USING CLINICAL GUIDELINES TO ASSESS THE POTENTIAL VALUE OF LABORATORY MEDICINE IN CLINICAL DECISION-MAKING

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Abstract - Background: It is often quoted that 70% of clinical decisions are based on laboratory results although there is a lack of evidence to substantiate this claim. The aim of this review was to review all CVD guidelines published by five leading authority bodies and to determine to the proportion that recommended laboratory testing.
Materials and Methods: This study examined all guidelines associated with cardiovascular disease (CVD), released by the European Society of Cardiology (ESC), the UK National Institute for Health and Clinical Excellence (NICE), the American College of Cardiology (ACC), the Australian Heart Foundation (AHF) and the Cardiac Society of Australia and New Zealand (CSANZ). Each document was evaluated for clinical recommendations for laboratory investigation.
Results: In total 101 guidelines were reviewed with 24 of the 33 ESC guidelines relating to CVD and 15 of the 20 NICE guidelines relating to CVD, made a direct reference to the use of clinical laboratory tests in either diagnosis or follow-up treatment. For of their CVD guidelines, while laboratory testing featured in 25/32 of the ACC and 15/16 of the AHF/ CSANZ guidelines.
Conclusions: This study shows that five of the most prominent authorities for cardiovascular disease state a requirement for the use of laboratory testing in an average of 78% of their guidelines. This shows that the contribution laboratory medicine provide to the diagnosis of CVD is underestimated.

Keywords - Cardiovascular Disease, Clinical Guidelines, Pathology Testing.

I. INTRODUCTION

The contribution of laboratory medicine to patient diagnosis, management and follow-up has proven difficult to quantify with systematic evidence of improved patient outcomes scarce (1). The phrase that 'laboratory medicine influences 70% of clinical decisions' has been published many times but the evidence to substantiate this claim is lacking. The International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) established a Task Force on the Impact of Laboratory Medicine on Clinical Management and Outcomes in 2012.
Its purpose was twofold: first, to evaluate the available evidence supporting the impact of laboratory medicine in healthcare; and secondly to develop a study design methodology for new retrospective and prospective studies capable of generating evidence to determine the contribution made by laboratory medicine to healthcare. The IFCC Task Force published a summary of its findings in 2015 which included as one of its suggestions that the contents of authoritative clinical guidelines could provide an objective means of assessing the role of laboratory medicine in the management of specific health conditions (1).
Clinical guidelines are documents which aim to guide decisions regarding diagnosis, management, and treatment in specific areas of health care by using the best evidence available. Cardiovascular disease (CVD) is the world's most prevalent cause of mortality encompassing many diseases including those of heart circulation, heart failure, rhythm, and valvular abnormalities as well as cerebrovascular diseases (2). Procedure for Paper Submission

II. MATERIALS AND METHODS

This study has chosen to examine national and international cardiovascular clinical guidelines, published on each organisations website and in current usage as of the 24th of April 2020, to determine what proportion of these documents recommend the use of laboratory services.
We conducted a review of each of the individual guidelines available on the websites of the UK National Institute for Health and Care Excellence (NICE), (3) the European Society of Cardiology (ESC), (4) the American College of Cardiology (ACC), (5). The Cardiac Society of Australia and New Zealand (CSANZ) (6) and Australian Heart Foundation (AHF) (7) guidelines were combined as they are used across both countries.
Additionally, the research recorded whether laboratory involvement was required for initial diagnosis or ongoing management of care. The proportion of guidelines containing laboratory medicine recommendations either was then calculated by simply dividing the number of guidelines indicating pathology testing by the total number of guidelines.

III. RESULTS

Table 1 shows the total number of guidelines (79 of 101) related to CVD available from NICE, ESC, ACC

and the AHF/CSANZ indicating pathology testing for either initial diagnosis, follow up pathology testing or a combination of both.

Tables 2, 3, 4 and 5 respectively shows a breakdown of the individual NICE, ESC, ACC and the AHF/CSANZ guidelines including the date published and the tests described as they are found within the body of the document.

IV. DISCUSSION

Guidelines are designed to inform optimum decision-making by clinicians, and therefore provide a measure of the value of laboratory medicine. This study has shown that an average 78% of clinical recommendation pathways across the UK (NICE), European (ESC), United States (ACC) and Australasian (CSANZ and AHF) guidelines related to cardiovascular diseases (CVD) state that laboratory testing of some sort is recommended.

The most common metric stated for the value of laboratory testing in patient care is the claim that 'laboratory medicine influences 70% or more of all clinical decisions. An editorial by one of us (MJH) in the Annals of Clinical Biochemistry stated that the 70% figure was first published in 1996 and was based on anecdotal evidence and unpublished studies (8). The editorial lists various examples of the use of this phrase, albeit with slight modifications, for example; Lord Carter's report on the UK Pathology service, the First Report of the UK House of Commons Select Committee on Health, and in the UK Department of Health report "Modernizing Pathology Services" (8).

A related and also oft-quoted statistic is that 70% of the electronic patient record is composed of laboratory data, but the main limitation of this observation is that the presence of laboratory results in a patient record does not necessarily equate to it being used in any clinical decision-making process (9). Over-requesting of testing is a common feature of many healthcare systems and panels of tests may include many analytes which are unrelated to the patient's clinical condition. A 2016 study of laboratory use by oncologists and cardiologists found that 75% of all their patients underwent laboratory testing, and that this testing led to a substantial clinical decision in 66% of the patients (10).

Over time the 70% claim has apparently gained legitimacy simply due to the number times that it had been repeated. In 2012, the IFCC established a Task Force on the Impact of Laboratory Medicine on Clinical Management and Outcomes. When it published its findings in 2015 one suggestion was that clinical guidelines could be used as a more accurate indicator of the laboratory's involvement in clinical decisions, the rationale being that the number of guidelines that required any laboratory involvement would show a direct connection between the laboratory and evidence-based practice (1).

We decided to look at guidelines associated with cardiovascular disease (CVD), as the World Health Organization (WHO) reported this to be the number one cause of death globally (2). The report estimated that 17.9million people worldwide die from CVDs which equates to 31% of all deaths and, of these, 85% were due to myocardial infarction or stroke (2). The British Heart Foundation report that CVD account for almost 170,000 deaths in the UK costing the National Health Service £6.8 billion in 2012/2013 (11). In Europe, cardiovascular disease (CVD) is responsible for 3.9 million (45%) of all deaths annually (12),(13). The American Heart Association has reported that Coronary Heart Disease is the leading cause of death among Americans, accounting for nearly accounting for 840,678 (30%) deaths in 2016 (14). According to the Australian Institute of Health and Welfare Alliance, CVD directly contributed to 43,500 deaths in 2017 which accounts for 27% of all deaths that year in Australia (15).

There are both limitations and strengths to the approach we have taken. One potential limitation is that clinical guidelines are not necessarily followed by all physicians or other healthcare staff. A clinician's own pathway for patients may therefore involve more or less testing than is being recommended. However, the main advantage of our method is that at least the guidelines define provide an evidence-based recommendation for best practice in each specific clinical scenario.

The guidelines also tend to be specific in the test or tests that are recommended, which is advantageous in two ways. First, it helps ensure that the contribution of laboratory medicine to healthcare is not exaggerated by over-requesting - as could be the case if health records were solely being examined; and, secondly, that a clinical decision relevant to the health condition is intended to be taken on the basis of the result.

It should be noted that the guidelines examined in this study were produced in relatively affluent countries with developed healthcare systems and so the use of laboratory medicine testing advocated in other, less wealthy, countries may well differ. Nonetheless, this does not preclude the same methodology that is here being applied to any alternative guidelines.

In summary, this study has found a requirement for the use of laboratory testing in 79 of the 101 or 78% of cardiovascular guidelines produced by five different organisations. While this number may not be significantly different to the 70% published globally. It

may be an underestimation in discrete jurisdictions such as Australia, where laboratory investigations are indicated in almost all CVD diagnosis.

It does not provide a direct link to improved patient outcomes but does provide an index of the value of laboratory medicine which can complement other metrics. Using this objective methodology, it ought to be possible to determine the contribution of laboratory medicine to other, less prevalent, disease groups. Together, these datasets should provide a more accurate measure of the significance of laboratory medicine in providing optimal patient care.

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