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ANALYSIS OF THE IMPORTANCE OF PHARMACOTHERAPY IN PREVENTING SERIOUS COMPLICATIONS CAUSED BY CARDIOVASCULAR DISEASES

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Abstract. Globally, cardiovascular disease (CVD) is the leading cause of death. Our goal was to use clinician-assessed absolute risk level to estimate the effects of CVD preventive double medication (a statin and an anti-hypertensive). For the entire population of New Zealand (NZ), a multi-state life-table model that has been proven and validated was modified. A published NZ-specific CVD risk equation was used to stratify the 60–64-year-old male population by risk in the updated model. Although a lifetime horizon was employed to measure benefits and costs, a five-year horizon was also used throughout the five-year intervention period of treatment. In all absolute risk categories, we discovered that providing double therapy was very cost-effective for this group (e.g., NZ$1580 per QALY gained in the >20% in 5 years risk stratum; 95%UI: Dominant to NZ$3990). The cost per QALY was only NZ$25,500 (NZ$28,200 and US$19,100 in 2018), even in the lowest risk stratum (≤5% risk in 5 years). Individual quality-adjusted life gains for those who accepted the screening offer and started preventive therapy varied from 0.6 to 4.9 months (or less than a month with a five-year horizon). However, at the individual level, patient considerations are crucial since some people may determine that taking daily medicine is not worth the average health advantage. According to the study's findings, over half of the participants had drug therapy issues, and 58% of them needed more medication. It has been discovered that using more than three medications increases the chance of drug therapy issues. This is an area that needs special attention and the collaboration of healthcare professionals to address because these issues are negatively impacting patients' treatment outcomes.

Keywords. Cardiovascular illness, drug therapy issues, needless drug therapy, noncompliance, need for extra drug therapy, inefficient pharmacological product, ineffective dosage.

Introduction. With an estimated 17.8 million deaths, cardiovascular disease (CVD) was the leading cause of death worldwide in 2017. Neoplasms came in second with 9.56 million deaths. Additionally, according to this Global Burden of Disease report, "the rising prevalence of obesity might explain why death rates for cardiovascular disease are no longer declining in Australia, Austria, Brazil, Germany, Netherlands, the UK, and the USA." Fortunately, CVD can be prevented at a reasonable cost with preventive medication and tobacco management. Statins are, in fact, economical for the primary prevention of CVD, according to international research. Both blood pressure-lowering and lipid-lowering medications are generally cost-effective or even cost-saving when used for primary prevention of CVD (even in combination), according to a systematic assessment of economic evaluations in low- and middle-income countries [1-5]. Additionally, it has been found that intensive cholesterol lowering treatment is cost-effective in all categories when compared to routine lipid lowering (i.e., in a research from the Netherlands—albeit this is for patients with existing CVD5). According to an Australian study, "recommending blood pressure-lowering drugs to everyone with at least 5% absolute risk and statin drugs to everyone with at least 10% absolute risk" would improve health and save the Australian government $5.4 billion over the population's lifetime. However, a paper claiming

that industry-funded statin studies yield more favorable cost-effectiveness estimates still raises questions. Policy-makers require jurisdiction-specific evaluations on health gain, costs, and cost-effectiveness because illness epidemiology and costs vary by country. Additionally, patients need to be properly informed at the individual level about the potential benefits of daily medication on their quality-adjusted life. Given that clinicians have long been encouraged to take absolute CVD risk into account, even though this approach is still not always prevalent in clinical practice, New Zealand is a perfect case study country to examine such issues [6-12]. Additionally, there is proof of effective initiatives to boost the usage of preventive medications, like as statins, among Māori10, the Indigenous community. Additionally, additional CVD prevention could result in significant net health sector cost savings. For example, a single salt reduction strategy could save NZ$1.1 billion over the course of an adult's lifetime in New Zealand. Large health sector cost reductions were also anticipated by another study on the effects of tobacco price rises in this nation, but this model also included effects on lowering cancer and respiratory illnesses in addition to CVD. In light of this, our goal was to model the effects of CVD preventive medication by clinician-assessed absolute risk level and determine the corresponding health benefit, influence on health system costs, and cost-effectiveness for males aged 60 to 64. This age group was chosen as a starting point for further research on evaluating this method of taking absolute CVD risk into account [13-19]. Additionally, this age group of men is particularly interesting because it is the working age group with the greatest risk of CVD, and increasing health in this age group may increase economic productivity (even for citizens who continue to work for pay after age 65). Since aspirin as a preventative medication is more debatable and statins and anti-hypertensives are already being used in this manner in New Zealand, we concentrated on double therapy. However, a paper claiming that industry-funded statin studies yield more favorable cost-effectiveness estimates still raises questions. Policy-makers require jurisdiction-specific evaluations on health gain, costs, and cost-effectiveness because illness epidemiology and costs vary by country. Additionally, patients need to be properly informed at the individual level about the potential benefits of daily medication on their quality-adjusted life. Our estimates of the average additional months of quality-adjusted life gained (Table 6) may be useful in helping patients and professionals make better decisions about preventative medication. These might be included into online resources that patients can utilize to decide whether or not to take their medications on a daily basis [20-28]. Confounding variables that obscured the true impact of a risk factor of several medications employed as a predictor of DTPs in binary logistic regression are most likely the cause of the discrepancy between unadjusted and AOR. However, when multivariate logistic regression is employed to run many variables at once, it's possible that confounding factors were adjusted and the link between various medicines used and DTPs was reversed [29-36].

The main purpose of this manuscript is to provide a brief overview of the results of reputable scientific studies on the importance of pharmacotherapy in preventing serious complications caused by cardiovascular diseases.

Incorporating data on CVD risk from a fictitious national population. We classified the cohorts into categories of absolute CVD risk because the TC-MSLT Model did not have information on classifying individuals by level of absolute CVD risk. We created a synthetic simulation population by utilizing earlier research that used CVD risk prediction algorithms unique to New Zealand. Age, sex, ethnicity, social deprivation, smoking status, diabetes status, personal history of cardiovascular disease (CVD), blood pressure and lipid-lowering medication treatment, systolic blood pressure, the ratio of total cholesterol to high density lipoprotein cholesterol (TC:HDL), and family history of premature CVD were all necessary variables for the risk equation predictions (with these from the PREDICT dataset, Auckland University). The

number and rates of CVD events were then estimated by applying these risk equations to a fictitious population of 2.45 million people in New Zealand. All anonymized 30- to 84-year-old respondents to the 2013 census were extracted to create this population, which included information on age, sex, ethnicity, social disadvantage, and smoking status [5-11]. Sampling from 100 artificial populations created uncertainty. This synthetic data production is described in more depth elsewhere. The authors concentrated on the male population between the ages of 60 and 64 who had no prior diagnoses of CVD in the TC-MSLT Model and who were not taking CVD preventive medication (with standard deviations of the sampling averages). In a similar vein, they were not previously diagnosed with congestive heart failure, rheumatic heart disease, chronic renal illness, or atrial fibrillation [15-20].

Constructing the CVD MSLT Model through CVD risk classification. The CVD MSLT Model was then developed by modifying the TC-MSLT Model. In order to do this, the simulated population was divided into three distinct components (with replication for each ethnic grouping in the age category of men 60–64 years). Population A: This group did not have prevalent CVD in 2011 and was not taking any CVD drugs. According to the proportions in the synthetic population work, this group was then split into five strata with varying five-year absolute risk of a CVD incident. This group, or those who would be given CVD preventative medication, comprised the model's intervention population. Population B: Those who were already using CVD preventative medicine but did not have a high prevalence of CVD in 2011. According to the synthetic population work, the predicted five-year absolute risk of a CVD event was used to calculate the incidence rates of CVD for this group. Population C: Regardless of medication status, this group had a high prevalence of CVD in 2011. Once more, the synthetic population distribution was used to determine the fraction in this category [21-30]. All New Zealand men in this chosen age bracket are included in these three groupings taken together. Furthermore, we had to give distinct case fatality rates for each of the Group A strata. We used the results of the meta-analysis by Zambon et al. and the regression equation for CVD mortality by CVD incidence (Figure 2(c) in Zambon et al.) to mathematically disaggregate the case fatality risks by absolute risk strata, ensuring the case fatality over all strata combined was preserved, since there were no published New Zealand data for this (the case fatality data exist by age-group only23). Additionally, there is evidence that people with higher rates of CVD also have comparatively higher rates of non-CVD mortality (e.g., data abstracted from the meta-analysis by Thomopoulos et al., albeit without age-standardization). We defined a two-fold increase in non-CVD mortality rates for the highest absolute risk strata relative to the lowest absolute risk strata based on this Thomopoulos et al. evidence, with a linear trend over intervening risk strata in Population A (with wide uncertainty around this 2.0 value included in our modeling [confidence intervals: 1.0 to 3.0 times]) [32-38].

Key conclusions and analysis. For all levels of absolute risk, the potential offer of CVD preventive double therapy was extremely cost-effective from a lifetime time horizon perspective at a 3% discount rate in the chosen demographic group of middle-aged males aged 60–64. However, we have only examined one age group of men in this case study, so we intend to do more research to examine both sexes and a much larger range of adult age groups, including older age groups where the advantages and disadvantages of preventive medication may be more evenly distributed. Given that these two drugs (statins and anti-hypertensives) are both efficacious and reasonably priced, as well as the positive results of prior worldwide research on cost-effectiveness, the results of double therapy being cost-effective in all risk categories were not unexpected (see Introduction). The latter is particularly true in New Zealand, where PHARMAC, a central government agency, actively bargains with the pharmaceutical industry for low pricing, even for generics, which are generally all modelled statins and anti-

hypertensives [11-21]. However, there are probably more cost-effective ways to prevent CVD, like improving tobacco management, lowering the amount of sodium in processed foods, and changing the environment that contributes to obesity. For instance, our modeling of tobacco control measures indicates that they, like almost all dietary salt reduction programs (e.g., in the processed food supply), are very cost-effective in New Zealand. Our study's individual level results cannot be strictly compared to previous research. Nevertheless, the estimated lifetime benefit per patient from using a statin in a Dutch study of individuals with established CVD was 1.7 months (i.e., 0.14 QALY at a 1.5% discount rate for a cohort with a mean age of 61 years). We have calculated an average per person gain of taking a statin at 1.4 months (i.e., for those with a ≥5% five-year risk over their remaining life course, median age in late 60s for men and early 70s for women, and a discount rate of 3%) based on Australian work6, which did not specifically provide per capita results [24-34].

Strengths and limitations of the study. The TC-MSLT Model, a well-known original model that identified declining trends in CVD incidence and case-fatality, was one of the study's strengths. With extremely precise epidemiological and health cost data for New Zealand, the model also featured a high degree of parameterization. The improved model benefited from the use of CVD risk data from a fictitious national population and a New Zealand-specific CVD risk equation that considered ethnicity (albeit this equation has since been further improved) [6-12]. Additionally, the CVD health issue being addressed is significant for all high-income nations and is well-defined in that doctors in New Zealand routinely evaluate their patients' absolute CVD risk and can prescribe inexpensive preventive drugs. The degree of modeling sophistication used in this work to determine health gain and cost-effectiveness within absolute risk strata is also noteworthy. Limitations include anticipating a future decline in CVD incidence and background mortality, which may not hold given the obesity pandemic (see Introduction), which could indicate that we have overestimated health improvements (and hence underestimated cost-effectiveness). The benefits of preventing peripheral vascular disease and chronic kidney disease, better controlling high blood pressure itself (such as headaches from hypertension), and perhaps the psychological comfort or anxiety reduction that comes with taking preventive medication could all be underestimated. Additionally, there is evidence linking statins to "lower risks of dementia and cognitive impairment, venous thrombo-embolism, fractures and pneumonia," yet there may also be an increased risk of diabetes and myopathy [17-24]. Lastly, our findings were limited to men between the ages of 60 and 64; nevertheless, the intervention's cost-effectiveness will surely differ for other age groups, a topic we are currently investigating. As has been effectively done with diabetes models through the Mount Hood Challenge method, we would also be open to model comparison exercises with other research organizations (i.e., to evaluate model structural uncertainty) [30-34].

Possible effects on next studies. This research needs to be expanded to include a larger variety of adult age groups (as mentioned above), particularly the extremely elderly, who may be more vulnerable to the negative effects of preventive medication. The effects of several lifestyle modifications, such as quitting smoking, changing one's diet to include less sodium, and increasing physical exercise, might be compared in a more complex analysis.possible effects on decision-makers. According to an online interactive league table for Australia and New Zealand, policymakers should take these findings into account in addition to numerous other estimates for health benefit, economic implications, and cost-effectiveness from CVD preventative programs [26-33]. System-level CVD prevention strategies (such as reducing tobacco use, altering the obesogenic dietary environment, etc.) will usually have a greater effect and are more likely to result in cost savings. However, providing double therapy as determined by this study appears to be an economical use of public health resources. Promoting preventive pharmacotherapy for

particular population groups might be given priority, since minimizing health disparities is also an objective of the health system in many nations. Our estimates of the average additional months of quality-adjusted life gained should be useful in helping patients and professionals make better informed decisions about preventive medication. These might be included into online resources that patients can utilize to decide whether or not to take their medications on a daily basis [34-40].

Discussion. The majority of drug-related issues can be avoided, making them a significant healthcare challenge. The incidence, prevalence, and preventability of medication therapy-related deaths were demonstrated in numerous investigations. Hospitalization and unfavorable drug side effects that have negatively impacted patients' quality of life have been linked to inappropriate pharmaceutical use. In the inpatient and outpatient clinics of medical facilities, this has been demonstrated to significantly increase morbidity and death. In light of this, the purpose of this study was to assess the prevalence of DTPs in both hospitalized and follow-up CVD patients at HFSUH's ambulatory clinic. The study also finds variables including age, sex, pregnancy, breastfeeding, comorbidity, and the amount of drugs provided to each patient that are associated with the development of DTP [5-10]. According to the study, a significant portion of the patients had both hypertension and CHF. This result is higher than that of other studies where the prevalence of hypertension and CHF was less than 30%. It does, however, align with a study carried out in Jordan. Additionally, our research showed that pneumonia and diabetes were the most common comorbidities among CVD patients. Due to the necessity for several medications to treat these illnesses in addition to other CVDs, patients are at a significant risk of developing DTPs. This may account for the fact that the majority of research participants were given three or more medications. These findings are consistent with a research carried out in the northwest of Ethiopia, where the majority of patients took more than five medications and had many comorbid conditions. Regarding DTP, the study found that patients who were hospitalized to the medical ward and those who had received follow-up at the HFSUH ambulatory clinic had different kinds of DTPs. These included inefficient medication therapy, improper dosage, disobedience with treatment, need for more drug therapy, and needless drug therapy. All of these have a negative impact on the patients' treatment outcomes and compel them to incur needless medical costs. This study found that over half of the participants had DTPs, with a ratio of 0.6 DTPs per patient [17-25]. This outcome, however, is less than that of research done in Ethiopia's northwest and southwest. Additionally, our results are less than those of an other study that reported 2.5 DTPs per patient. This discrepancy is most likely because to our study's small sample size, which resulted in comparatively lower DTPs when compared to research done in other fields. The requirement for extra medication therapy was the most common DTP found in this investigation, followed by noncompliance and needless medication therapy. This result is consistent with a study done at Jimma University Specialized Hospital in the Southwest of Ethiopia and a study done in Jordan among patients with chronic illness48, where the requirement for extra medication therapy was greater than that of other DTP groups. However, our results are higher than those of a study carried out in the northwest of Ethiopia about the requirement for extra medication therapy [27-32]. Additionally, compared to the results of our investigation, this study found a higher prevalence of noncompliance and incorrect dosage. In a similar vein, compared to the findings of our investigation, a study conducted at Ambo General Hospital revealed a lower prevalence of the need for extra medication therapy and a higher percentage of unneeded drug therapy. This discrepancy may be explained by a number of factors, including the degree of expertise among medical staff in these facilities regarding the proper indication of medications, the appropriate selection of medications based on observed cases, and problems pertaining to comorbidities and the patient's condition [33-40].

Conclusion. Based on established QIs and backed by evidence-based clinical guidelines, we found a high incidence of cardiovascular risk factors and potential for intervention through medication review to optimize cardiovascular pharmacotherapy. However, following guidelines alone did not result in better control of risk factors, demonstrating the need for a multimodal approach to managing cardiovascular disease. This study could lay the foundation for more extensive, multicentric research demonstrating the beneficial effects of pharmacist-led drug reviews on CVD.

By conventional criteria, the offer of CVD preventive double therapy (a statin and an anti-hypertensive) was very cost-effective for all levels of absolute CVD risk in the chosen demographic group of middle-aged men aged 60–64. However, greater population-level measures, like improving tobacco control, are more likely to save money and produce significant health benefits. However, at the individual level, patient considerations are crucial since some people may determine that taking daily medicine is not worth the average gain of 0.6 to 4.9 months of extra life (or less than a month with a five-year time horizon).

Patients who were hospitalized to the medical ward and those who received follow-up care in the ambulatory clinic showed a high prevalence of DTPs, with almost 60.65% of patients developing DTPs. The need for further medication therapy was the most common DTP, accounting for 58% of all DTPs, while the proportion of nearly all other DTPs was smaller. This is an area that needs special attention and the collaboration of healthcare professionals to address because these issues are negatively impacting patients' treatment outcomes.

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