The Role of Diagnostic Protocols as a Classification System in Diagnosing Hypothyroidism

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On my honor as a University Student, I have neither given nor received unauthorized aid on this assignment as defined by the Honor Guidelines for Thesis-Related Assignments

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Introduction

Constant exhaustion, inability to sleep, difficulty waking up, brittle hair, cold hands and feet, lightheadedness when standing up, no sex drive, brain fog making everyday tasks difficult, mood swings, mild depression or feeling blue, these are just a few symptoms that now 52-year-old Lizzy experienced from early childhood into adulthood. Over 35 years, Lizzy would repeatedly trek to a doctor only to be dismissed, some even misjudging her as someone looking for a quick fix to lose weight. During this time, Lizzy also suffered from chronic illnesses such as sinus infections, allergies, and asthma, as well as a diagnosis of high cholesterol by age 20 (*A Success Story*, 2020). The condition described in the case of Lizzy is hypothyroidism, a medical term that describes the various etiologies and manifestations of the underproduction or imbalance of thyroid hormones (Patil et al., 2022).

Lizzy now runs a hypothyroidism blog to help inform and save others from the same frustrations of undiagnosed hypothyroidism. She continues to run the blog because she says that if she "can help one person change their life, [she has] helped dozens of people in their world. If [she] can save one person from losing years of their life, or getting years that they would have lost, [she has] done [her] job in this lifetime" (*A Success Story*, 2020). Lizzy's case serves as a prime example of how various symptoms can negatively impact the quality of life of individuals with hypothyroidism. It is worth noting that Lizzy's experience is not uncommon, as approximately 5% of Americans have received a hypothyroidism diagnosis, and an additional 5% are believed to remain undiagnosed (Chiovato et al., 2019). Undiagnosed is the keyword, as with any condition or disease, to receive proper treatment of hypothyroidism, a healthcare professional must recognize the undiagnosed patient and their symptoms. The diagnostic protocols for hypothyroidism primarily involve biochemical measurements, but healthcare

professionals may also consider the individual's overt symptoms and quality of life measurements (Garber et al., 2012). However, as stated by the American Thyroid Association, these procedures are not fully standardized, granting healthcare professionals autonomy to individualize treatment plans from patient to patient (Jonklaas et al., 2014). This lack of standardization can lead to over-generalized treatment plans and healthcare professional complacency, inhibiting symptomatic hypothyroid patients from receiving proper treatment and care.

This paper contends that the information infrastructure of diagnostic classification systems in hypothyroidism has adverse effects on patient care and diagnosis by hindering proper treatment for symptomatic patients through standardized treatment plans and healthcare professionals' complacency. First, I provide an overview of the literature on information infrastructure, classification systems, diagnostic classification systems, hypothyroidism, the diagnostic classification system of hypothyroidism, and issues within these diagnostic classification systems. Then, I analyze relevant clinical recommendations released by the American Association of Clinical Endocrinologists and the American Thyroid Association through discourse analysis and newly released research findings regarding thyroid health and information infrastructure through literature synthesis. Through this analysis, I find the need for a closer and more careful analysis of symptoms and biomarkers of patients within the context of diagnostic classification systems of hypothyroidism. Finally, I end with a discussion of the inherent flaws in information infrastructure and the potential changes that could improve patient diagnoses via information infrastructure.

Literature Review

Information infrastructure refers to the technical, organizational, and social systems that enable information creation, management, and dissemination. Classification systems play an essential role in this infrastructure by providing a standardized means of organizing and accessing information based on common characteristics. Diagnostic classification systems are a specific classification system used in healthcare to code and classify diseases, disorders, and other health conditions. They are an essential component of the healthcare information infrastructure, used for clinical decision-making, billing and reimbursement, public health surveillance, and research. Developing and implementing diagnostic classification systems requires collaboration among healthcare providers, researchers, and policymakers, as well as ongoing evaluation and refinement to ensure their continued usefulness and relevance (Bowker & Star, 2000; Whitley, 1997; World Health Organization, 2021).

Classification systems are critical tools for organizing and making sense of complex information, but they are not without flaws. As an information infrastructure, classification systems can be challenging to analyze and understand. Star (1999) notes that good, usable systems tend to disappear, and the larger they are, the harder they are to see. Classification systems are inherently flawed due to heterogeneity, bias, reliability, and validity. Diagnostic classification systems, in particular, face issues with comorbidity and overlap, which can make accurate diagnosis difficult (Bowker & Star, 2000). These inherent flaws have the potential to result in errors in diagnosis and treatment, which are frequently encountered despite being acknowledged less openly. Diagnostic classification systems are essential in medical practice as they help diagnose patients and impact treatment and prognosis. However, diagnostic errors can lead to severe patient harm and are responsible for the highest fraction of malpractice claims

(Jones, 2013).

Heterogeneity is one of the main challenges with classification systems. Patients with the same diagnosis may exhibit different symptoms or respond differently to treatment, making it challenging to classify patients accurately. Additionally, with diagnostic classification systems comorbidity acts as a form of heterogeneity that can complicate classification systems by making it more difficult to accurately diagnose and treat patients and interpret data (Feczko & Fair, 2020). It highlights the need for a more nuanced approach to classification that considers the complex and varied medical histories of individual patients. Patients with multiple conditions may have overlapping symptoms, leading to misdiagnosis and inappropriate treatment.

Bias can arise from various sources and affect diagnostic classification systems, leading to disparities in healthcare outcomes for specific demographics. For example, the manner in which diagnostic categories are defined and the criteria used to make a diagnosis. If diagnostic criteria are based on symptoms more commonly experienced by specific demographic groups, such as white men, individuals from other demographics may be underrepresented or misdiagnosed. Bias can also arise from how diagnostic tests or screening tools are developed and validated. For example, suppose a test is developed using a sample of patients predominantly from one racial or ethnic group. In that case, the test may be less accurate or less useful for patients from other groups. This can result in misdiagnosis, delayed diagnosis, or inappropriate treatment. Another way bias can affect diagnostic classification systems is through healthcare provider biases. Providers may hold conscious or unconscious biases based on a patient's race, ethnicity, gender, or other factors, which can influence their clinical decision-making and ultimately impact the accuracy of the diagnosis (Garb, 2001). Addressing bias in diagnostic classification systems is critical for ensuring that all patients receive timely and appropriate care;

this may involve increasing diversity in the development and validation of diagnostic criteria and screening tools and providing ongoing training to healthcare providers to recognize and mitigate their biases. Additionally, involving patients in the diagnostic process and considering their unique experiences and perspectives can help ensure that diagnostic decisions are made more equitably and accurately.

Reliability and validity also present concerns, as classification systems may not always be consistently applied or accurately reflect the underlying conditions they represent. Reliability is an important aspect of diagnostic classification systems because it ensures that the classification of patients is consistent and accurate. In the context of diagnosis, reliability refers to the degree to which different clinicians or healthcare providers can arrive at the same diagnosis when presented with the same patient and diagnostic criteria (Kapadia et al., 2020). If a diagnostic classification system is unreliable, it can lead to different diagnoses for the same patient, depending on the healthcare provider or setting. This can result in inappropriate treatment and serious consequences for the patient's health. For example, a patient who is misdiagnosed with a condition that they do not have may receive treatment that is unnecessary or even harmful. Conversely, a patient who is not diagnosed with a condition that they do have may not receive the appropriate treatment, leading to worsening symptoms and potentially lifethreatening complications. Ensuring reliability within diagnostic classification systems involves establishing clear and consistent criteria for diagnosis, as well as providing training and guidance to healthcare providers to ensure that the criteria are consistently applied. Ongoing evaluation and refinement of diagnostic classification systems are also important to ensure that these systems remain reliable over time as medical knowledge and understanding of diseases and conditions continue to evolve. Reliability is a crucial component of diagnostic classification

systems as it ensures that patients receive accurate and consistent diagnoses, which is essential for appropriate treatment and, ultimately, positive health outcomes.

Validity is another critical consideration in diagnostic classification systems. Validity refers to the degree to which a classification system accurately reflects the underlying conditions it is intended to represent. In other words, a valid diagnostic classification system should accurately identify the presence or absence of a particular condition or set of conditions. This is important because an inaccurate diagnosis can lead to inappropriate treatment, seriously affecting patient health outcomes (Kapadia et al., 2020). For example, if a patient is misdiagnosed with one condition when they have a different condition, they may receive ineffective or harmful treatments. Ensuring the validity of diagnostic classification systems can be challenging, particularly when conditions have complex or varied presentations. However, researchers and healthcare providers work to develop and refine classification systems to ensure that they accurately represent the conditions they are intended to diagnose. One approach to evaluating the validity of a classification system is to compare its results to those obtained from other diagnostic tests or methods. For example, a diagnostic classification system for a particular condition may be compared to the results of imaging tests, blood tests, or other diagnostic tools to ensure that it is accurately identifying the condition. Overall, confirming the validity of diagnostic classification systems is essential for ensuring that patients receive accurate diagnoses and appropriate treatment. This requires ongoing evaluation and refinement of classification systems to ensure that they remain accurate and effective in the face of changing medical knowledge and patient populations.

To mitigate the risks associated with classification systems, it is essential to recognize their limitations and work towards ongoing evaluation and refinement of these systems.

Healthcare providers can use multiple sources of information to confirm a diagnosis, involve patients in the diagnostic process, and continually evaluate the accuracy and effectiveness of classification systems. Ultimately, a better understanding of the inherent flaws of classification systems can lead to improved patient outcomes and reduced rates of diagnostic errors.

Hypothyroidism is a condition that occurs when the thyroid gland does not produce enough thyroid hormone to meet the body's needs. The diagnostic classification system for hypothyroidism typically involves measuring thyroid hormone levels in the blood, specifically thyroxine (T4) and thyroid-stimulating hormone (TSH). The American Thyroid Association recommends using a TSH cutoff of 4.0 mIU/L as the upper limit of the reference range for TSH in adults (Jonklaas et al., 2014). However, this may vary depending on the individual and the laboratory's reference range. If TSH levels are high and T4 levels are low, this may indicate primary hypothyroidism. If TSH levels are low and T4 levels are low or normal, this may indicate secondary hypothyroidism.

Several factors can complicate the diagnostic classification of hypothyroidism, including heterogeneity, bias, reliability, and validity. Heterogeneity is a significant concern, as patients with hypothyroidism may exhibit a wide range of symptoms and variations in thyroid hormone levels. For example, some patients with hypothyroidism may have normal TSH levels but low T4 levels, while others may have elevated TSH levels but normal T4 levels. Bias can also be a concern in the diagnostic classification of hypothyroidism. For example, studies have shown that specific populations, such as older adults and women, may be more likely to be diagnosed with hypothyroidism, potentially leading to overdiagnosis and overtreatment. Reliability is important in the diagnostic classification of hypothyroidism, as consistent and accurate measurements of TSH and T4 levels are crucial for making an accurate diagnosis. Variations in laboratory

methods and reference ranges can affect the reliability of these measurements. Validity is also important in the diagnostic classification of hypothyroidism. The use of a TSH cutoff of 4.0 mIU/L as the upper limit of the reference range for TSH in adults has been questioned by some researchers. However, the American Thyroid Association maintains that this cutoff balances sensitivity and specificity for detecting hypothyroidism (Jonklaas et al., 2014). Overall, the diagnostic classification system for hypothyroidism involves measuring TSH and T4 levels in the blood. However, heterogeneity, bias, reliability, and validity can all affect the accuracy and consistency of this classification system. Healthcare providers need to be aware of these factors and use multiple sources of information, including patient symptoms and history, to make an accurate diagnosis and select appropriate treatment options.

Geoffrey C. Bowker and Susan Leigh Star's Sorting Things Out: Classification and Its Consequences (2000) described how classification systems can shape both worldviews and social interactions. As an infrastructure, the diagnostic classification displays embeddedness meaning the "infrastructure is sunk into and inside of other structures, social arrangements, and technologies," transparency meaning "infrastructure is transparent to use, in the sense that it does not have to be reinvented each time or assembled for each task, but invisibly supports those tasks," reach or scope meaning "infrastructure has reach beyond a single event or one-site practice," learned as part of membership meaning "the taken-for-grantedness of artifacts and organizational arrangements is a sine qua non of membership in a community of practice…New participants acquire a naturalized familiarity with its objects, as they become members," links with conventions of practice meaning "infrastructure both shapes and is shaped by the conventions of a community of practice," embodiment of standards meaning "...infrastructure takes on transparency by plugging into other infrastructures and tools in a standardized fashion"

(Star, 1999, p. 381). I will use this framework to develop context, a relationship between my technical and socio-technical theses, and an understanding of the power of diagnosis as a classification system and its socio-technical impacts on hypothyroidism patients. Furthermore, I will use this framework to analyze the current state of the hypothyroidism diagnostic process, its effects on patients, and how it acts as an infrastructure that healthcare professionals have become complacent towards.

Methods

I gathered primary sources to build the context of the current diagnostic classification systems for hypothyroidism. I focus on information published by the American Thyroid Association, the American College of healthcare professionals, and the American Association of Clinical Endocrinology. In my review of this literature, I perform discourse analysis to gain a deeper understanding of who is utilizing the clinical recommendations released by these organizations. I gather secondary sources, mainly technical and social research focusing on the prevalence of hypothyroidism, issues within hypothyroidism diagnosis, and new technical findings that implicate changes in the diagnostic classification. Lastly, I gather and examine case studies documenting hypothyroid patient journeys to better understand the shortcomings of current diagnostic processes. In my review of this literature, I carefully note any social factors considered, as well as the healthcare professional's actions and the patient's impact.

Analysis

Thyroid-stimulating hormone, while useful as a screening tool for thyroid disorders, is a poor stand-alone diagnostic due to its susceptibility to fluctuations and possible missed diagnoses. TSH levels can be influenced by several factors, including medications, stress,

illness, and pregnancy. This dissonance in evaluating thyroid health is concerning as it can lead to many patients being misdiagnosed or undiagnosed, affecting the overall healthcare of the patient population (Humphreys, 2020). Despite this, TSH tests are still frequently ordered as stand-alone diagnostics, with a reported 59 million tests in the US in 2013, while only 18 million free thyroxine (FT4) tests were ordered, exemplifying the healthcare industry's reliance on TSH as a diagnostic tool despite its limitations (Soh & Aw, 2019). Jones (2010) discusses how if the upper limit of the normal range of the TSH test were reduced from 5.0 mIU/L to 3.0 mIU/L, as recommended by some professional societies, an additional 22 million to 28 million people would be considered hypothyroid. Additional testing, including free thyroxine and free triiodothyronine measurements using more advanced technology such as liquid chromatography with mass spectrometry or mass spectrometry, may be necessary to obtain a more comprehensive picture of a patient's thyroid health and ensure accurate diagnoses and treatments (Alexander et al., 2017). Ongoing research is necessary to improve thyroid disorder screening and diagnosis to provide optimal care for patients.

The primary methodology for diagnosing hypothyroidism is biochemical measurement testing, which presents various associated issues as the current thyroid lab panels' normal ranges are too broad and unspecified, which can result in patients remaining undiagnosed or partially treated. According to Amy Myers MD, even when doctors order a complete thyroid function test panel, they often rely on broad and inaccurate reference ranges for "normal" thyroid test results (*Optimal Thyroid Levels: Decoding Test Results* | *Amy Myers MD*, n.d.). Furthermore, five patterns of hypothyroidism cannot be detected by these panels, including pituitary dysfunction, under-conversion of thyroxine to triiodothyronine, hypothyroidism caused by elevated thyroid binding globulin, hypothyroidism caused by decreased thyroid binding globulin, and thyroid

resistance (Kresser, 2010). By tailoring reference ranges to each patient's specific characteristics, such as age, sex, and race, healthcare professionals can improve the diagnosis rate and provide appropriate treatment to these populations.

The diagnostic classification system is an essential infrastructure in healthcare that healthcare professionals rely on to diagnose and treat their patients. According to Susan Leigh Star's concept of the ethnography of infrastructure, the diagnostic classification system is an infrastructure that both shapes and is shaped by the conventions of a community of practice (Star, 1999). In the case of a diagnostic classification system, this community of practice refers to healthcare professionals. Healthcare professionals' complacency and bias can shape the diagnostic classification system, leading to potential limitations in accurately diagnosing and treating patients. The healthcare professionals' dependence on the diagnostic classification system has allowed the infrastructure to predominantly shape their practice rather than a backand-forth between the two. This means the diagnostic classification system can limit healthcare professionals' decision-making processes, leading to bias and potentially inaccurate diagnoses. Healthcare professionals could mitigate the bias presented by the diagnostic classification system and provide more personalized and accurate diagnoses and treatments by focusing more on a patient-to-patient approach rather than solely relying on the diagnostic classification system.

The U.S. Preventive Services Task Force does not recommend preventative thyroid health screening despite the 5% diagnosed and 5% estimation of the undiagnosed patient prevalence of hypothyroidism in the U.S. population. The sum of these prevalence values gives us an estimated 10% of the U.S. population that suffers from hypothyroidism (Chiovato et al., 2019). Other studies have estimated that around 56% of treated hypothyroidism patients

continue to experience persistent symptoms (Eligar et al., 2016; Holtorf, 2014). From this knowledge arises the question of what magnitude of prevalence is necessary for the US to recommend preventative screenings. Widespread preventative thyroid health screening with improved diagnostic classification holds the potential to curb the number of undiagnosed cases of hypothyroidism. However, implementing widespread thyroid health screening would be an expensive project that must be supported by healthcare infrastructure. As we discussed before TSH does not serve as a great standalone diagnostic, so implementing this is arguably infeasible from a cost standpoint and the necessity of frequent testing. Widespread testing of more specific populations arguably has the potential to be more effective in diagnosing the 5% undiagnosed population of hypothyroidism patients (Chiovato et al., 2019). Additional research would be required to analyze the costs and benefits of implementing such a preventative measure and define these specific groups.

Conclusion

Hypothyroidism is a prevalent condition affecting millions of people worldwide, yet many patients go undiagnosed or continue to suffer persistent symptoms despite treatment. This is often due to incomplete or inadequate information infrastructure within the diagnostic system. The good news is that changes in information infrastructure hold the potential for improved care for hypothyroidism patients. Healthcare professionals, administrators, medical students, government health officials, and researchers, academic and commercial alike, might come across this research and be inspired to make changes within their area of work to promote enhanced treatment for hypothyroidism patients. For instance, healthcare professionals may be encouraged to conduct more thorough thyroid screening tests for at-risk populations or to adopt more advanced diagnostic technologies that can help detect thyroid dysfunction more accurately. Administrators and

government officials may consider implementing policies that promote early detection and treatment of hypothyroidism, such as funding for public health campaigns or increasing access to affordable healthcare. Medical students and researchers may be motivated to study hypothyroidism more profoundly and contribute to the development of new treatments or diagnostic tools. Moreover, this research may also inspire readers to advocate for preventative screenings of thyroid health, raise awareness of hypothyroidism, empathize with hypothyroidism patients, and promote developments and advancements within information infrastructure, specifically in regard to diagnosis. By working together and sharing knowledge, healthcare professionals, researchers, and policymakers can collaborate to improve the care and quality of life for hypothyroidism patients.

Looking ahead, future researchers should analyze potential changes to improve the diagnostic infrastructure both generally and specific to hypothyroidism as well as the viability of implementing preventative screenings of thyroid health. For example, they may explore the effectiveness of different diagnostic tests and treatments or investigate how to better educate patients about thyroid health and the importance of early detection. However, it is essential to recognize that as infrastructure evolves, there will never cease to be inherent flaws in the infrastructure and biases in healthcare professionals. Therefore, ongoing research and development efforts will be needed to continue to improve the information infrastructure and care for hypothyroidism patients. In conclusion, enhanced information infrastructure of diagnostic classifications holds the potential to close the gap between diagnosed and undiagnosed patients and to improve the care and quality of life for those living with hypothyroidism. By continuing to invest in research and development and working collaboratively across the healthcare system, the healthcare industry can help ensure that all patients receive the best possible care and support for their thyroid health.

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