method. However, the presented windows only seemed to work with normal rhythms (Mallawaarachchi, 2014).

- Coronary angiography is an invasive image modality, which is widely used in interventional cardiology to detect luminal obstructions in coronary arteries. It has been reported that most of the recorded coronary cine-angiograms (CCA) are contaminated with various visual artifacts, such as noise, non-uniform illumination, low contrast and epicardial motion. Consequently, the diagnostic visualization of CCA degrades.



A study proposed a frequency filtering-based frame enhancement method for CCA to improve its diagnostic visualization. The method consisted of five major implementation phases, namely noise removal, application of homomorphic filter, contrast stretching, calculating motion vector and creating a stabilized frame. In order to correct the epicardial deformations, optical flow-based frame stabilization method has been applied in later stages of the proposed method. Study results clearly showed the visual improvement obtained through this novel method. The enhanced CCA frames produced in this study could be further used to improve the angiography image modality for quantitative stenosis assessment (Wajiramali et al., 2017).

- Glutathione peroxidase and paraoxonase-1 is reported to be a useful marker for monitoring CAD, however its role in assessing the severity of CAD is not well-demonstrated in Sri Lankan patients. A feasibility study among 85 CAD patients aged 40-60 years (cases) and another 85 age- and sex-matched healthy volunteers (controls) assessed the severity of CAD using coronary angiographic scoring system based on vessel, stenosis and extent score (Wickramasinghe, 2015). Results showed that cases had significantly low glutathione peroxidase and paraoxonase-1 activity compared to controls, highlighting its role as an accurate marker in ruling out major coronary vessel disease and luminal narrowing by atheroma.

A few tests/procedures are identified as having the ability to detect early stages, severity and complications of CVD.

#### **4.2.2.2 Evaluation of diagnostic tests/procedures related to DM**

Most of the methods tested have been related to diagnosis of DM and pre-DM conditions.

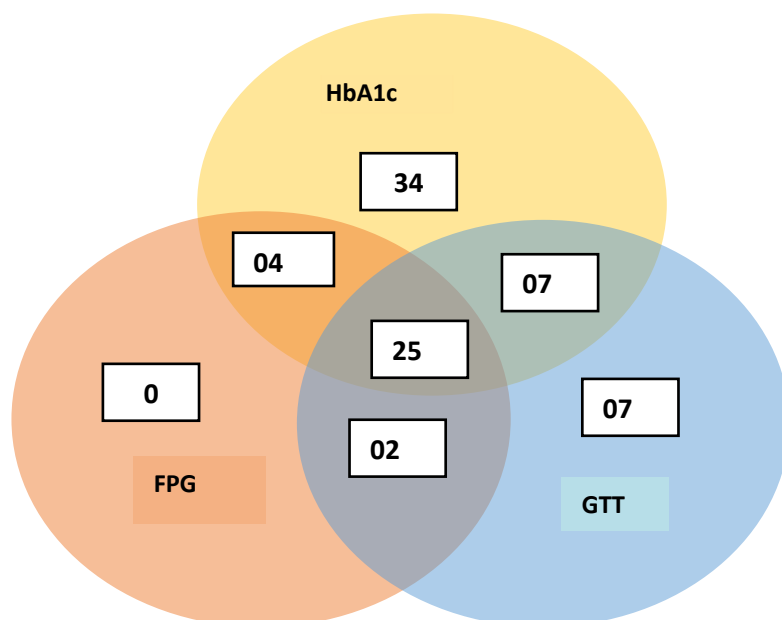
##### **a. Accuracy of tests in the diagnosis of DM**

- HbA1c is well-known to be effective in predicting DM especially in Caucasians, however there is limited evidence on its diagnostic capacity in high-risk Sri Lankan adults.

A community-based study was carried out to determine the optimal HbA1c cut-off points for detecting DM in a suburban locality in Southern Sri Lanka. Two-stage cluster sampling was used to select 196 persons aged 20 years or more with no previous history of DM but with a history of DM among first degree relatives. They were subjected to FPG (usually practised test), OGTT (reference) and HbA1c (test) following 8-10 hour fast. As shown in Figure 4.4, the prevalence of DM was 16.1% with OGTT testing; and 12.2% according to

FPG testing. It was increased to 27.6% with HbA1c testing using a cut-off value of 6.5% (Herath et al., 2016c).

**Figure 4.4: Comparison of the prevalence of DM according to FPG, GTT and HbA1c**

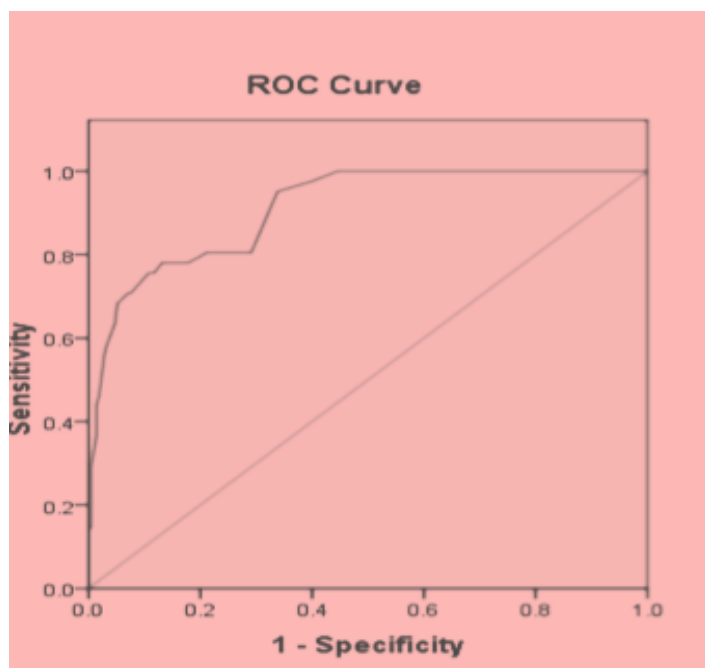


*Note:* FPG=fasting plasma glucose; GTT=glucose tolerance test; DM was diagnosed by 2-h GTT >11.1 mmol/l (red circle); FPG >7.0 mmol/l (purple circle); and HbA1c >6.5 (black circle).

*Source:* Herath et al. Diabetes & Metabolic Syndrome: Clinical Research & Reviews 2016; 644

In further analysis, HbA1c showed a positive and significant correlation with GTT ( $r=0.78$ ;  $p<0.001$ ) and FPG ( $r=0.7$ ;  $p<0.001$ ). According to the ROC curves (Figure 4.5), the optimal cut-off of HbA1c (test) to predict DM (OGTT as reference) was 6.35% (80.5% sensitivity; 79% specificity). The study highlighted that the prevalence of DM would double if HbA1c was used for screening purpose, instead of FPG (Herath et al., 2016c).

**Figure 4.5: Receiver operator characteristic (ROC) curve drawn for DM detected by OGTT (reference) and HbA1c (test)**



Source: Herath et al. Diabetes & Metabolic Syndrome: Clinical Research & Reviews 2016; 644

A similar study was carried out among 2516 individuals with no previous history of DM (Wijekoon et al., 2017a), to compare the diagnostic value of HbA1c (test) against FPG (reference) for detecting DM in an urban community aged 35-64 years. This study utilized the baseline data of a large prospective study on NCDs (Ragama Health Study), while the assays of HbA1c and FPG were performed on 10 ml of venous blood. Results showed that 9.7% had FPG  $\geq 7$  mmol/l, while 6.9% had HbA1c  $\geq 6.5\%$  (concordance between the two tests was 95%). The HbA1c at cut-off of  $\geq 6.5\%$  showed 98.9% specificity and 60% sensitivity in the detection of DM (FPG  $\geq 7$  mmol/l). According to the ROC curve, the optimum HbA1c threshold for diagnosing DM was 5.9% (84% sensitivity: 88.8% specificity; 0.91 area under the curve) (Table 4.10).

The study concluded that HbA1c is relatively high in specificity to detect DM, but not so in its sensitivity. This needs cautious interpretation in view of the limitations identified. Confounders such as severe iron deficiency anaemia and haemoglobinopathies which could alter the HbA1c value have not been excluded. The reference criterion used to assess the performance of HbA1c was FPG, and not OGTT which is the gold standard. This may have missed out the group of people with normal FPG but having elevated 2-hour plasma glucose. Nevertheless, the aim of this study was to explore the performance of HbA1c as compared to the widely used FPG in the detection of DM. As compared with the

FPG criterion, the optimum HbA1c threshold for detecting DM in this sample was 5.9%, which is lower than the ADA cut-off. This is consistent with most of the studies from other countries.

**Table 4.10: Sensitivity and specificity of different HbA1c cut-off values (test) compared to FPG reference criterion (FPG >7 mmol/l)**

HbA1c cut-off value (%)	Sensitivity %	Specificity %
≥ 4.9	98.4	11.6
≥ 5.4	93.4	49.8
≥ <b>5.9</b>	<b>84.0</b>	<b>88.8</b>
≥ 6.2	70.5	96.3
≥ 6.5	59.9	98.9
≥ 7.0	43.4	99.7
≥ 8.0	27.1	99.9
≥ 8.3	25.0	100

Source: Wijekoon et al. Ceylon Medical Journal 2017; 62(1): 57-62

HbA1c demonstrates its predictive ability of DM compared to the conventional diagnostic tests used.

- With regards to DM, a major issue is the large number of patients remaining undiagnosed in the community, owing to the high cost and invasiveness of the blood sampling. In response, Katulanda et al. (2016) developed and validated a risk score to screen undiagnosed DM among Sri Lankan adults, and compared its performance with the Cambridge Risk Score (CRS), the Indian Diabetes Risk Score (IDRS) and three other Asian risk scores. Individual scores were generated for selected factors commonly found among undiagnosed diabetics and cut-offs were developed by using ROC curves.
- Knowing the diagnostic performance of screening tests of DM in different risk categories would help in selecting the most appropriate tool for the given setting. For this purpose, a validation study was conducted (Dahanayake et al., 2018) to compare the detection of DM and pre-DM status by FBG, capillary blood glucose test, HbA1c and paper-based Finland Diabetes Risk Score (FINDRISC) questionnaire against OGTT in the first degree relatives aged above 35 years of patients with DM. Those with known DM, who were on long-term steroids, anti-psychotics or having chronic liver, pancreatic or kidney disease were excluded. The ROC curve analysis revealed that HbA1c has the highest discriminatory

power, while the FBG and capillary blood glucose test possess lesser but almost similar discriminatory power in recognizing abnormal glucose tolerance (Table 4.11).

**Table 4.11: Sensitivity, specificity and area under the curve (AUC) for different screening tests against OGTT to detect diabetes and pre-diabetes**

Test	Sensitivity %	Specificity %	AUC (95% CI)	p
<b>To detect diabetes</b>				
HbA1c	77.3	97.8	0.96 (0.93, 0.98)	<0.001
Fasting blood glucose	68.2	99.3	0.87 (0.77, 0.98)	<0.001
Capillary blood glucose	45.5	97.8	0.88 (0.80, 0.96)	<0.001
FINDRISC	4.5	100.0	0.65 (0.51, 0.79)	0.03
<b>To detect pre-diabetes</b>				
HbA1c	Not given		0.83 (0.75, 0.91)	<0.001
Fasting blood glucose			0.75 (0.66, 0.84)	<0.001
Capillary blood glucose			0.74 (0.64, 0.83)	<0.001
FINDRISC			0.55 (0.45, 0.65)	0.29

Source: Dahanayake et al. Sri Lankan Journal of Cardiology 2018; 1(1): 20-25

HbA1c demonstrates its predictive ability of DM compared to the conventional diagnostic tests used.

#### **b. Accuracy of tests in the monitoring of DM control**

The value of PPBS in the monitoring of DM patients on their glycaemic control has been explored against FPG.

- For this purpose, a study was carried out among 120 patients with DM attending a medical clinic who were randomized into either receiving PPBS or FPG (Herath et al., 2014a) (abstract). This cohort was followed-up for 6 months, and at end of this period showed that there was no significant difference between the FBS and PPBS values. The mean HbA1c of FBS and PPBS groups were 7.2% and 7.33%. During the study period, HbA1c was dropped by 0.2 in FBS arm compared to 0.25 in the PPBS arm. The study concluded that PPBS was a reliable substitute to FBS in order to manage patients with DM.
- Herath et al. (2014a and 2016d) (abstract) conducting another study to evaluate the effectiveness of using either FBS or PPBS for monitoring the glycaemic control in DM

patients have concluded that both are equally effective in terms of monitoring, however it did not assess the power of risk prediction via these investigations.

- Muthalib et al. (2014a) (abstract) have shown that glucometers demonstrate a wide variation in its accuracy. Some were less accurate in the high glycaemic range, while some were less accurate in the low glycaemic range. However, overall, they report that capillary blood sugar measurements are almost always 20% higher than serum glucose values.

### **c. Applicability of tests in disease conditions to screen for DM**

- It is recommended that patients with CVD are screened for DM and pre-DM. Whether there are differences in the yield of DM and pre-DM status when applying FPG testing against HbA1c testing has been evaluated in Sri Lankan settings.
- In a cross-sectional study conducted in a medical ward at a tertiary care hospital, both FBS and HbA1c were estimated in 125 patients without a previous history of DM admitted with ACS (ST elevation myocardial infarction, non-ST elevation myocardial infarction and unstable angina) and selected for the study through convenience sampling (Nanayakkara et al., 2015). The glycaemic category was ascertained according to FPG and HbA1c level, as per recommended by the ADA. Results revealed that according to HbA1c testing, 47% and 53% of the patients with ACS had DM and pre-DM, respectively. The corresponding percentages in each category according to FPG testing were 4% and 16%. The study highlighted that based on HbA1c testing, every patient with ACS has either DM or pre-DM, thus pointing out that patients with ACS should undergo HbA1c, if they are either diabetic or pre-diabetic. This highlights the need for better diagnostic tools than FBS in detecting the diabetic status in CVD.
- Screening for DM in high-risk populations is encouraged, as the WHO recommends bi-directional screening for tuberculosis (TB) and DM. Its relevance in Sri Lanka has been studied in the Sri Lankan context.

A cross-sectional study was carried out in Ampara District. All non-diabetic TB patients attending the chest clinic were requested to undergo FBG at the nearby general hospital. Patients with FBG  $\geq 126$  mg/dl were diagnosed as having DM, while those with FBG of 100-125 mg/dl were diagnosed as having IFG. Among the TB patients, 83 did not have pre-existing DM, of whom 2% and 20% were found to have DM and IFG, respectively,

highlighting the relevance of incorporating FBG screening in TB management. Despite displaying the importance of screening a high-risk population, the study had following limitations. This study was implemented in a single district and therefore, the findings may not be generalized to the whole country. Moreover, the cohort of TB patients screened was small while only FBG was performed to screen for DM; FBG is known to be less sensitive compared to HbA1c or OGTT. Furthermore, some of the cases could be due to stress-induced hyperglycaemia (caused by a chronic infection such as TB), and therefore need to be re-tested for confirmation after completion of anti-tuberculosis treatment (Rajapakshe et al., 2015).

A few tests have shown their diagnostic power (e.g. HbA1c against OGTT or FPG and non-invasive methods to identify endothelial function and obstructions in coronary arteries); accuracy in monitoring disease control (e.g. PPBS, FBS); and applicability of DM screening tests in other disease conditions (e.g. TB).

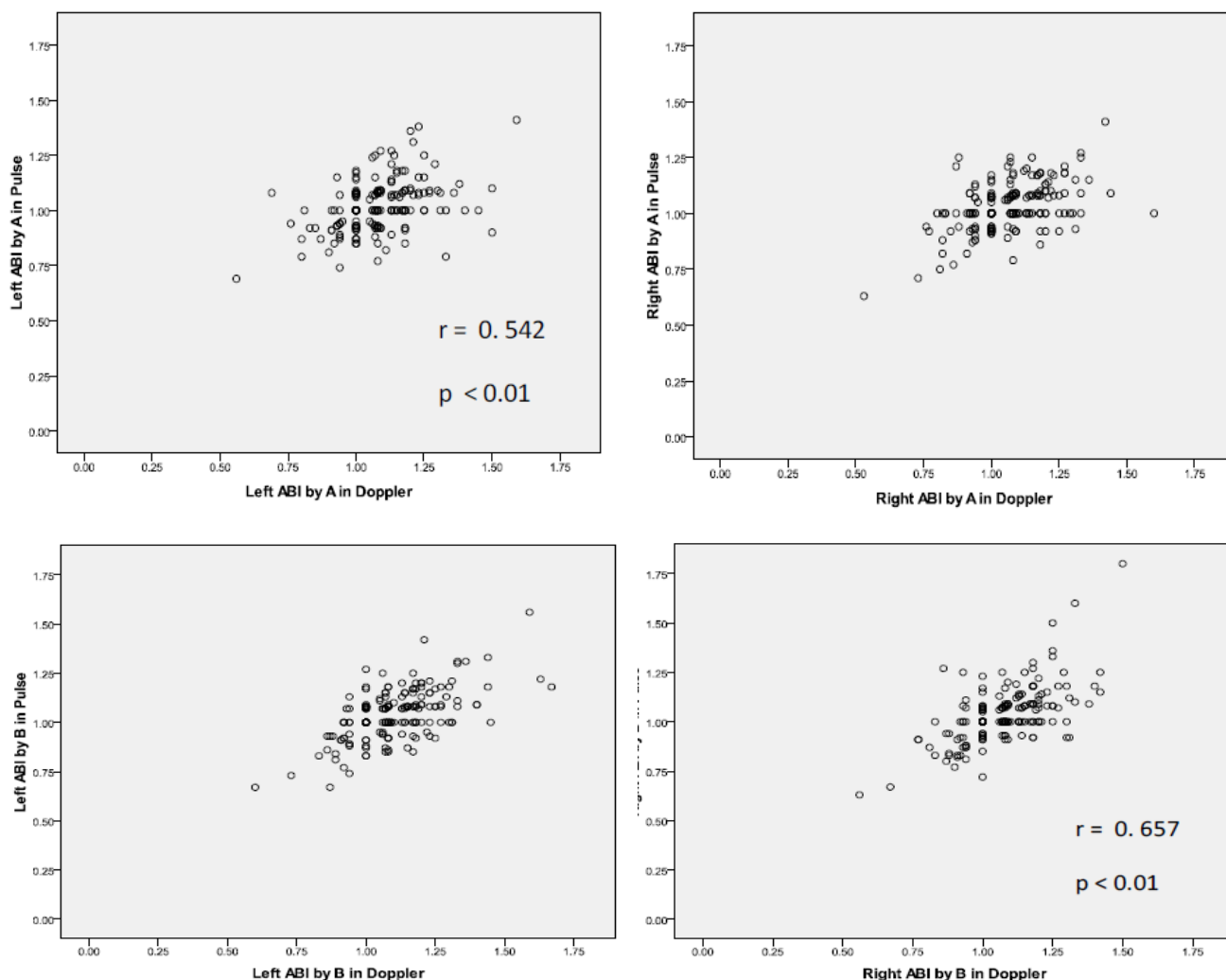
#### **4.2.2.3 Evaluation of tests to screen for complications in DM**

- Peripheral arterial disease (PAD) is a common complication among patients with DM. Ankle brachial pressure index (ABI) is the useful screening test to detect PAD. However, limitation for the widespread use of this test is the lack of doppler devices in most of the resource-poor settings. In contrast, the pulse palpation method requires only a BP apparatus with a suitable cuff, thus provides a cheaper and readily available alternative.

A study was carried out to evaluate the accuracy and reproducibility of ABI measured by pulse palpation method (pABI) and correlate it with doppler method (dABI) (Ranasinghe et al., 2015d). The study was conducted in DM clinics at NHSL among 193 patients who were examined using both methods by two trained medical officers separately. Following a 10-minute resting period, SBP in the brachial, dorsal, pedal and posterior tibial arteries were obtained by pulse palpation method and doppler method with a sphygmomanometer cuff placed 2cm proximal to the malleoli or elbows. The first palpable or Doppler pulse was used to identify the SBP at each location. In doppler method, the pulses were located by palpation and the tip of the doppler probe was placed until an audible pulse signal was obtained. Then the pressure cuff was inflated 20mmHg above the point where the pulse was no longer audible. The cuff was slowly deflated at a rate of 2mmHg per second, noting the manometer reading at which the first pulse signal is heard and that was recorded as SBP. In pulse palpation method, pulse palpation was used instead of doppler signal to obtain SBP using the same technique. The ABI was

calculated by dividing the highest systolic ankle pressure (either posterior tibial or dorsal pedal) in each leg by the highest systolic brachial pressure.

**Figure 4.6: Scatter plots with regression showing the correlation between dABI and pABI**



*Source:* Ranasinghe et al. Sri Lanka Journal of Diabetes, Endocrinology and Metabolism 2015; 5: 65-68

The study highlighted (Figure 4.6) that the pulse palpation method had a sensitivity of 62% and a specificity of 90%. Even though it was seen that the doppler method cannot be replaced by pulse palpation method, there was a significant positive correlation between the two methods, indicating that the pABI can be utilized to predict the dABI in resource poor settings (Ranasinghe et al., 2015d).



- Nisansala & Wimalasekera (2015) (abstract) carried out a cross-sectional study on 384 patients attending the diabetic clinic of CSTH to determine the use of Michigan Neuropathy Screening Instrument (MNSI), Diabetic Neuropathy Index (DNI) and Monofilament tests in the screening for diabetic neuropathy. Diabetic neuropathy was confirmed by a positive score obtained for two of the three tests and accordingly, 45.6% of the 175 patients studied had diabetic neuropathy, while 43% of them were positive for both MNSI and DNI. On inspection of the clinic records, only 16% of them had been previously diagnosed with neuropathy.
- Wijesundere et al. (2006) (abstract) carried out a study to evaluate the monofilament as a screening device in detecting peripheral sensory neuropathy. All patients attending the Family Practice Centre at the University of Sri Jayewardenepura were screened using both the Semmes-Weinstein monofilament and conventional method (sensory functions tested for pain, vibration touch and proprioception, in which loss of pain or touch with or without vibration was coded as being positive). The number detected to have peripheral sensory neuropathy via the conventional method was 30 (32%) in comparison with 48 (51%) detected through the monofilament test.
- Evidence is available to suggest that microalbuminuria may have a limited role as a screening tool to detect the onset of diabetic nephropathy, especially among patients who do not exhibit distinct clinical features that facilitate identification of them using clinical information (Liyanage et al., 2018). This was based on a study conducted among 456 DM patients in medical clinics at TH Galle, in whom 13.2% patients had low eGFR and 26.7% of them had normo-albuminuria, showing a considerable proportion being normoalbuminuric despite a low eGFR.

Less time consuming and simple tools such as pulse palpation method to detect PAD and monofilament to detect peripheral sensory neuropathy are shown to be effective in low-resource settings.

#### 4.2.2.4 Applicability of electronic- or web-based applications related to CVD and DM management

A few electronic- or web-based applications have been researched into, with regards to the management of CVD and DM. A summary of these techniques is given in Table 4.12.

**Table 4.12: Summary of the studies conducted to assess the use of electronic- or web-based applications in the management of CVD and DM**

Authors and year	Application used	Results
Kurupparachchi et al., 2015	Non-invasive technique based on wireless sensor networks to monitor the temperature, BP and pulse rate automatically	The prototype device performed at 99.8%, 88.4% and 92.7% accuracy levels on monitoring the temperature, BP and pulse rate, respectively.
Perera, 2011	Mobile- and web-based telemedicine application to facilitate DM detection and self-monitoring of blood glucose	A system for laboratory investigation of DM and self-monitoring of blood glucose was developed. Mobile app was developed as an IVR, which can run on a basic mobile phone without internet facility, hence could also be used in remote areas.
Karunathilake et al., 2017 (abstract)	Non-invasive method to assess endothelial dysfunction indicative of early stages of CVD	Peripheral arterial tonometry (PAT) signal simultaneously with digital thermal monitoring (DTM) signal were found to significantly predict endothelial damage.
Kitchilan & Samankula, 2017	An intelligent medical knowledge-driven approach for the prognosis of heart disease using a weighted voting ensemble classifier	The original dataset holds predictable attributes ranging from 0 (healthy heart) to 10 (severely unhealthy heart). The proposed voting classifier deals with all types of attributes and out-performs the highest accuracy of 92.1%, F1 score 91.9%, precision of 92.2% and recall 92.5%. For the conclusion of this research to be applied clinically, it requires further elaboration with the aid of professionals in both cardiac and machine learning domains.
De Silva et al., 2016a	To develop a system which can predict whether a patient has DM or not	Focused on developing a system based on three classification methods, namely Decision Tree, Naïve Bayes and Support Vector Machine algorithms.

		<p>Currently, the models give 84.7%, 76.7% and 77.3% accuracies for the three methods, and have been verified using ROC curves in a cost-sensitive manner. The developed ensemble method uses votes given by other algorithms to produce the final result. This voting mechanism eliminates the algorithm dependent misclassifications. Results showed a significant improvement of accuracy of ensemble method compared to other methods.</p>
<p>Kurupparachchi et al., 2015</p>	<p>A non-invasive technique based on wireless sensor networks to monitor the temperature, blood pressure and the pulse rate automatically without having to disturb a resting patient.</p>	<p>The wireless sensor node captures these vital health parameters and are sent to a smart phone via Bluetooth. The smart phone handles all the processing tasks and produces systolic and diastolic heart rates and gives alerts whenever an abnormal condition occurs. The prototype device managed to perform at 99.8 %, 88.4% and 92.7% accuracy levels on monitoring the temperature, BP and pulse rate, respectively. The system designed using low-cost peripherals with minimal electronic devices, can be used to monitor patients even from a remote location via wireless technology.</p>

There is evidence supporting technology-enabled non-invasive real-time investigations that could be used safely and effectively in the prevention, diagnosis and management of CVD and DM.



### 4.2.3 Interventions for adequate treatment and follow-up of patients with CVD & DM

This section reviews the evidence available on the following aspects pertaining to the treatment and follow-up of patients with CVD and DM. Wherever relevant, the underlying factors are also highlighted.

- Self-management practices of patients (Section 4.2.3.1)
  - Adherence to medication (a)
  - Adherence to lifestyle modifications (b)
  - Self-monitoring of disease control (c)
  - Perception on disease progression and outcomes (d)
  
- Service provision in healthcare settings (Section 4.2.3.2)
  - Availability of the services (a)
  - Access to services (b)
  - Quality of the services provided (c)
  - Costing (d)
  - Knowledge and management practices of healthcare providers (e)

#### 4.2.3.1 Self-management practices of patients

Self-management practices of DM and CVD include adherence to medication and non-medication treatment, as well as self-monitoring of the disease status and perceptions on disease progression and outcomes.

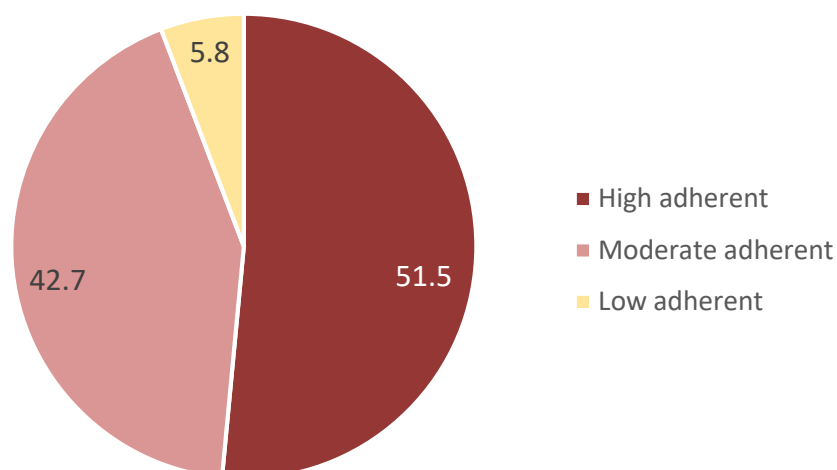
Many studies have been conducted in Sri Lanka on these aspects in clinic settings, which highlight the self-care practices of patients followed-up, as well as their knowledge and attitudes underlying these practices (KAP studies). Few of these studies are described in detail in Annex 1, while most others showed poor generalizability of the findings, as they were confined to a single unit, done in relatively small samples or selected using convenience sampling. A few more studies provided good quality data and unique findings, which are described below.

### a. Adherence to medication

Adherence to daily medication is a crucial issue for any life-long condition, including DM, CVD and HT.

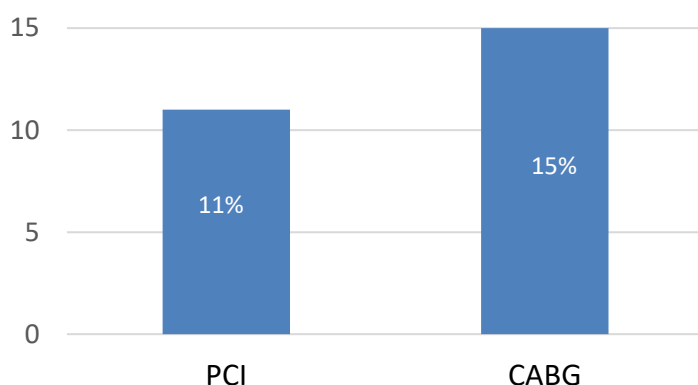
- With regards to drug adherence in IHD, Bandara et al. (2018) conducted a clinic-based study among 103 patients with MI occurring within last 0.5-5 years and receiving treatment at the Cardiology Unit of TH Kandy, to describe their drug adherence and knowledge on further advance therapeutic options available. According to the four-item Morisky Medication Adherence Scale, 51.5% had 'high' adherence to treatment, whereas 'moderate' and 'low' adherence was reported as 42.7% and 5.8%, respectively (Figure 4.7). The mean number of drugs used in poly-medicated patients was 7.5 (SD=1.6).

**Figure 4.7: Distribution of self-reported non-adherence to medication among post-MI patients**



Source: Bandara et al. Journal of Clinical and Preventive Cardiology 2018; 7(2): 9656450: 40-48

Only 33% had discussed the necessity of advanced therapeutic options following their acute coronary event. Though 63% had heard about the availability of advanced therapeutic options, only 11% and 15% had an adequate knowledge on what is meant by percutaneous coronary intervention (PCI) and CABG in non-medical management, respectively (Figure 4.8). The study concluded that sub-optimal drug adherence, lack of knowledge about their disease and inadequacy of health communication are the major issues to be addressed in post-MI patients in Sri Lanka.

**Figure 4.8: Self-perception of therapeutic options among the study group**

Source: Bandara et al. Journal of Clinical and Preventive Cardiology 2018; 7(2): 9656450: 40-48

- With regards to adherence to anti-hypertensives, a study among 303 hypertensive patients recruited from all general medical outpatient clinics at TH Jaffna (Pirasath et al., 2017) revealed that almost all (99%) thought that taking medicine plays a key role in the control of BP, yet the majority (84.5%) had poor drug compliance. Ironically, only a few ever stopped or recommenced medication without telling doctor (14.2%) and felt hassled about sticking to the treatment plan (15.2%). The most common reasons for non-adherence were forgetfulness (23.1%) and interruptions of daily routine (17.5%) (Table 4.13).

**Table 4.13: Reasons for poor adherence to drugs on hypertension**

Reason	No.	%
Poor knowledge of the disease and its long-term treatment	27	8.9
Religious beliefs and cultural practices	31	10.2
Adverse drug reactions	26	8.6
Not believing that health depends on medicine	23	7.6
Worrying about taking medicine	33	10.9
Forgetfulness	70	23.1
Drugs out of supply	24	7.9
Poor communication/ insufficient patient information	35	11.6
Expenses (doctors' fees, transport, medicine, hospitalization)	45	14.9
Interruptions of daily routine	53	17.5
Lack of reminders	35	11.6
Being busy or late for work	36	11.5
Being away on weekend/ vacation	23	7.6
Too many medications to take	33	10.5

Source: Pirasath et al. International Journal of Hypertension 2017; 9656450: 6

The findings are compatible with several other studies conducted in teaching hospitals, highlighting the deficiencies in patient education in such hospitals most likely due to heavy patient load.

Adherence to daily medication is a major challenge faced by patients with HT.

- With regards to the use of anti-diabetics in DM, many patients fail to achieve optimal drug treatment. This was the pertinent finding by Weeraratne et al. (2018b) when looking at the self-reported drug and dietary compliance of patients with DM presenting to the outpatient department. Self-reported drug and dietary compliance was elicited on a visual analog scale, ranging from 0 to 10 (0=no compliance at all; 10=complete adherence to prescribed medications and dietary advices given by the dietician). An HbA1c <7% and LDL-C <100 mg/dL were used to define optimal glucose and lipid control, respectively. According to results, 30% and 62% achieved optimal glucose and LDL-C control, while both were achieved by 23%. Regression analysis revealed significant association of self-reported high dietary compliance with achievement of both targets.
- With regards to adverse effects of anti-diabetics in DM, a few studies have been conducted.

A cross-sectional survey was conducted among 358 patients attending the general medical clinic at CNTH to assess the prevalence of psychological insulin resistance using Insulin Treatment Appraisal Scale (ITAS) (Thillainathan et al., 2015a). Results indicated that 52.2% of the patients considered commencement of insulin therapy as personal failure ( $p=0.0001$ ). Overall negative appraisal for insulin was similar in both genders, however females had a higher negative score on fear for needles (mean=3.39) compared to males (mean=3.18) ( $p=0.04$ ). 49.1% feared that once insulin is started, it is needed permanently while 0.8% opposed it. No difference in the mean score for negative items was noted between patients on oral drugs (mean=3.19) and insulin (mean=3.10) ( $p=0.1$ ). Further, educational level and duration of DM did not have a significant influence on insulin perception. The study concluded that health care workers need to probe into the patient perceptions on insulin and focus on groups with more negative appraisal towards it.

Another study conducted in a cohort of 70 DM patients with dyslipidaemia showed that after a mean duration of 12.8 months of statin therapy, the mean ALT level had increased more than three times the upper limit of normal compared to its baseline of 32.86 U/L (Antonypillai et al., 2018). The study concluded that routine monitoring of ALT may not be cost-effective, based on the finding of clinically significant increase in liver ALT level being rare.

Sub-optimal adherence to medication is apparent with all types of CVD and DM treatment, highlighting poor awareness and negative attitudes of the patients with respect to secondary prevention.

To improve the adherence to daily medication, a few interventions have been carried out in hospital settings.

- A non-randomized controlled trial was carried out in a tertiary level hospital to determine the impact of a ward-based clinical pharmacy service on hospital re-admissions related to NCDs in Sri Lanka. In addition to the standard care provided to control group (CG), the intervention group (IG) received a clinical pharmacist's service, in which the pharmacist recorded the patients' medication history on admission and prospectively until transfer or discharge; reconciled the medication history taken at admission with that of the physician; noted any discrepancies (deletions, additions, changes) in the lists; identified and recorded any potential drug-related problem; discussed with patients and health care team for resolutions during the hospital stay; and gave verbal and written instructions in the local language on the safe administration. Both groups were followed-up monthly for six months to identify drug-related hospital re-admissions. As shown in Table 4.14, significantly higher incidence of drug-related hospital re-admissions due to non-compliance and non-reconciliation was recorded in the CG. It was also significantly higher for re-admissions per patient due to unintentional omission of drugs on the discharge prescription (4.5% vs. 0.3%;  $p < 0.001$ ), but not for re-admissions per patient due to adverse drug reactions. The study concluded that ward-based clinical pharmacy service is useful in reducing drug related hospital re-admissions in patients with chronic NCDs (Lelwala et al., 2017a).



**Table 4.14: Drug-related problems, medication appropriateness and hospital re-admission for patients with NCDs**

Outcome	Control (n=354)	Intervention (n=361)	p value
No. of drug related problems	1217	1027	0.25
No. of resolved drug related problems (%) <sup>a</sup>	161 (13.2)	592 (57.6)	<0.001
Mean MAI at discharge score per patient (SD) <sup>b</sup>	4.3 (6.5)	1.3 (2.9)	<0.001
Mean MAI at discharge score per medication (SD) <sup>b</sup>	0.7 (2.7)	0.2 (1.2)	<0.001
No. of patients with appropriate medicines at discharge (%) <sup>c</sup>	105 (29.7)	202 (56)	<0.001
No. of patients reached and interviewed	311	334	
No. of drug-related hospital readmissions (%) <sup>d</sup>	93 (29.9)	44 (13.2)	<0.001
No. of readmissions due to non-compliance to drugs (%) <sup>d</sup>	49 (52.7)	15 (34.1)	0.03
No. of readmissions due to non-reconciliation of drugs (%) <sup>d</sup>	17 (18.3)	1 (2.3)	<0.001

MAI=medication appropriateness index; SD=standard deviation

<sup>a</sup> Percentages calculated out of the total drug related problems in each group; <sup>b</sup> MAI scores range from 0-18, with lowest score for most appropriate medication; <sup>c</sup> Patients with zero score for all their medications categorised as receiving appropriate medication; <sup>d</sup> Percentages calculated out of the total no. of patients interviewed in each group

Source: Lelwala et al. WHO Bulletin 2017; 96(3): 155-164.

- In agreement, Mamunuwa et al. (2018) (abstract) also showed that pharmacist counseling could improve medication adherence, glycaemic control and patients' knowledge. In this study, 800 patients with DM attending the OPD clinic were either assigned to the intervention group to receive pharmacist's counseling visits for four consecutive months, and to the control group to receive only standard care.
- To assess the effect of three different management protocols on the glycaemic control, a prospective study was conducted among 60 poorly controlled DM patients (FBS >200 mg/dl on two consecutive occasions) on strict dietary control with maximum pharmacological doses of glibenclamide and metformin (Weerarathna & Hidelaratchi, 2004). Three drug regimens were initiated: pioglitazone added to existing oral hypoglycaemic drugs (OHD) for those with FBS between 200-300 mg/dl; single daily dose of lente insulin added for those with FBS >300 mg/dl; and OHDs replaced by lente insulin for those with FBS >300 mg/dl and recent weight loss. Results showed that after six months, the mean reduction in FBS was comparable.

### **b. Adherence to lifestyle modifications**

As much as pharmacological agents, adherence to lifestyle modifications is considered important for achieving better control in DM and CVD.

- Medagama & Widanapathirana (2015) as well as Senadheera et al. (2016) have shown that dietary habits of DM patients in Sri Lanka are relatively better than in the general population, but there is ample room for improvement (refer section 3.2.2.5). For this purpose, reasons for non-adherence of DM patients to healthy lifestyles should be identified, thus knowledge and attitudes of patients underlying their compliance to treatment have been a concern in many studies.
- Studies have shown that DM patients have poor knowledge on dietary practices in DM (Bandara et al., 2009b) (abstract). It is also noteworthy that a considerable number of overweight/obese DM patients has been found to be unaware of their body status, while some showed reluctance in accepting their status, according to a study in a semi-urban and rural setting (Medagama & Widanapathirana, 2015). These point to knowledge as well as attitudinal issues.
- Another reason for not complying with recommended diet could be the barriers they face in translating the dietary advice given into action.

A qualitative study (Ranasinghe et al., 2015e) at the University Medical Unit of NHSL among 50 DM patients identified through focus group discussions, that despite almost all (n=45) being aware that diet plays an important role in the management of DM, most (n=35) had difficulty in incorporating the dietary advice given by medical personnel into their life. Social circumstances seemed to have the greatest impact on the difficulties faced. Some (n=12) admitted of being diet-conscious only after developing complications. Sweetened food, milk products, white starch as well as fruits were widely considered as 'bad' food items which should be completely avoided, while 'good' foods were believed to be consumed all the time in any quantity. There were several other myths regarding diet, some of which have originated from healthcare professionals. It should be noted that this study excluded patients with co-morbid diseases where diet plays a major role (e.g. IHD, HT, chronic kidney and liver disease), thus highlighting a deficiency related to self-management of DM.

- As much as in diet, research studies highlight the barriers for physical activity in Sri Lanka.

It is evident that most patients with DM do not achieve the required blood sugar control. As shown by Amarasekara et al. (2015a), this is because although most adhere to regular medication and dietary control, exercise is not always being carried out. In concurrence, the study cited previously by Ranasinghe et al. (2015e) at the University Medical Unit of NHSL highlighted that many (n=37) had received advice on physical activity from healthcare personnel through direct conversation or via mass media. However, only a few stated that they received enough guidance on the recommended duration of physical activity per week. Among the very few who were on regular physical activities, most stated afternoon as the preferred time and walking as the most common activity.

- The adherence to exercise according to medical advice was compared among 253 DM patients attending three clinical settings, namely hospital DM clinic, hospital general medical clinic and general practitioner. Of them, only 45.1% were properly educated on exercise as part of DM management (Siyambalapitiya et al., 2012). They comprised 60.6%, 26.5% and 49% of those attending the DM clinic, general medical clinic and general practitioner. However, their adherence to exercise recommendations was poor (11.5%) irrespective of the clinical setting. Walking was the commonest mode of exercise (72.4%) followed by exercise machines (13.8%) and running (13.8%). In the non-exercising group, 51.6% believed that activities of daily living are adequate as daily exercise; 18.3% claimed to have no time to exercise; and 14% are less motivated. The study highlighted the need for novel approaches on health promotional and information delivering techniques, which seemed to have contributed as barriers to achieving desired attitudinal changes.

Despite understanding the importance of diet and physical activity in the management of DM, adherence to healthy lifestyles appears to be poor, mainly due to poor clarity in the information provided and not addressing the underlying determinants during patient education.

- Barriers to physical activity have been studied extensively using in-depth interviews.

A qualitative study in a sample of 40 patients with long-standing DM from TH Peradeniya explored the contextual reasons for their restricted physical activity. Inability of patients to differentiate household and daily activities from physical activities emerged as a recurring theme, while most did not have a clear understanding of the type or duration of PA that they should perform (Medagama & Galgomuwa, 2018). Health issues, poor time

management and prioritizing household activities over PA were important factors that limited PA. Most stated that the concept of exercising was embarrassing and alien to their culture and lifestyle, highlighting the societal determinants that they faced. This sample was able to capture the catchment population of semi-urban and rural dwellers of Central Province. The situation in cities in Colombo District however may differ, considering the recent initiatives taken on creating an environment that facilitates and normalizes an 'exercise culture' among residents.

- Cultural and religious beliefs, practices and customs may play an exclusive role in lifestyle modification and drug control of DM.

A qualitative study was carried out using ethnographic approach in two communities reporting high prevalence of DM in Colombo District using purposive sampling (Amarasekara et. al., 2014b). Information was obtained from 14 key informants who were DM patients of more than six months, having either controlled and uncontrolled DM and receiving care from a tertiary care center or a primary health care center within the district. The themes that emerged from the analysis showed that most of these respondents depended on religious support by various means, and were of the strong view that Ayurveda or traditional treatment could cure their disease, as it may contain only natural herbs and vegetables. Most believed that 'bad karma' (unwholesome deeds) had resulted in their disease condition and prayed for better health and improvement. Most of the respondent struggled with changing food habits and exercising and were of the view that western medicine could cause long-term consequences. They believed that it would harm the body and therefore omitted or skipped medicine. This study was limited to two communities in Western Province, thus may not be generalized to all Sri Lankans. However, the findings help support the view that more researching into culturally appropriate nursing care is needed to improve the glycaemic control.

Evidence highlights the importance of taking into consideration the cultural and traditional beliefs of patients in-order to ensure compliance to healthy lifestyles.

- Evidence on the effect of different types of meals on glycaemic control of Sri Lankan is limited.

A study had been conducted to assess whether the glycaemic response would differ between white and brown rice based meals (Muthalib et al., 2014b). For this purpose, eight meals using string hoppers made of white or brown rice consumed with typical local

curries were tested among 30 healthy volunteers who were given all eight menus on different days, containing 50 g of available carbohydrates. Results showed different glycaemic index (GI) values for the same quantity of available carbohydrates of string hoppers, when eaten with various curries (Table 4.15). The study concluded that despite the popular belief that brown rice flour has a better glycaemic response than white rice flour, the response was shown to be similar for every meal, highlighting that adding vegetables would reduce the GI significantly, irrespective of the type of rice.

**Table 4.15: Meals, portion size and glycaemic index for eight meals in healthy volunteers**

Type of meal	GI % for meals mean (SD)
Brown rice flour string hoppers + beans curry	39.93 (8.14)
White rice flour string hoppers + beans curry	41.96 (9.36)
Brown rice flour string hoppers + lentil curry	44.3 (9.25)
White rice flour string hoppers + lentil curry	53.46 (9.57)
Brown rice flour string hoppers + fish curry	45.26 (9.25)
White rice flour string hoppers + fish curry	56.13 (9.94)
Brown rice flour string hoppers + coconut gravy + polysambol	50.46 (9.74)
White rice flour string hoppers + coconut gravy + polysambol	69.2 (9.47)

*Source:* Muthalib et al. Sri Lanka Journal of Diabetes, Endocrinology and Metabolism 2014b; 4: 12-16.

In another study conducted among 20 healthy volunteers to determine the GI value of commonly consumed 'idly' with side dishes, 75g digestible carbohydrate containing different combinations of selected black gram-based combined food items were administered to the same volunteers on separate days (Pirasath et al., 2013). The interpretation was that the GI values were decreased when 'idly' was given with plantain; and were increased when mixed with 'sampar'. The GI values were increased when the food was consumed with 'sampar' alone or 'sampar' and 'sambol'. The study concluded that when consuming basic traditional meals, mixing with foods with different side dishes significantly alter the GI value. This should be considered when giving dietary advice.

### c. Self-monitoring of disease control

Self-monitoring of the disease control (e.g. glycaemic control) including adherence to routine procedures (e.g. sharp disposal) also plays a major role in the self-management of long-term diseases.

- A study was carried out in a sample of 158 patients randomly selected from the DM clinic of CNTH to assess the self-management practices with regards to disposal of syringes in home settings (Atukorale et al., 2015) (abstract). 83% of the patients were using insulin for more than one year, of whom the majority had used syringes to inject insulin. Only 6% regularly checked their blood glucose level using needles/lancets. The majority (84%) injected insulin more than twice a day (>50% of them used the same needle more than six times on more than three days a week). Also, majority (98%) of the syringe users recapped the needle. A significant proportion (46%) also involved others when injecting and disposing needles. Patients disposed the used needles/pens into common household garbage bins (42%), sharps containers (6%), toilet pits (5%), garbage dumps (8%) and indiscriminately (7%). Some just collected the sharps without disposing (9.5%). Many respondents had received no information on how to dispose of their sharps, highlighting the importance of educating DM patients using insulin on proper disposal.

### d. Perception on disease progression and outcomes

Perceived knowledge on diseases and their outcomes is important for long-term disease management.

- Knowledge on the disease process is important for prevention of stroke through lifestyle modification as well as for timely health seeking behaviour in the event of warning symptoms. Patient education could be applied both at primary (in the general public) and secondary (e.g. in those at risk such as DM, HT, CVD patients) levels of prevention.
- A study by Liyanapathirana (2014) indicated that only 40% perceived their disease condition (i.e. CHD) as either 'serious' or 'very serious', while a higher proportion believed that these conditions can lead to serious complications if not treated properly. The majority (88%) believed that there is effective treatment available (88%) and they could be benefited from the currently available treatment (91.5%), but only 41.7% expressed that there is a possibility of controlling the disease without treatment.

Perception of the disease progression is found to be relatively low among CVD patients, which could adversely affect the disease outcomes.

- Oral health is an important component in health care among DM as well as CVD patients.

De Silva et al. (2015b) (abstract) carried out a clinic-based study among 427 DM patients. More than half of the respondents were aware that DM is associated with oral health, however whether more prone to oral fungal infections was known by only 15%. Oral cancer (72%) was recognized as a complication of poor oral hygiene, but the majority were unaware of its risk for endocarditis. Nearly 98% knew that diabetics should be vigilant on their oral hygiene, but only 29% believed that they should visit a dentist at least twice a year, while there was only one practising it. The majority (93%) believed that brushing teeth twice a day is important to maintain oral hygiene and 92 % claimed to do so. This study highlights the importance of targeting oral health of patients with DM in preventive programs.

#### **4.2.3.2 Service provision in healthcare settings**

Service provision in healthcare settings include the availability and access to services including costing with regards to treatment and follow-up, as well as knowledge and management practices of healthcare providers.

##### **a. Availability of the services**

The availability of pharmacological interventions may assist the management of CVD and DM. In this regard, a few studies have assessed the availability of services in relation to medication.

- With regards to the availability of essential medicines to treat NCDs, Dabare et al. (2014) conducted a country-wide survey of 109 facilities representing the public hospitals, OPD pharmacies, Rajya Osu Sala (outlets of the State Pharmaceuticals Corporation of Sri Lanka) and private pharmacies to study the availability of 50 essential medicines that are commonly prescribed in Sri Lanka for NCDs. Following a similar methodology as per the WHO Health Action International Manual (2<sup>nd</sup> edition), the availability was calculated using percentage availability, median price of originator brand (OB), lowest priced generic (LPG) and median price ratio to the international reference price (IRP). The results showed the semi-government community pharmacies to have the highest availability (>80%), while that of outdoor pharmacies of public healthcare facilities, private pharmacies and outdoor pharmacies of private hospitals was around 50-80%. In further analysis, the survey showed that Rajya Osu Sala had the highest availability (>80%) of LPG, with prices less than Rs. 10 for 62% of the surveyed drugs.

- Dabare et al. (2014) has further shown that essential medicine for NCDs were readily available in both private and public sectors and that such medicines were affordable even to the lowest income earners in the community. In contrast, Pinidiyapathirage et al. (2006) (abstract) in a sample representing all three levels of healthcare institutions (primary, secondary and tertiary) in the districts of Colombo, Anuradhapura, Monaragala and Matara demonstrated that the satisfactory availability of essential drugs of NCDs differed according to the level of healthcare (drug available in at least 75% of the institutions of a particular level) (Table 4.16). The authors suggest that this may be the reason for bypassing smaller institutions by patients and poor functioning of the back referral system in the country. They further pointed out that non-availability of these drugs cannot be explained by the inadequacy of national stocks, as this survey was done in July/August.

**Table 4.16: Availability of essential medicine used in NCDs by the level of healthcare**

Level of healthcare	Satisfactory availability	Unsatisfactory availability
I	thiazides, beta-blockers, aspirin, nitrates	benzathine benzylpenicillin, glibenclamide, prednisolone
II	methyldopa, nifedipine, beta-blockers, aspirin	benzathine benzylpenicillin, insulin (isophane/soluble), spironolactone
III	benzathine benzylpenicillin, captopril, spironolactone, methyldopa, glibenclamide, insulin (isophane/soluble), timolol eye-drops	streptokinase, inhalation steroids and salbutamol, ipratropium bromide, losartan, tamoxifen

Source: Pinidiyapathirage et al. Ceylon Medical Journal 2006; 50(S1): 46

- With regards to CVD medication, Ranaweera (2014) has shown that the supply of CVD medicines to hospitals of Kalutara District was irregular. The availability of atorvastatin, aspirin and clopidogrel was less than 50%, in contrast to the excess availability of nifedipine and GTN isosorbide dinitrates. In further studying the price fluctuations of CVD medicines in private pharmacies, nifedipine showed the highest price inflation (285%) followed by aspirin (135%) and atenolol (94.3%) with brand substitution.

The availability of NCD medication varies according to the level of healthcare. This needs to be corrected to reduce the over-crowding in larger hospitals.



As much as pharmacology related interventions, the availability of non-pharmacological interventions, such as promotion of healthy lifestyles would greatly assist in the management of CVD and DM.

- As already highlighted (refer Section 4.2.2.1), despite being aware of the importance of lifestyle modifications in the management of DM, patients show poor adherence to such practices, mainly due to lack of clarity in the information provided. There are also many myths with regards to diet, some of which have originated from healthcare professionals contributing to the poor dietary practices adopted by DM patients. These highlight deficiencies in the service provision, leading to lack of consistency in maintaining a healthy lifestyle.

Research findings prompt the strengthening of primary healthcare settings to enable patients with DM and CVD to initiate healthy lifestyles.

- Compliance to drug management and lifestyle modification of DM patients is shown to vary according to the service availability. Hendawitharana et al. (2005) (abstract) have shown that although drug compliance was best among DM patients attending a general practice, compliance to exercise was seen most among the patients attending government hospitals. In concurrence, another study conducted among 120 patients attending family practice centres and the DM clinics at CSTH showed the diabetic care to be satisfactory (Seneviratne & Gunasekera, 2005) (abstract). Furthermore, male sex, elderly age, married, better education attainment were found to be factors associated with better compliance. Those with co-morbidities including overweight, having good knowledge and attitudes, and receiving advice from the physician were found to compliant as well (Karunarathe et al., 2005).

Adequacy of the facilities to screen for complications is an important element in the long-term management of DM.

- Although microvascular complications are shown to be prevalent in substantial proportions among DM patients in Sri Lanka, Perera et al. (2015b) have shown that screening facilities for such patients offered by the state health sector is sub-optimal. The adherence to guidelines depended on the healthcare facility of follow up, sex and age of the patient. This study was conducted at NHSL among DM patients warded in a single medical unit. Those newly diagnosed or within one month were excluded. Presence of DM related complications were identified and documented (Table 4.17).

**Table 4.17: Number of patients diagnosed to have diabetes related microvascular complications compared with the proportion of the patients screened during follow up of diabetes (N=147)**

Presence of diabetes related microvascular complication	Screening performed during follow-up, No. (%)			
	Never	Occasionally	Regularly	Total
Diabetic nephropathy	9 (23.7)	11.6	18 (47.4)	38 (25.8)
Proteinuria with preserved renal function	4 (20.0)	5 (25.0)	11 (55.0)	20 (13.6)
Chronic kidney disease	5 (27.8)	6 (33.3)	7 (38.9)	18 (12.2)
Diabetic neuropathy	13 (25.0)		16 (30.8)	52 (35.4)
Diabetic retinopathy	7 (17.1)	9 (21.9)	25 (61.0)	41 (27.9)

Source: Perera et al. Journal of Diabetology 2015; 3: 1

- A study by De Silva et al. (2016b) highlighted that irrespective of the social status, DM is poorly managed by patients, resulting in several complications. This study was carried out in a sub-sample derived from a community-based study in Gampaha District, in which all detected of DM were assessed for complications. Diabetic retinopathy was diagnosed by clinical examination, while IHD was diagnosed by 12-lead ECG using the Minnesota coding system.

Of the 202 DM patients, poor control was seen in 90.7%, with 49.6% not being on regular treatment. The annual HbA1c, microalbuminuria, retinal and neuropathy screening was performed in less than 6.0. Most (76.6%) had accessed the private sector while those in estates (58.1%) accessed the state system. The microvascular complications of retinopathy, neuropathy and microalbuminuria were observed in 11.1%, 79.9% and 54.5%, respectively. Among the macrovascular diseases, angina, IHD and PAD were seen in 15.5%, 15.7% and 5.5%, respectively. These complications did not show a social gradient.

In contrast, Wickramasinghe et al. (2012) (abstract) showed in a sample from NHSL that, despite the monitoring of glycaemic status and complications being a vital part of DM management, the relevant investigations were often not performed regularly, due to poor awareness or high cost of these investigations, which are not available in the state sector. They also showed that awareness regarding HbA1c was poor.

Despite the high treatment coverage maintained in Sri Lanka, screening for complications among DM patients is at a low level.

- In response to the availability of services in the management of diabetic foot, NIROGI Paadha component of the NIROGI Lanka Project (Wijeyaratne et al., 2016) established a pioneer cohort of prosthetic and orthotic technicians, who have been trained to provide patient support in the care of diabetic foot. In this regard, 10 trained prosthetics and orthotics officers and technicians from the industry, in conjunction with the Sri Lanka School of Prosthetics and Orthotics, conducted a national-level training program for 50 other prosthetics and orthotics officers at Ragama Rehabilitation Hospital, targeting the government and private sector.

With regards to providing a low-cost service, in collaboration with a shoe manufacturer, DM-specific protective footwear were developed by the NIROGI Paada Project, addressing a major gap in service provision with regards to prevention of diabetic foot ulcers.

A major limitation in further advocating the initiative taken on providing DM foot care, is the lack of evidence on its cost-effectiveness in the prevention of DM foot ulcers and amputations in Sri Lanka.

#### **b. Access to services**

Several studies provide evidence on the access and health system responsiveness to the management of CVD and DM.

- Liyanapathirana (2014) carried out a study to describe the utilization, perceived access and health system responsiveness to the management of CVD. For this purpose, the study developed and validated two instruments initially, namely 'Access to Ambulatory Care Questionnaire for CHD' (AAQ-CHD) and Health System Responsiveness Assessment Questionnaire (HES-RAQ), both of which were proven to be valid, reliable and culturally acceptable to assess perceived access and health systems responsiveness in relation to ambulatory care service provision for CHD or selected risk factors in Sri Lanka.

According to the study findings, only 57% of those with CHD, HT, DM or dyslipidaemia had sought ambulatory care in the preceding six months. Ambulatory care was sought mainly from non-specialists (80.3%) with an almost equal percent visiting the private sector (48.4%) and government sector (51.6%) facilities. The claim that ambulatory care utilized was necessary was made by 86%, indicating high compliance and high level of realized access (utilization) to ambulatory care in the health system. Ratings of the six domains of responsiveness were relatively high ranging from 75% to about 90% 'very good' or 'good' in relation to each of the six domains, indicating good response to the non-medical

expectations of the clients of ambulatory care services for CHD or selected risk factors. As for the perceived access to ambulatory care services, the domains on availability (90.0%) and acceptability (83.4%) received high ratings by the majority, while accessibility (58.6%), affordability (58.6%) and accommodation (57.3%) received moderate ratings.

- Wellappuli (2018) carried out a study to describe the follow-up care services received, health status, unmet needs and household expenditure due to illness among stroke survivors in Western Province during the post-stroke period.

This was a cross-sectional study carried out among 502 first-ever stroke survivors recruited from all 11 secondary and tertiary care hospitals of Western Province. Information related to the essential follow-up care services received, health status and unmet needs were gathered by visiting their houses at six months in the post-stroke period by trained team medical graduates. Only 9.6 % (95% CI=6.57, 12.63) had received a 'satisfactory' level of essential follow-up stroke care services on monitoring of risk conditions. More than half (59.8%; 95% CI=54.76, 64.48) had received 'satisfactory' level of treatment services. A satisfactory level of essential stroke care services to limit disabilities had been received by only a minority (1.7%; 95% CI=0.37, 3.03). The proportions who had received a satisfactory level of essential follow-up stroke care services to prevent complications and to modify lifestyle were 5.0% (95% CI=2.76, 7.24) and 3.9% (95% CI=1.91, 5.89), respectively. None had received a satisfactory level of essential stroke care services related to social welfare.

- Based on a desk review and expert opinion (Wellappuli, 2018), the essential follow-up services to be delivered to stroke survivors in Sri Lanka were defined and incorporated into an interviewer-administered questionnaire to assess the receipt of services. Their health status was assessed by the re-occurrence of stroke, ability to perform activities of daily living, disability status, cognitive function and presence of depression. The tools used were BI, mRS, MMSE and Personal Health Questionnaire- 9 (PHQ-9), all of which were validated to Sri Lanka. Longer term Unmet Needs after Stroke (LUNS) tool was also validated among stroke survivors prior to use. Validity of the LUNS tool to assess unmet needs of the stroke survivors in the local context was confirmed through construct, and convergent and divergent validity. Further, reliability and acceptability of the LUNS and was shown to be high. Nearly half (45.18%; 95% CI=36.74, 53.46) reported seven or more unmet needs. The average unmet needs was 6.61 (SD=4.83).

The proportion who had received satisfactory follow-up stroke care services to prevent complications and to modify lifestyle was as low as 5.0%. Unmet needs after stroke are also shown to be numerous.

### c. Quality of the services provided

There is evidence to suggest that, though considerable emphasis is laid on diet and medication for preventing complications, these aspects are not adequately addressed in the follow-up of patients with DM or CVD, despite the required facilities being available to the patients (Perera & Fernando, 2008) (abstract).

- Quality of the services provided in DM clinics was assessed at NHSL among 3000 patients (Arambewela et al., 2018b). Monitoring of the BP, BMI, HBA1c and lipid profile had been performed in 95.8%, 96.5%, 59.6% and 42.3%, respectively, while none had their WC measured. As for complications, screening for retinopathy, diabetic foot and microalbuminuria was done in 89.3%, 99.9% and 31.2%. The majority of patients were on state-funded anti-diabetic agents. Only 24.3% of the young diabetics without comorbidities, 29.3% of the elderly diabetics with comorbidities and 22% of the rest of the diabetics achieved glycemic targets. Among the patients with very poor glycemic control (HbA1c >10.9%), 9.1% were on mono-therapy; 71.3% on dual therapy; and only 56.7% on insulin. The study concluded that screening for metabolic parameters and complications was high other than for HBA1c, lipid profiles and nephropathy needs to be improved.
- Quality of the services provided for HT in medical clinics was assessed in three base hospitals (BH) in Western Province (Wijemanne, 2011). Facilities available for patient care including human resources were assessed in a survey, while patient satisfaction, waiting time and the availability of supportive services were assessed through questionnaires. The survey revealed that the seating was adequate in two out of the three hospitals, while the availability of equipment and laboratory investigations was satisfactory in all three hospitals. However, despite adequate availability, in the sample of 422 patients with HT, BP was not checked in 2.8%, 6.2% and 9.9% in the three hospitals. The majority were satisfied with the frontline services (88.2%), facilities (78.8%), care given (83.1%) and time spent (86.3%), respectively. The main reasons for dissatisfaction were lack of space and seating accommodation in one hospital and poor cleanliness in the other two hospitals. In contrast, the facilities in one BH under study were appreciated by all the patients. Waiting time was prolonged due to inadequate directions given from clinic to the dispensary and laboratory; and pre-packaging of essential drugs in the dispensary. The

pre-scheduled appointment system in all three hospitals was found to have minimized the waiting time, yet has led to 39% of the patients missing out on health education, which took place at every clinic session.

Screening services for WC and psycho-social issues need to be incorporated in the care plan. Pre-scheduled appointment system should be introduced to all hospitals.

A few audits have been conducted on the hospital-based management of NCDs, and are summarized below.

- An audit in a tertiary care hospital (University Medical Unit of NHSL) compared its findings on the level of care against the clinical practice recommendations made by the Ministry of Health and the Sri Lanka and American Diabetic Association (Rodrigo et al., 2009) (abstract). In the first cycle of the audit, 224 patients were randomly included and 94 in the second round. Health care providers were educated on correct practices between the two cycles. Significant improvements were seen in care, such as patients screened with dilated fundoscopy (42.4% vs. 60.6%;  $p=0.003$ ); having cardiac risk assessments (80.8% vs. 94.7%;  $p=0.002$ ); satisfactory BP control (65.6% vs. 77.7%;  $p=0.03$ ) and prophylactic aspirin therapy (76.7% vs. 87.2%;  $p=0.03$ ). There was no improvement shown with regards to satisfactory glycaemic control and screening for nephropathy using urine full report and renal function tests.
- Another audit was conducted in a tertiary care hospital (general medical clinic at CSTH) to evaluate the quality of DM management against the standards of ADA Guidelines published in 2012 (Ratnapala et al., 2014) (abstract). The audit involving 144 patients revealed marked improvements in most management aspects, however lack of consultation time and cost of investigations were identified as major barriers for further improvements.
- Another audit was conducted in DGH Kalutara to determine the treatment time and outcomes of a sample of 69 acute uncomplicated STEMI patients following thrombolysis with streptokinase (Ranasinghe et al., 2014d). Median ischemic and door to needle times were 3 hours and 50 minutes, respectively. Only 30% achieved guideline-recommended door to needle time of 30 minutes and an optimal ischaemic time of 2 hours. Although in-hospital mortality rate was low (3%), 35% had one or more complications before discharge. Hypotension was the commonest complication (17%), while no intracranial

bleeding nor other adverse reactions to thrombolytic agent was reported. Results indicate the need for optimizing STEMI care.

- An audit in a tertiary care hospital ward setting (CSTH) on diabetic foot conditions was conducted (Siriwardana and Weerasekera., 2006) (abstract). It revealed that the standard of foot care remains low among these patients, highlighting the serious impact on the patient and family.
- An audit in a general practice (clinic in Ratmalana) assessed the process and outcomes of care in DM (Seneviratne & Gunasekera, 2005) (abstract). In a sample of 130 DM patients of more than one year, BMI, BP and foot care including neuropathy and retinopathy were found to be assessed in 100%, 100%, 96% and 64% of the patients, which was highly satisfactory. With regards to investigations, other than ECG (52%), LDL-C (68%), microalbumin (75%) and serum creatinine (59%), FBS, TC, urine albumin had been tested in over 83%. However, with regards to outcomes, only 47% had good glycemic control; 30% of the obese had achieved ideal BMI; 77% had their BP controlled; and 95% with microalbuminuria were on ACE inhibitors.

Audits conducted in hospitals point to many important health system improvements and policy implications, thus highlights the need for making audits a regular monitoring tool in hospitals.

#### **d. Costing**

With regards to costing, many studies have been carried out to look at the cost associated with the management of CVD, DM as well as related risk factors. A summary of the costing studies is given in Table 4.18.

**Table 4.18: Summary of the studies conducted to assess the management cost of CVD and DM**

Authors and year	Sample and the assessment made	Cost
Kasturiratne et al., 2005	Medical units of CNTH, Ragama	The median household cost of the total hospital stay was Rs. 852 (inter-quartile range=Rs. 351-1,885), of which 70% were due to direct costs. Median daily cost was Rs. 340 (interquartile range= Rs.165-666) in people who visited to hospital with NCDs. Only 44% of the patients incurred an indirect cost. Cost of travelling was the main contributor (36%) to the household cost. Laboratory investigations contributed by 16%.
Siriwardene & Weerasekera, 2006	Economic burden of DM patients with foot complications when admitted to hospital for foot care	Daily paid worker lost Rs 1076.36. Each family spent Rs 1811.60 during visits. The state spent Rs. 10, 102.55 during the stay.
Mihirini et al., 2010 (abstract)	Out of pocket expenditure of 117 DM patients having foot ulcers in the surgical wards of NHSL	Mean daily direct cost was Rs. 1591.53; and indirect cost was Rs. 2290.93. The mean total cost for a patient was Rs. 3,888.46 per day and this was 42.64% of the of the patients' mean monthly income. Of the total cost, direct cost was 40.93% and the indirect cost was 59.07%. Most of the patients received financial support from the spouses. The mean duration of hospital stay was 6.5 weeks.
Seneviwickrama, 2013	Household expenditure related to percutaneous trans-luminous angioplasty procedure; data collected peri-operatively during the hospital stay and at the first review visit	Procedural cost was Rs.255,916 (IQR=190,010-343,200) with 95.2% of the cost associated with surgical instruments (Median cost=Rs 250,000; IQR=Rs. 185,000-328,625)
Dabare et al., 2014	Pricing of 50 essential medicines for NCD in 109 public and private pharmacies and affordability using daily income of the lowest-paid unskilled government worker	Unit price of 76% of the surveyed medicines was less than Rs. 10.00, of which 28% cost less than Rs. 1.00. For 21 of the medicines, the median price ratio was less than one. The price of seven lowest priced generics (LPGs) was below the IRP, while the



		<p>price of originator brands (OB) for 14 medicines were five times more than that of LPGs.</p> <p>For most of the population, the generic medicine prices were affordable. Less than a single day's wage was adequate to purchase a month's supply of the LPGs of 48%. Price of 62% of the surveyed medicines was less than Rs. 10. There was no significant difference in prices between Rajya Osusala and private pharmacies, but was noted between LPG and OB.</p>
Ranaweera, 2014	Mean daily costs for patients with HT, IHD, stroke and MI	Mean daily costs were Rs. 1.65, 4.66, 4.78 and 7.27, respectively.
Liyanapathirana, 2014	Household costs and catastrophic expenses for CHD and risk factors	Household were experiencing high out of pocket expenses due to CHD or selected risk factors amounting to a high proportion of catastrophic expenses (25.3%) among the households. The median monthly out of pocket expenses for ambulatory care for CHD or selected risk factors of CHD were Rs. 1500.00 with IQR of Rs. 1600.00. The cost component reported most frequently by nearly 80% of the sample was for laboratory tests, followed by transport costs (72%) and for pharmaceuticals (45%).
Mahesh et al., 2017b	Financial burden among 270 survivors of myocardial infarct managed only with drugs in 13 hospitals in Western Province	Around 40% sought financial support for out-of-pocket expenditure. Nearly 5% were previously employed and lost their job due to illness. Of the employed, 40% had limitations of employment time. 15.4% had applied for a loan and 7.8% had sold their property. Around 19.1% had an income loss and 33.8% had to restrict usual expenses. Social support and health infrastructure were shown to have significant associations with the occurrence of financial burden.

Authors and year	Sample and the assessment made	Cost
Pallegedara, 2018	National household out-of-pocket health expenditure in Sri Lanka based on the Household Income and Expenditure Survey 2012/2013	Chronic NCD affected households appear to spend significantly higher out-of-pocket health care expenditure and encounter greater economic burden than matched control group, despite having universal public health care policy in Sri Lanka
Ranaweera et al., 2018	Economic cost of selected alcohol related diseases in Sri Lanka in 2015 (Data from the Ministry of Health, Registrar General's Department, Dep. of Census & Statistics and the National Cancer Registry; Systemic and house costs and population attributable fractions were obtained from research studies)	The estimated present value of current and future economic cost of the alcohol-related conditions for Sri Lanka in 2015 was USD 885.86 million, 1.07% of the GDP of that year. The direct cost of alcohol related disease conditions was USD 388.35 million, which was 44% of the total cost, while the indirect cost was USD 497.50 million, which was 66% of the total cost.
Wellapulli, 2018	Household expenditure among 100 stroke patients	The total household expenditure was Rs. 6,099,039 with median value of Rs. 35,000 (IQR=13,400-83,545) for the post stroke period of six months. The average cost incurred by one survivor per one month due to stroke was Rs. 10, 165

Even though free health services are available, a considerable amount of out of pocket expenditure is still incurred by people for managing CVD, DM and risk factors.

### e. Knowledge and management practices by healthcare providers

Updated knowledge of healthcare providers is the key for effective management of CVD and DM patients.

- With regards to stroke rehabilitation, Gunaratne et al. (2014) showed that although doctors had good knowledge and favourable attitudes towards it, they were not adequately competent in discharging their duties in stroke rehabilitation. More than 90% of doctors felt that the teaching they received on rehabilitation as an undergraduate was inadequate while 75% felt that they were incompetent in stroke rehabilitation. However, 86% were willing to received training in this regard.
- With regards to diabetic foot ulceration, Bandara & Corea (2010a) (abstract) showed that although majority of nurses were aware that it could be prevented, detailed knowledge required for prevention of diabetic foot ulceration was not satisfactory.
- With regards to drug prescription, Dahanayake and Lekamwasam (2005) showed that although the use of salicylates had been satisfactory in survivors of acute MI, beta-agonists were under-prescribed. Although the prescription of statins and ACE inhibitors had improved, there was still room for improvement.
- A study among 132 medical officers working in cardiology units all over Sri Lanka and those in medical wards of the NHSL assessed their knowledge on secondary preventive methods and perceived role in risk-factor prevention. As given in Table 4.19, they identified routine clinic visits and public seminar days as the most effective methods of secondary prevention, while the commonest barriers for it were poor patient knowledge, too many drugs, co-morbid conditions and cost of medication. Guidelines were the most popular method for medical education. Further, knowledge about prevention with regards to diet was inadequate and for exercise & lipids, it was adequate but not good. Knowledge on smoking cessation was much higher than for other CVD risk factors. 56 doctors in the sample had no previous training in a cardiology unit, but their knowledge did not differ by training. This study however had limitations, for example the questionnaire used to obtain data was not validated (Mathias et al., 2014).

**Table 4.19: Assessment of doctors' knowledge and barriers related to secondary prevention of CHD**

Knowledge	No. (%)
<b>Method of secondary prevention No. (%)</b>	
Routine clinic visits	85 (65%)
Public awareness day seminars	30 (22.2%)
Visits to General Practitioners	15 (11.1%)
Consultation with consultant cardiologist	3 (2.2%)
<b>Barriers to secondary prevention, Mean (SD)</b>	
Adverse effect of drugs	2.51 (1.10)
Patient adherence	3.44 (1.15)
Presence of co-morbid condition	3.68 (0.97)
Cost of medication	3.74 (0.98)
Poor knowledge/understanding of patients	3.82 (1.06)
Not enough time	2.76 (1.23)
Lack of knowledge of doctors	2.58 (1.15)
Recommendation on prevention are unclear	2.62 (1.00)
Received little or no training in prevention	2.96 (1.10)
Not interested in prevention	3.07 (1.21)
Value acute care more than preventive care	3.25 (1.26)
<b>Sources of CME, No. (%)</b>	
Research papers	42 (31.1)
Guidelines	95 (70.4)
CME	51 (37.8)
Consultation with specialist	49 (36.3)

Source: Matthias et al. BMC Medical Education 2014; 14: 113

Health care providers showed deficiencies in knowledge related to specific areas of clinical management, such as stroke rehabilitation, foot care in DM and drug prescription. These should be addressed in medical curricula and in-service training.

#### 4.2.4 Effectiveness of specific interventions

Pharmacological and non-pharmacological interventions for controlling the disease outcomes including adverse side effects have been assessed in Sri Lanka.

Inline, evidence on the following aspects is reviewed in this section.

- Effectiveness of treatment for CVD (Section 4.2.4.1)
- Effectiveness of treatment for DM (Section 4.2.4.2)
  - Pharmacological interventions
  - Plant-based interventions
- Effectiveness of screening for complications of DM and CVD (Section 4.2.4.3)
- Effectiveness of lifestyle interventions (Section 4.2.4.4)

##### 4.2.4.1 Effectiveness of treatment for CVD

Evidence is available on a few important interventions.

- In keeping with evidence-based practices derived from research done globally, the use of mortality lowering drugs in the management of MI such as beta agonists, statins and angiotensin converting enzyme inhibitors (ACEI) has increased over the years in Sri Lanka (Dahanayaka & Lekamwasam., 2005). However, local studies indicate that delays in presentation and the initiation of thrombolytic therapy and coronary interventions are the key hurdles that need to be overcome in order to optimize the management of ACS in Sri Lanka.

These observations were made in a prospective study carried out at the Professorial Medical Unit of TH Peradeniya over a period of six months (Medagama et al., 2015b) among patients presenting to the OPD with chest pain in the preceding 24 hours. Their ECG changes were compatible with acute STEMI in 32.8% and NSTEMI or unstable angina (UA) in 67.1%. The median time (IQR) from onset of pain to presentation was 60 minutes (319) for STEMI and 120 (420) for NSTEMI/UA ( $p=0.06$ ). A median delay of 240 minutes was noted in patients who had presented initially to smaller hospitals. Cardiac markers were assessed in only 35% of participants, but in-hospital anti-platelet use was as high as >92%. Only 70.2% of STEMI patients received fibrinolytic therapy, and fewer than 20% of them did so within 30 minutes of arrival. Major adverse cardiac events (MACE) were recorded in 11.9% with STEMI and 11.6% with NSTEMI/UA ( $p=0.5$ ).

- The effectiveness of sublingual nitroglycerin spray as a bridging option during the inevitable delay encountered in setting up intravenous (IV) nitroglycerin has been assessed, based on data gathered from a clinical audit at the emergency department of a tertiary care centre.

The study comprised 27 patients who required IV nitroglycerin administration following hypertensive emergencies. Their mean values of SBP, DBP and mean BP on admission were 217, 137 and 163 mmHg. At 5 and 10 minutes after sublingual nitroglycerin, the mean reduction in arterial BP was 12.3 and 16.3%, respectively. Only 2 patients (5.4%) showed an over-correction of BP. The minimum time required to set up the nitroglycerin intravenous infusion was 15 minutes. The study concluded that hypertensive emergency sublingual nitroglycerin spray is effective in reducing BP until an IV preparation is made available in Sri Lanka (Prasanna et al., 2018).

Interventions related to CVD have focused mainly on minimizing the impact of delays during the acute phase on subsequent patient outcomes.

- Evidence on the major cardiac adverse events following rescue PCI and primary PCI is provided in a study conducted at the Cardiology Unit, NHSL among patients who underwent PCI within 72 hours following STEMI, either with balloon or coronary stent implantation performed by interventional cardiologists (Rahuman et al., 2017). In the study, those who received prior thrombolysis at the first contact point for the current event underwent rescue PCI due to failed thrombolysis, while those who did not receive such prior thrombolysis underwent primary PCI. Failed thrombolysis was confirmed when there was <50% ST segment resolution in a single lead showing maximum ST elevation in the baseline ECG, persistent ongoing chest pain or cardiogenic shock.

Of the 159 patients, 78 underwent rescue PCI while 81 underwent primary PCI. Procedural outcomes and adverse cardiac events assessed after 90 minutes are given (Table 4.20). Procedural success (97.4% vs. 97.5%;  $p=0.98$ ) and mortality rates (5.1% vs. 3.8%;  $p=0.67$ ) were similar with both procedures. Also, the incidence of MACE occurred at a similar rate (7.7% vs. 12.4%;  $p=0.33$ ). Hence, the authors recommend that rescue PCI could be used as a viable option in rural areas as well, where immediate fibrinolysis can buy time until PCI could be performed in the patients. However, this was a single centre study, with no randomized control design. Also, the study centre consisted of skilled medical officers, thus the generalizability of findings to other institutions in the country is questionable.

**Table 4.20: Procedural results according to PCI procedure (primary or rescue) in patients**

Characteristics	Rescue (n=78)	Primary (n=81)	p value
<b>Procedural outcomes</b>			
• Stenting completed	75 (96.2%)	75 (92.6%)	0.33
• Stent length	21.92 (7.26)	22 (7.50)	0.64
• Stent diameter	3.69 (1.01)	3.83 (1.21)	0.43
• Thrombolysis in myocardial infarction	76 (97.4%)	79 (97.5%)	0.97
• Final diameter stenosis	3.04 (0.27%)	3.05 (0.26)	0.83
• Haematoma	1	1	0.98
<b>Major adverse cardiac event (MACE)</b>	6 (7.7%)	10 (12.3%)	0.33
• Emergency bypass	0 (0%)	0 (0%)	-
• Target vessel revascularization (TVR)	0 (0%)	3 (3.7) *	-
• Heart failure	1 (1.3%)	1 (1.2%)	0.99
• Re-infection	1 (1.3%)	3 (3.7%) *	0.33
• Death	4 (5.1%)	3 (3.8%)	0.67

\*One patient had both a re-infarction and TVR

Source: Rahuman et al. Indian Heart Journal 2017; 69(S1): S57-S62

Secondary interventions on PCI have been tested in CVD that could be used to buy time until the primary interventions are provided.

- Ayurvedic medicines have been tested on their use along with atorvastatin in the management of dyslipidaemia.

Swastha Triphala<sup>®</sup> is one such preparation containing three herbs, namely Terminalia chebula 318 mg, Terminalia bellerica 105 mg and Phyllanthus emblica 211 mg. This, taken along with atorvastatin 10mg has been found to be more efficient than taking atorvastatin alone (Ekanayaka et al., 2017). This evidence is based on a randomized, double-blind and parallel arm clinical trial conducted among patients aged 35-70 years. The quality of this trial is satisfactory, with the inclusion of a placebo control, parallel allocation and allocation concealment. Results revealed (Table 4.21) that the reduction in TC and TC/HDL-C was significant ( $p < 0.0001$ ) in the treatment group (atorvastatin and Swastha Triphala<sup>®</sup>) compared to the control group (atorvastatin and placebo caplets) that showed a negligible reduction in TC ( $p = 0.28$ ) and increased TC/HDL-C. The decrease of both values was significantly greater ( $p < 0.0001$ ) in the treatment group than in control group.

**Table 4.21: Summary of the laboratory findings of patients tested on Swastha Thriphala**

Component of primary composite endpoint	Mean difference at 3 months and at recruitment		p value
	Treatment group	Control group	
Total cholesterol (mg/dL)	-22.00	3.12	<b>&lt;0.0001</b>
HDL-C (mg/dL)	-0.12	1.66	0.36
LDL-C (mg/d/L)	-2.52	2.74	0.06
Total non-HDL-C (mg/dL)	-21.88	6.06	<b>&lt;0.0001</b>
Triglyceride (mg/dL)	-3.57	4.81	0.12
Total cholesterol/ HDL-C	-0.42	0.18	<b>0.01</b>
HS-CRP (mg/dL)	-0.02	0.77	0.17
AST (IU/L)	-0.70	-1.00	0.55
Fasting blood glucose (mg /dL) *	0.00	0.00	1.00
Creatinine (mg/dL)	-0.01	-0.01	0.86
ALT (IU/L) *	-0.02	0.01	0.25
Alkaline Phosphatase (IU/L) *	0.05	0.04	0.65
Gamma GT (IU/L) *	0.02	0.03	0.82
Bilirubin (mg/dL) *	-0.02	0.05	0.09

\* Parameters transformed to log scale to achieve normal distribution. HS-CRP=highly sensitive C reactive Protein; AST=aspartate aminotransferase; ALT=alanine aminotransferase; HDL=high density lipoprotein; LDL=low density lipoprotein

Source: Ekanayaka et al. Ceylon Medical Journal 2017; 62: 128-140

Swastha Thriphala® is found to be more efficient than taking atorvastatin alone in the reduction of TC and TC/HDL-C.

- Many studies have highlighted the importance of taking into consideration the adverse drug reactions when looking at the effectiveness of drugs prescribed for NCDs.

Lelwela et al. (2017b) and Wijekoon et al. (2017b) showed that the incidence of adverse drug reactions was high among patients with NCDs, of which a large proportion comprised serious adverse events. They showed that the reactions that required re-hospitalization were caused by widely used drugs and were potentially avoidable. Factors associated with a higher incidence of reactions were age  $\geq 65$  years,  $\geq 5$  drugs in the prescription and presence of DM.



- Ekanayake et al. (2018) states that resistance to aspirin and clopidogrel is 17.3% and 68.8% in the Sri Lankan population with stable CAD. In this regard, dual antiplatelet therapy appeared to be associated with least resistance, as the responder rate is double than with aspirin or clopidogrel alone. However, the cause for high resistance to clopidogrel is unknown and needs further research.
- Inflammatory status influences the biochemical response to diet, suggesting an additional mechanism for increasing the coronary artery risk. Thoradeniya et al. (2012) (abstract) showed that nutrition counselling was effective in reducing TC and LDL-C as well as increasing serum folate in women without CAD having a low baseline inflammatory status. Authors suggest that the hindering effect of underlying inflammation on the biochemical response to dietary modification, should be considered in dietary interventions in CAD risk reduction.
- Streptokinase is the main thrombolytic used for the management of STEMI in Sri Lanka. A study was conducted to assess the efficacy of streptokinase in restoring myocardial perfusion following acute STEMI among 108 patients, in which 56% responded to streptokinase in relation to the pattern of ST elevation (44.4% of anterior STEMI; 72.7% of inferior STEMI; and 13.3% of antero-lateral STEMI). In further analysis, the response to streptokinase differed by the type of infarction (anterior vs. inferior STEMI ( $p=0.007$ ); anterior vs. antero-lateral STEMI ( $p<0.001$ ); and antero-lateral vs. inferior STEMI ( $p<0.001$ )), highlighting the significantly higher reperfusion rates with inferior myocardial infarctions. Further, delayed hospital admission had a major impact on non-response to treatment (137 minutes from the onset of pain to arrival at hospital in responders compared to 339 minutes in non-responders) (Gurugama et al., 2012).

#### 4.2.4.2 Effectiveness of treatment for DM

Pharmacological interventions are the main stay of treatment for DM in Sri Lanka. However, plant-based drugs have also been tested, with evidence generated on their effectiveness.

##### a. Pharmacological interventions

There is limited evidence on the pharmacological interventions of DM.

- Katulanda et al. (2012c) (abstract) showed that sitagliptin therapy leads to a significant improvement in the glycaemic control of Sri Lankan patients who have failure of conventional oral hypoglycaemic drugs and is useful in delaying insulin therapy.

- It is shown that the 2-hour post-prandial blood glucose response is significantly related to the pre-snack blood glucose value, but not to the type of fruit used in snack. De Abrew et al. (2015a) in their study compared the 2-hour post snack blood glucose response to selected fruits of similar ripeness. banana, papaw, mango, star fruit, and dragon fruit. Multivariate analysis found this response to be significantly related to the pre snack blood glucose value, anti-diabetic treatment and HbA1c value, of which the pre-snack value was identified as the most important predictor of post- snack blood glucose value ( $r=0.65$ ).

It is evident that the pharmacological management of DM, though it entails long-term administration, would positively benefit those with low activation, if received consistently over time (Aung et al., 2014).

- In line, pharmacological drugs are widely prescribed in the management of DM. However, prospective observational data from patients show that the occurrence of adverse drug reactions is quite traumatizing. Based on local evidence, it is shown that most of the patients with NCDs had required re-admissions, while the most common adverse drug reactions for re-hospitalization had been hypoglycemia due to anti-diabetic drugs, and hypotension due to anti-hypertensives (Lelwela et al., 2017b). According to another study (Dissanayake et al., 2018) among 1000 DM patients attending a private sector clinic, 26.1% (mild- 20.7%, moderate- 3.9%, severe- 1.5%) experienced symptomatic hypoglycaemia. Sudden change in diet (46.7%), unaccustomed exercise (15.7%) and increase in anti-hyperglycaemic therapy dosage (14.9%) were the recognized causes. Interestingly, non-prescribed native food items accounted for it in 16.9%. Severity of hypoglycaemia was positively correlated with age and duration of DM. Hence, these observations should be taken into consideration in the management of DM.

Though widely administered, pharmacological treatment is shown to have issues related to adverse events. In this regard, attention should be paid to establishing monitoring mechanisms in clinic set-ups and providing patient education for self-monitoring of medication.

- Studies have been carried out to look at different ways in which drug compliance among DM patients could be improved.

Receiving extra support has been shown to enhance drug compliance. In concurrence, a randomized control trial carried out among 800 patients with DM has shown that pharmacists' counseling improved the patient compliance, their glycaemic control as well as their knowledge (Mamunuwa et al., 2018) (abstract).

Jayasinghe et al. (2015) (abstract) studying 306 DM patients on achieving optimal BP with anti-hypertensives highlighted that among the 90 patients who were on anti-hypertensives, the use of ACE inhibitors or Angiotensin receptor blockers was 29.4%, while the majority (64.1%) were taking one antihypertensive drug (25.9%) and the rest, 2, 3 and 4 drugs (7.5%, 2.5%), respectively. Of them, 42.2% were sub-optimally controlled (BP>130/80 mmHg), suggesting that multiple drug regimens could reduce the compliance of patients.

In concurrence, another study (Amarasekara et al., 2015a) conducted on glycaemic control behaviour in a sample of 230 patients having DM for more than six months and visiting a teaching hospital or primary care centre in Colombo District for the first time revealed that most participants had not achieved the recommended FBS <126 mg/dL, although 77% of them claimed that they had adhered to regular medication. The authors presume that this could be a result of poor compliance to lifestyle modifications along with drug management.

There is a need for adopting new strategies in patient education, in order to enhance drug compliance of patients, such as pharmacists' counselling.

#### **b. Plant-based interventions**

During the past decade, a substantial number of studies has been carried out locally to assess the pharmaco-dynamic properties of plant extracts in the prevention and treatment of DM.

- Studies have shown that polyphenolic compounds have a role to play in the antioxidant capacity of medicinal plant extracts (Attanayake et al, 2015). The phenolic extracts of Bael (*Aegle marmelos*) flower too has notable inhibitory activity against hydroxyl and peroxy radical-induced DNA scission and LDL oxidation. The authors suggest that this knowledge

be used in the preparations of herbal drinks made of Bael flower extracts to prevent NCDs (Chandrasekara et al., 2018).

Anti-oxidative properties of plant extracts could also be used to control hyperglycaemia. The plant *Aronia melanocarpa* or black chokeberry was found to be a good source of antioxidants, which was effective in preventing hyperglycaemia induced oxidative stress (Banjari et al., 2017).

- Studies have also proved the inhibitory effects of *Costus speciosus* (COS) leaves on  $\alpha$ -amylase and  $\alpha$ -glucosidase activities, fructosamine formation, protein glycation and glycation-induced protein cross-linking, thus proving that these leaves could be used not only for its hypoglycaemic properties but also for slowing down protein glycation (Perera et al., 2016a).

Bandara et al. (2009a) have also shown that *Gymnema Lactiferum* leaves could significantly reduce FBS, cholesterol, LDL-C and PPBS.

- Many studies have been carried out in animals and trials to assess the efficacy of *Salacia reticulata* (Kothala himbutu) as a management option for DM and obesity. Although a larger evidence base is required from well-planned studies to confirm its efficacy, a review of literature by Medagama (2015a) on the effectiveness of *Salacia reticulata* on DM and obesity, shows that it effectively improves insulin resistance, glucose metabolism and reduces obesity. Another review on the current evidence found on cinnamon in improving the glycaemic targets in animal models and humans concludes that, although cinnamon has the potential to be a useful add-on therapy in the discipline of integrative medicine in managing DM, the current evidence is inconclusive and that long-term trials aiming to establish the efficacy and safety of cinnamon should be carried out. He further states that *cinnamomum cassia* is of concern owing to its high coumarin content, but not the *cinnamomum zeylanicum*, which could be a safer alternative in the management of DM.

Even though herbal preparations have been widely researched upon in the management of DM, Medagama et al. (2015a) have also pointed out that the regulation of sale, provision of key safety information and reporting of adverse events of these products should be a priority, as key safety information was absent in most products.

- Perera et al. (2017) have confirmed the presence of gallic acid, ellagic acid and umbelliferone in *Syzygium cumini* bark decoction, which are proven to have anti-diabetic activities. These properties have been demonstrated by them in a ready-to-serve herbal drink prepared with the decoction.

Decoctions prepared with medicinal plants having antiglycation and antioxidant properties have the therapeutic potential in preventing DM complications, as non-enzymatic protein glycation and oxidative stress are the key molecular basis of the macro- and micro-vascular complications observed in chronic DM. Perera et al. (2015c) analysed the decoctions of five anti-diabetic plants, namely *Syzygium cumini* bark, *Mosbeckia octandra* leaf, *Phyllanthus emblica* fruit, *Cassia auriculata* flower and *Scoparia dulcis* whole plant, and found that the first three decoctions had significantly high antiglycation potential ranges with correspondingly high anti-oxidant potentials and total phenolic contents.

- The hypoglycaemic activity of mushrooms has been documented (Jayasuriya et al., 2015a) in relation to *Pleurotus ostreatus* and *Pleurotus cystidiosus*, which are proven to exert significant hypoglycaemic effect in healthy volunteers challenged with glucose, and in DM patients on diet control. Mushrooms are neither hepatotoxic nor nephrotoxic, hence this study confirms the suitability of both types as a functional food for DM patients. The freeze dried suspensions of mushrooms exert their oral hypoglycaemic activity via several possible mechanisms viz; increasing the glucokinase activity and promoting insulin secretion and thereby increasing the utilization of glucose by peripheral tissues; and inhibiting glycogen synthasekinase, and thereby promoting glycogen synthesis.
- Rooibos tea (*Aspalathus linearis*) has been shown to prevent the onset and progression of DM through its effect on reactive oxygen species, catalas and superoxide dismutase through in-vitro studies that have been carried out (Waisundara & Hoon, 2015).
- Glycation inhibitors and glycation reversing agents are important in therapeutics to reduce the progression of DM related complications. Studies carried out by Premakumara et al. (2014) (abstract) have shown that all parts of *Salacia reticulata* possess anti-glycation and glycation reversing agents, which could attribute in this respect. Wijayabandara et al. (2017) have also shown that *Aberrhoa carambola* (star fruit) contains scopoletin, which is responsible for the anti-hyperhlycaemic effects caused by this fruit. The leaves of *Passiflora suberosa* L (Family: Passifloraceae; common name: wild passion fruit, devil's

pumpkin) used in Sri Lankan traditional medicine for treating DM has been shown through in-vivo studies, which could be used to manage blood glucose and cholesterol levels (Sudasinghe & Peiris, 2018).

- The evidence available from experimental studies and clinical trials supports the suggestion that the modulation of the intestinal microbiota by probiotics in functional drinks may be effective towards prevention and management of DM.

A review was carried out by Perera et al. (2016b) to appraise the current literature on probiotic bacteria for controlling blood sugar and preventing DM, with the aim of producing a functional drink. The review indicated that the probiotics *Lactobacillus acidophilus* and *Bifidobacterium animalis* may have health benefits in patients with DM. This identification of the most appropriate strain for the intervention is beneficial, as the efficacy of probiotics is directly linked to the type of strain used.

The subsequent interventional study has shown that daily consumption of 200 ml of a shake containing  $4 \times 10^8$  CFU/100 ml of *Lactobacillus acidophilus*,  $4 \times 10^8$  CFU/100 ml of *Bifidobacterium bifidum* and 1 g/100 ml of fructooligosaccharides results in blood glucose reduction of DM patients. Probiotic bacteria, which is facultatively anaerobic and microaerophilic is encapsulated and inoculated to the functional drink. Thus, after ingestion the probiotics become active in the existing optimal temperature around 37°C, withstanding the conditions of the gastrointestinal tract.

- It is shown that porridge made with *Scoparia dulcis* (SDC) leaf extract decreases FPG and HbA1c ( $p > 0.05$ ) of DM patients, but does not have any effect on cholesterol measurements. Since no toxicity was observed at the dose tested, this porridge can be recommended as a suitable meal for diabetic patients (Senadheera et al., 2015).
- The use of household ingredients as complementary medicine is commonly practised in Sri Lanka. Medagama & Senadhira (2015) have observed that, though frequently used by DM patients, only a few herbal remedies and their methods of preparation have been tested for efficacy in Sri Lanka.

Strong evidence is available on the hypoglycemic potential of several plant-based therapies. Such benefits however need to be further explored against adverse events on other organs.

#### 4.2.4.3 Effectiveness of screening for complications of DM and CVD

Screening for complications is the mainstay secondary preventive strategy to prevent/delay patients moving to disabilities following poor disease outcomes.

- A cross-sectional study was carried out in a single medical unit at the NHSL among DM patients of more than one month duration, to evaluate the adequacy of screening for complications during clinic follow-up (Perera et al., 2015b). Of the 147 patients, 65.9% had been followed-up, during which 90.5% claimed to have undergone patient education. Patients who had been followed-up at the NHSL had received better microvascular complication screening (Table 4.22).

**Table 4.22: Relationship of the presence of DM related microvascular complications and screening frequency**

Presence of microvascular complication	Screening performed during follow-up, No. (%)			
	Never	Occasionally	Regularly	Total
Diabetic nephropathy	9 (23.7)	11 (28.9)	18 (47.4)	38 (25.8)
Proteinuria with preserved renal function	4 (20.0)	5 (25.0)	11 (55.0)	20 (13.6)
Chronic kidney disease	5 (27.8)	6 (33.3)	7 (38.9)	18 (12.2)
Diabetes neuropathy	13 (25.0)	23 (44.2)	16 (30.8)	52 (35.4)
Diabetes retinopathy	7 (17.1)	9 (21.9)	25 (61.0)	41 (27.9)

Diagnoses were made: diabetic retinopathy following slit lamp examination; neuropathy if sensory modalities of pressure, vibration or pain were either impaired or absent in one or both feet; nephropathy with presence of microalbuminuria (>20 mg/l), macroalbuminuria or renal impairment (serum creatinine >1.5 mg/dl); IHD by a history of ACS, stable angina or being on IHD treatment, and the new cases based on 12-lead ECG abnormalities or elevated cardiac markers; stroke by a history of sudden onset neurological deficit or TIA detected by physician

*Source:* Perera et al. Journal of Diabetology 2015; 3: 1

According to the multivariate regression, the follow-up at non-NHSL was significantly associated with poor screening of almost all complications. Although this study provides good quality data, whether the non-NHSL groups exclusively included those attending local hospitals or general practitioners is not clear. Also, the adequacy of screening has not been tested against the frequency prescribed in the currently practised guidelines in Sri Lanka.

- The yield of rare complications of DM identified through screening has been estimated, in order to consider the suitability of incorporating such tests for poorly controlled DM patients.

Karuppiah et al. (2018) carried out a prospective study to estimate the prevalence of cushing syndrome in a cohort of 287 overweight (BMI  $\geq 27$  kgm<sup>-2</sup>) patients with HT (BP  $\geq 140/80$  mmHg or on anti-hypertensive medication) and poor glycaemic control (HbA1c  $\geq 8\%$ ), attending the DM clinic at NHSL. Overnight Dexamethasone Suppression Test (ODST) was used to test for cushing syndrome. Further, patients who failed to suppress serum cortisol less than 50nmol/l were re-tested by low dose dexamethasone suppression test. Basal ACTH levels and imaging studies with pituitary MRI, abdominal CT or CT scan of chest abdomen and pelvis were also performed. 46.2% patients failed to suppress cortisol to less than 50nmol/l on ODST, while 39.1% (n=9) patients had cortisol more than 140 nmol/l on midnight cortisol test, confirming true CS. Imaging studies revealed one with pituitary adenoma and one with adrenal adenoma among them. The prevalence of definitive cushing syndrome identified among poorly controlled DM patients with HT and obesity suggests that it is not rare as suggested previously, however the evidence is not conclusive to recommend screening of DM patients.

- Ruwanpathirana et al. (2018) (abstract) carried out a study to evaluate the effect of DM duration on the alteration of FPG, serum creatinine and urinary microalbumin levels among 98 patients attending the diabetic centre at TH Jaffna. Patients with known evidence of chronic kidney disease were excluded. Results showed that with the increase in duration of DM, FPG ( $r=0.25$ ), serum creatinine ( $r=0.1$ ), random urine albumin ( $r=0.35$ ) and urine albumin to creatinine ratio ( $r=0.43$ ) increased. Further, with the increase in the duration of DM, patients had macroalbuminuria rather than normal- or microalbuminuria. However, the study failed to quantify if the patients recruited were adequately controlled. Hence, whether these findings would hold true even in well-controlled patients with DM is questionable.



- Agreement between the specialists and non-specialist on the follow-up decisions related to retinopathy has been assessed.

Wijesinghe et al. (2013a) studied a cohort of 658 DM patients randomly recruited from the Sri Lanka Young Diabetes Study (SLYDS). They were examined by a group of non-specialist doctors (by direct ophthalmoscopy after mydriasis) against another group of specialists (by slit lamp biomicroscopy). Both groups were blinded to others' findings. The agreement between non-specialists and specialists in relation to retinopathy grading (according to the International Clinical Diabetic Retinopathy Disease Severity Scale) and follow-up decisions was assessed. Specialists identified 123 (18.7%) with retinopathy and 54 (8.3%) as requiring early referral. Exact agreement between the two groups for detecting retinopathy was 0.82 (Kappa=0.48;  $p<0.001$ ) while the agreement in diagnosing the grade was 0.76 (Kappa=0.347;  $p<0.001$ ). Against the specialists, non-specialists detected retinopathy with a sensitivity and specificity of 0.68 and 0.86, respectively. Exact agreement on the follow-up decision was 0.92 (Kappa=0.48;  $p<0.001$ ), with 0.52 sensitivity and 0.96 specificity for early referral.

Adequate screening of complications, follow-up decision making, and the yield of tests are shown to be crucial in secondary prevention. However, the long-term benefits of screening in terms of morbidity or survival need to be further explored.

#### 4.2.4.4 Effectiveness of lifestyle interventions

It is of utmost importance that DM patients adhere to lifestyle modifications along with pharmacological treatment, in-order to reap the benefits of the management therapy to its fullest. Evidence is scarce on trials carried out on interventions targeting patients with DM.

In developed countries, DM management guidelines recognize the importance of self-management and the role of patient. It is essential that the management of a chronic condition such as DM adopts an approach that addresses patient goals, priorities and lifestyle as well as their illness.

- Karunapema (2007) carried out a cluster randomized trial (n=190) in a rural area in Gampaha district to evaluate the effectiveness of a lifestyle intervention aimed at preventing DM in a high-risk IFG group. Compared to the control group, intervention group demonstrated a significant reduction in FPG ( $p<0.01$ ); weight ( $p=0.03$ ), SBP ( $p=0.03$ ), DBP ( $p=0.01$ ), added sugar ( $p=0.03$ ) and fat consumption ( $p<0.01$ ); and a significant

improvement in all physical activity domains except leisure time activity ( $p < 0.01$ ). In addition, there was improvement shown in the intervention group in relation to insulin sensitivity, higher conversion to normoglycemia (43.6% vs. 36.8%) and lower conversion to diabetes (5.9% vs. 13.7%), but none of these was significant. This intervention was conducted via utilization of the existing public health system, and therefore the findings can be applicable to Sri Lankan settings.

- Dabrera et al. (2018) carried out a cluster randomized controlled trial to change diet, physical activity, smoking and alcohol consumption among people having DM through funeral societies. In Ragama MOH area, 21 administrative sub-divisions were randomized into intervention and control groups, in addition to another control group recruited from 10 administrative subdivisions in North Western Province. The study showed only a modest, non-significant increase in the proportion of people consuming five servings of fruits and vegetables or more per day. Of the other outcomes, their intake of green leaves and mean MET minutes spent on leisure activities increased significantly more in the intervention group than in the control groups, but the differences were small.

Despite lifestyle modification being an integral part in DM management, only a few patients achieve the given targets following interventions related to lifestyle.

- Jayasuriya et al. (2015b) carried out a randomized control study to look at the effectiveness of an intervention to improve self-management of patients having DM. Patients were recruited from CNTH who were aged 40-60 years; on regular medication; having DM of less than five years; and attending the clinic for the first time with an HbA1c  $> 7.5\%$ . They were randomized into treatment ( $n=43$ ) and control ( $n=42$ ) groups. The control group continued to attend the regular monthly clinic at CNTH, while the intervention group was in addition followed-up at primary care clinic located in the University of Kelaniya. The intervention was developed based on behavioural theory and implemented as face to face interviews by nurses. At 6 months, there was a significant difference ( $p=0.001$ ) in HbA1c between the two groups after controlling for baseline values. Further, 28% in the intervention group achieved the target value of 6.5% HbA1c, compared to only 8% in the control group ( $p < 0.001$ ;  $p=0.65$ ). The reduction in total energy intake and increase in physical activity from the baseline was significant in the intervention group.

The study claims to have limited any contamination of the intervention, by recruiting the two groups from different locations (though this contradicts with the randomization procedure adopted in the study) and requesting them to visit the facilities on separate days with separation of research personnel to the maximum extent possible. Another limitation of the study was that it did not measure medication compliance. While the intervention arm nurses stressed on the importance of regular medication, no goals were set on ensuring regular supplies of medication and compliance to medical treatment. The study demonstrated the feasibility of using DSM within existing care arrangements. However, more representative studies should be carried out in the country to include both urban and rural sectors.

- Jayawardena et al. (2017b) has developed a model plate diet for facilitating dietary changes in DM patients. However, the effects of this intervention on cardiometabolic risk factors in patients with ACS have not yet been assessed (Figure 4.9).

**Figure 4.9: Illustration of model plate diet**



Source: Jayawardena et al. *Trials* 2017; 18: 314

- Snacking between main meals, which is common among Sri Lankans has been shown to impair the glycemic control of DM patients (Naser et al., 2014a). This was evident in a study conducted at TH Peradeniya among 10 healthy individuals and 10 well-controlled DM patients aged between 20–70 years. Patients were all given 15 different types of snacks (biscuits and other snacks in usual portion sizes) on 15 different days with one week interval. As for controls, 25 g of glucose was given on a separate day. Postprandial plasma glucose was measured three hours after consuming a snack and at 30 minute intervals up to 3 hours.

The food items that gave highest and lowest mean glycaemic response in controlled DM one hour after consumption were a slice of papaw and two kurakkan crackers respectively, while the corresponding food items in the controls were roasted bread and kurakkan crackers. Consumption of all snacks by DM patients showed significantly higher glucose value in one hour than in the controls, while it was higher for all snacks except yoghurt in the controls in 120 minutes.

Novel non-pharmacological interventions have been developed as aides to change the dietary behaviour of patients. These need to be further tested using experimental designs on their beneficial effects.

### 4.3 Tertiary prevention of CVD and DM

Rehabilitation following complications of DM and CVD is the mainstay of treatment in tertiary prevention.

- Weerasinghe et al. (2011) (abstract) carried out a study to identify the factors associated with non-adherence to home-based exercise program prescribed by the rehabilitation therapists for stroke patients discharged from hospital. This cross-sectional study recruited 100 patients diagnosed of stroke attending the monthly follow-up clinic of Stroke Unit and the department of physiotherapy of the Neurology Unit at NHSL. The study population consisted of two groups: compliant (n=50) and non-compliant (n=50) patients. The non-compliant group demonstrated a significantly higher education level ( $p=0.03$ ), negative perception score ( $p=0.006$ ) and higher fatigue ( $p=0.029$ ) compared to the compliant group. A significant difference was also not observed regarding the ability to perform activities of daily living. There was no correlation between the duration since stroke and non-compliance to home-based exercises.
- Hamsanathy et al. (2015) carried out a hospital-based study among 270 first-ever post stroke patients at six-month follow-up at the stroke clinics of NHSL. The study showed that a very high proportion of unmet needs were present among these patients. The study recommended the following as potential tertiary interventions: early review and detection of post stroke psychological problems through mood assessments; encourage diet and exercise; convey information on post-stroke care to relatives through a booklet; and provide social support in collaboration with the Department of Social Services.

- Ruberu et al. (2012) carried out a retrospective study to identify the factors that determine post-stroke functional outcomes and patients' discharge destination, following rehabilitation. The study participants consisted of 426 stroke patients admitted to a rehabilitation centre following ischaemic or hemorrhagic stroke, in whom 68 variables were analyzed using partition modeling to identify the significance of variables. The mean length of rehabilitation of stroke survivors was 48.36 days. Prior to stroke, majority of the patients were residing at home, of whom 80% returned back home following their rehabilitation, which was 45.22 days in average length. A significant difference was noted in the total functional independence measure (FIM) for patients who were discharged home compared to those discharged to high level residential care ( $p < 0.001$ ) or to low level residential care ( $p = 0.05$ ), and also for those discharged to low level residential care compared to high level residential care ( $p = 0.004$ ). Among patients obtaining FIM score  $\geq 77$ , carer support and age less than 77 years were associated with returning home, while these factors among patients obtaining FIMS of 36-77 were carer support and age less than 82 years. High level of residential care was predictable, with age more 82 years, length of stay in acute hospital of  $\geq 14$  days and FIM for upper body dressing of  $< 5$ .

An important aspect of the effectiveness of long-term management of a chronic disease condition is improved quality of life.

- A study was carried out to assess the health related quality of life (HRQOL) of stable CAD (Seneviwickrama, 2013). Newly validated Mac New Heart disease specific HRQOL and the validated WHO QOL-BREF questionnaire were applied on 260 CAD patients, to assess the impact of coronary angioplasty using percutaneous transluminal coronary angioplasty (PTCA) on their HRQOL three months after the procedure. The study concluded that there is a clinically and statistically significant gain in HRQOL following PTCA in stable CAD. However, variation in HRQOL was observed in sub-groups of people, for which demographic, socioeconomic and clinical and disease related correlations were identified.

Studies assessing the survival following medical interventions are scarce.

- A retrospective study was carried out to determine the survival of patients treated with PTCA following ST segment elevation. Participants were those diagnosed with STEMI and treated with PTCA in a private hospital in Colombo District (Abey Suriya et al., 2013) (abstract). Secondary data were collected from medical records and wherever relevant from the next of kin on their survival status, cause and date of death. Data of 197 patients

were obtained (77.7% males). Results showed that 11.7% had died due to all- cause mortality and 6.6% due to CVD, while 82.7% (95% CI=77.9, 90.5) of patients survived for 3 years. Based on Cox Proportional Hazards model (adjusted), the site of arterial occlusion (proximal vs. distal segment of LAD) (hazard ratio=10.98; 95% CI=1.096, 110.205) was significantly associated with poor survival of patients, after controlling for other risk factors. Low ejection fraction, not on regular medication and delay of more than 3 hours between onset to door time were significantly associated with poor long-term outcome of patients who had coronary artery involvement other than the LAD artery.

A few studies have attempted to predict mortality following CVD using different parameters.

- Though NAFLD is known as an independent risk factor for CAD, its effect on the severity of ACS is not clear. In this regard, a descriptive study conducted among 120 non-fatal ACS admitted to CSH showed that NAFLD (identified based on liver scans) was present in 46.7% (Perera et al., 2016c). Such patients had ACS in greater severity (as predicted by Global Registry of Acute Coronary Events (GRACE) Risk Score) compared to those without NAFLD (120.2 vs. 92.3) ( $p < 0.001$ ). This reflected NAFLD having a higher predicted mortality risk for ACS during in-ward stay (aOR=31.3; 95% CI=2.2, 439.8) and at 6 months after discharge (aOR=15.59; 95% CI=1.6, 130.6), highlighting the requirement for aggressive treatment of CAD.
- Another study conducted among 348 patients admitted with ACS (refer Section 3.2.3), the physical activity levels did not affect the severity of ACS (assessed by Thrombolysis in Myocardial Infarction (TIMI) Scores) ( $p=0.24$  for NSTEMI/UA;  $p=0.1$  for STEMI) (Matthias et al., 2018). In multiple regression analysis, physical inactivity, age and sex and BMI did not significantly predict the TIMI score.

Studies on long-term outcomes of stroke and CVD patients are sparse. Studies on survival and quality of life of survivors need to be identified as a research priority.

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**Key studies on knowledge, attitudes and self-management practices in the management of CVD and DM**

Author and Year	Objective	Methods	Study findings
Bandara et al., 2009b (abstract)	Knowledge of DM patients on foot care	128 patients admitted to general surgical wards in GH Kandy	Only 55% patients attended the monthly clinic regularly; 40% knew that DM has multi-organ involvement; 44% knew that wounds heal poorly and can become serious in DM; 39% knew that proper foot care was very essential; 38% knew that good glycaemic control can prevent DM complications; 42% used footwear but only 35% had cut their nails; only 18.7% had done a daily inspection of the feet. In 29%, ulceration was due to minor preventable trauma.
Jinadasa et al., 2009 (abstract)	To determine the knowledge and practices on foot care	110 patients with foot ulcers	82.7% of the sample had non-healing ulcers and 38.2% had amputations. 95.5% were aware of the occurrence of foot complications, out of which 76.4% were aware of the risk factors and 88.2% were aware of the complications. 75.5% had scored more than the mean knowledge. With regards to foot care practices, 47.3% had a score below the mean.
Amarabandu & Hewage, 2017 (abstract)	To determine the preventive measures followed by DM patients attending the Primary Medical Care Unit in Yatiyana to minimize foot ulcers	330 patients	62.1% had good glycemic control. However, 60.3% had poor foot care practices. 83.6% washed their feet regularly but only 32.1% washed feet with warm water; 54.8% did not properly dry their feet; 75.8% did not use any moisturizing cream on their feet; 57.3% did not inspect their feet regularly; 63% did not trim their nails straight across; 58.5% did not wear correctly fitting foot wear; 77.3% elasticized hosier; 58.2% did not walk barefoot.
De Silva et al., 2015b (abstract)	To assess the knowledge, attitudes and practices regarding oral health among patients at the DM clinic at CSTH	427 patients	56% recognized the association between DM and oral health. Only 15% knew they were more prone to oral fungal infections.  Although 72% knew that oral cancer was a complication of poor oral hygiene, majority were unaware of the risk of endocarditis. Nearly 98% believed that they

			should be more vigilant on oral health. Although 29% believed that a dentist should be visited twice a year, only one person practised this.
Niruththan et al., 2011 (abstract)	To determine the secondary preventive care practices on common complications among DM patients attending medical clinics at TH Jaffna	203 patients	Preventive care practised in medical clinics were annual eye examination (74.4%), foot examination (66%), screening for microalbuminuria (61.6%), screening for LDL level (78.8%), statin therapy (74.9%) and aspirin therapy (65.5%).  Only 4.4% of the participants were screened for HbA1c. The adherence to preventive care practices were associated with age and duration of DM ( $p<0.05$ ). Diagnosed nephropathy and neuropathy were associated with poor secondary care practices ( $p<0.05$ ).
De Silva et al., 2010a (abstract)	To determine the causes of delay in presentation to hospital and delay in management after STEMI	138 patients	Time taken to come to hospital was less than 1 hour in 15.2%. Door to needle time in streptokinase was <1 hour in 58.5%, 1-3 hours in 31.1%, 3-6 hours in 5.7%, and > 6 hours in 4.7%. A distance from hospital >10 km was significantly associated with late presentations.
Perera et al., 2007 (abstract)	To describe the knowledge on chronic complications among DM patients attending clinics in the Provincial General Hospital Ratnapura	385 patients from the medical clinics of the provincial general hospital	89.6% knew the importance of regular blood sugar monitoring; 96.9% knew that lifelong medication was necessary. 98% knew that there was a risk of foot ulceration; 58% had hear of the risk of stroke. Although 98.7% knew that uncontrolled blood sugar was a risk factor, only 19.3% identified smoking as a risk factor.
Rodrigo et al., 2014 (abstract)	To compare the knowledge, attitudes and beliefs among DM and non-DM patients at the University Medical Unit of CNTH		Knowledge on DM did not significantly differ between the two groups. DM patients with higher education had significantly better knowledge compared to non-DM patients ( $p<0.001$ ). Of the DM patients, only 17.3% knew about BP and TC control; 29.6% knew that they should screen their vision annually; only 9.9% knew about daily checking their feet; only 13.8% had heard of HbA1c investigation. Of the patients with DM, 46.9% thought as jaggery was better than sugar; 40.7% brown sugar was better than white sugar; and 21% honey/treacle was better than sugar. No significant difference between the two groups in

			relation to these beliefs. Among all, bitter gourd (66.7%), thembu (56.22%), thumbakarawila (54.9%) and kurakkan (55.6%) were thought to help in blood sugar control.
Amarasekera et al., 2014a (abstract)	To determine the level of glycaemic control and to explore the reasons and barriers to achieving glycaemic control among health care personnel and DM patients	230 patients in the Colombo district; data collected using questionnaire  FGD with 30 nurses; In-depth interviews with 16 doctors and 17 patients	Glycaemic control was achieved in 71%, with mean FPG of 175.17 mg/dl. The identified barriers to glycaemic control were insufficient knowledge about the illness, low socio-economic status, lack of family support, poor compliance to health advice and insufficient diabetes care.
Amarasekera et al., 2014b	To explore the health beliefs and practices of adults with DM	An ethnographic approach of participant observations, in-depth interviews with 14 key informants	Findings revealed unique, informative insights into sociocultural worlds of the participants. Themes that emerged were gaining religious support, changing food habits is a struggle, exercising is challenging, Western medicine causes long-term consequences and Ayurveda/traditional treatments can cure.
Ranawaka et al., 2014 (abstract)	To assess stroke awareness among patients with stroke	Case control study at the University Medical Unit at CNTH, with 80 cases and 78 age and sex matched controls	Overall awareness was inadequate in 63.8% cases and 56.4% controls in relation to risk factors, available treatment options and preventive methods. Mean awareness score did not differ between cases and controls (18.38 vs. 18.91; $p>0.05$ ). Awareness was better in younger patients. The main sources of knowledge were doctors (73.6%), television (36.5%), other health care workers (15.1%), radio (8.8%) and health educational material (12.6%).

Amarasekera et al., 2015a	To explore the perspectives among DM patients on their glycaemic control behaviour	In-depth interviews among 17 adults	Reasons for good glycaemic control were understanding the illness, sufficient family support, adequate income and higher level of motivation and education. Barriers for good glycaemic control were insufficient knowledge about the illness, low socio-economic status, lack of family support and poor compliance to health advice. Challenging aspects were diet control, regular exercise and taking medications on long term basis.
Amarasekera et al., 2015b	To assess knowledge, attitudes and practice of CVD and its risks among urban adults (35-55 years) with metabolic syndrome	423 patients	Attitudes scores were high in this sample although their knowledge and practice scores on CVD risk factors were moderate. Participants with high mean knowledge scores had significantly lower WC and showed a trend toward reduced FPG. Participants with high practice scores had significantly lower BMI and WC, which signify that better knowledge and practices are associated with decreased CVD risk markers in these patients.
Walpola & Paranewithana, 2016 (abstract)	To describe the knowledge, attitude and glycaemic control and factors for poor control among DM patients in GP clinics in Colombo	425 DM patients	57.2% had good glycaemic control. Not missing main meals, good adherence to medication and not smoking were significantly associated with glycaemic control.
Wijesinghe et al., 2016a	To assess the knowledge on symptoms of dysglycaemia, complications of DM and knowledge on preventive strategies of complications in DM outpatient clinics in a tertiary hospital in Colombo	279 DM patients	70.6% of the patients had 'good' or 'very good' overall knowledge about their condition and the complications associated with DM. However, significant gaps in knowledge were seen in the patients' awareness of hypoglycaemic symptoms and symptoms of diabetic neuropathy. Patients with a poor education and of low socio-economic status showed poorer knowledge of DM.