

**The Role of the National Institute of Diabetes and Digestive and Kidney Diseases in Regard
to Racial Health Disparities Surrounding Chronic Kidney Disease**

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On my honor as a University Student, I have neither given nor received unauthorized aid on this
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Introduction

The federal spending budget for the 2022 fiscal year for the National Institutes of Health (NIH) totals approximately \$45 billion (Fogarty International Center, 2022). Furthermore, the National Institute of Diabetes and Digestive and Kidney Diseases budget request for the 2023 fiscal year totals approximately \$2.2 billion (NIDDK, 2023a). Despite the grandiose federal spending and continued biomedical innovation, one in every three Americans with diabetes are unaware that they have such conditions (NIH & CDC, 2015). Additionally, according to the Centers for Disease Control and Prevention (CDC), currently one in every seven Americans are predicted to have chronic kidney disease with 90% of those individuals unaware of their conditions (CDC, 2022). Given the evident variance in funding and health outcomes, it is paramount to investigate the prominent historical effects that the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) have had in regards to racial health disparities surrounding chronic kidney disease (CKD).

Methods

The focused research question is as follows: how has the formal institutionalization of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) affected racial health disparities present with regards to chronic kidney disease (CKD)? In order to properly evaluate the role of the NIDDK, documentary research methods in combination with policy analysis are considered. Documentary research methods are essential in accounting for unbiased sources demonstrating clinical and non-clinical research pertaining to racial health disparities and CKD. Policy analysis is essential in reference to the current and past outlined governmental initiatives and functional capacities. The primary matters of interest are the NIDDK initiatives addressing health initiatives in chronic diseases released during the height of the COVID-19 pandemic. The

supplementary matters of interest are the clinical trials, translation research, and governmental policy pertaining to the diseases of interest of the NIDDK. The keywords used in guidance of research include CKD, health disparities, social determinants of health, and race. The sociotechnical concepts of technological politics and the relationship of knowledge as power are contextualized within the initiatives of the NIDDK and evaluated with regards to apparent responsibility and efficacy in its current functional state.

The Role of Health in Society

Institutional definitions of health are often ambiguous in that there are no set criteria to define a conditional perfect state of health. The obscurity is apparent in that the definitions merely outline the general components that should be considered when reviewing the health of an individual or group. Setting precedent as an international intergovernmental entity, the World Health Organization (WHO) defines health to be “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity,” (WHO, 2023). Although most definitions of health may be lacking actionable and measurable criteria, there is comprehensive acknowledgement of the series of factors not confined to the internal physical processes of the body. The concept that health is a comprehensive measure affected by factors including environment and social conditions is the foundational conjecture of social determinants of health.

As defined by the WHO and affirmed by the Centers for Disease Control and Prevention (CDC), social determinants of health (SDOHs) are composed of all non-medical conditions that influence the health of an individual including location of residence, social norms, and political and economic agendas (NCHHSTP & CDC, 2022). In order to understand the complexity of SDOHs, it is critical to first deconstruct the two descriptive terms of association: social and determinant. The social denotation of SDOHs emphasizes the concept that human action

implicates more than the original human person regardless of the immediate foreseeable interactions and consequences. In reference to the social term of SDOHs, the argument can be made that SDOHs is a functional societal system with continuous assessment and classification driven by those within the society (Hahn, 2021). Divergent from legal constructivism, it can be argued that SDOHs are mutable on the basis that these social constructs are dictated by the nature of the society in which they are adopted. The determinant denotation of SDOHs distinguishes the idea that the action of an individual can be reactive in regards to the health of either themselves or others. The deterministic attribute does not dictate a causal relationship between individuals but instead illustrates a potential common risk factor with reference to public and personal health (Lundberg, 2020). Recognition of these culminating qualities of SDOHs builds the foundation for analysis of health disparities.

Health disparities are definitive forms of marginalization present amongst a specific group or population that have resulted from negatively occurring SDOHs. In reference to the social aspect of SDOHs, health disparities can ensue in response to both covert and overt forms of action taken by those with authority. Likewise, the characterization of health disparities is dependent on the shared quality of the population and is discriminatory based on aspects including race, gender, and sexuality (Braveman, 2014). The history of the U.S. has perpetuated racial health disparities through various avenues including restrictive economic policy and residential zoning. The destructive policy known as redlining barred individuals from residence in a specific area on the basis of their race, forcing residency in areas that lacked specific resources while also forcing exposure to harmful scenarios (Sewell, 2016). These consequences are still apparent in the value an individual's zip code can have on their potential exposure or risk

to various underlying diseases as well as opportunities for care given their financial background and pre-existing barriers from their location (Ritchie, 2013).

The NIDDK and CKD

The National Institutes of Health (NIH) are a direct subset of the U.S. Department of Health and Human Services (USDHHS) and serve as the national medical research agency. The NIH is divided into 27 separate institutes and centers, each with a specific focus in relation to the improvement of health and safety (NIH, 2023). The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) was formally recognized in 1986 with a foundational mission “to conduct and support medical research and research training...to improve people’s health and quality of life” (NIDDK, 2022). The research areas of interest for the NIDDK include diabetes, digestive diseases, endocrine and metabolic diseases, hematologic diseases, kidney disease, liver disease, nutrition, obesity, and urologic diseases.

Chronic Kidney Disease (CKD) is a disease affecting the functional capacity of the kidneys whereby the proper filtration of blood is hindered or disabled completely. The disease has various known risk factors including diabetes, high blood pressure, and heart disease. Additionally, CKD is a progressive disease with asymptomatic tendencies and no known sustaining cure. Within a study conducted by Dr. Hoerger et al, a simulation of the future burden of CKD within the United States was conducted, projecting approximately 38 million people would be affected by CKD by 2030. Additionally, the study projected that over half of adults above the age of 30 will be diagnosed with CKD by 2030 (Hoerger et al., 2015). The importance and public health concern surrounding CKD becomes more urgent when aspects such as population demographics are considered. Within a study conducted by the CDC, as of 2021, approximately 16.3% of Non-Hispanic Black adults are affected by CKD compared to Non-

Hispanic White adults whereby only approximately 12.7% of the adult population is affected. In reference to SDOHs and health disparities, the variation in populations affected reveal an underlying inequality surrounding education, assessment, and prevention concerning CKD (Norris & Nissenon, 2008). Given the overarching federal authority of the NIDDK in improving and protecting renal health as well as the persistent health disparities in reference to CKD, it is preeminent to investigate the role of the NIDDK in relation to CKD.

Technological Politics and Knowledge as Power

In order to properly evaluate the role of the NIDDK, it is imperative to discuss the two particular frameworks: the Theory of Technological Politics proposed by Langdon Winner and the Theory of Knowledge as Power proposed by Michel Foucault. Langdon Winner is an American theorist whose work primarily focuses on the interactions between technology and politics. One of Winner's most notable theories, termed the Theory of Technological Politics, claims technology to inherently have association with the disposition of power. Winner's theory dictates that technology is inherently political via two methods. The first method is that the conception and execution of the technology was originally brought about with the intent to harness or achieve power. The second method is that the technology was assumed by a political entity resulting in politicization through its contextualization (Winner, 1980). The main criticism of the Theory of Technological Politics is expressed in the causational relationship between technology and politics. As opposed to technology functioning as an artifact of politics, some scholars argue that politics are artifacts of technology (Joerges, 1999). Regardless of the debatable cause and effect relationship, Winner's theory is ambivalent to the moral or ethical implications of a specific technology and its usage. Instead, the theory enables examination of intricate sources of power and political leverage associated with the use of technology while also

elucidating potential artifacts that may not be apparent upon superficial examination. Winner's Theory of Technological Politics is requisite in the review of the NIDDK as it can reveal any underlying historical artifacts still present within the governing body of knowledge.

Michel Foucault was a notable French philosopher with great influence over the structuralist and post-structuralist movement. Throughout his various works and lectures, Foucault developed numerous theories surrounding the dynamics of power, sexuality, authority, and control. One of the most notable theories is the recognition of knowledge as a foundational unit of power whereby power in itself is transactional and dynamic (Foucault, 1980). Unlike modernist viewpoint whereby power can be viewed as relational, Foucault challenges these preconceived ideals through the proposition that power is an intricate system with economic-like tendencies. In speaking on the relationship between government and power, Foucault states, "Government therefore entails more than just implementing general principles of reason... Knowledge is necessary; concrete, precise, and measured knowledge as to the state's strength," (Foucault, 1988). Depending on the philosophy by which an individual subscribes to dictates the reaction to the statements made by Foucault. In reference to the conceptual identity of knowledge, one major challenge that some academics state is Foucault's separation of historical and philosophical function in the construction of new ideologies and arguments (Shiner, 1982). Foucault's theory on knowledge as power is useful in recognition of the associated power that the NIDDK holds in its position as a federal medical research center.

Results and Discussion

Exploration into the proclaimed initiatives of a given organization is beneficial as conditional policies reflect the overt focus or directed concern of a given group. The contextualization provided offers unmediated insight into the form and functioning of the

organization in question. In order to effectively understand the associated impact of the NIDDK with regards to racial health disparities and CKD, analysis of the ongoing initiatives of the federal research agency must be conducted.

The current initiatives of the NIDDK are centered around reducing the harmful effects ensued by health disparities while also increasing the resilience of medical research surrounding kidney disease. Although these initiatives are developed in support of affected communities with the intent to eradicate health disparities, their conception and implementation reveal stark artifacts of the institution. Utilizing the Theory of Technological Politics and Foucault's rational of knowledge as power, a definitive authority is placed upon the programs developed. Sequential assessment of the ongoing initiatives of the NIDDK followed by substantial review of reflected responsibilities and implications is significant in determining the inherent role the organization pertaining to the reduction in prevalence of CKD and racial health disparities.

Initiatives of the NIDDK

The pandemic resultant from the novel coronavirus known as SARS CoV-2 forced major reconsideration of aspects of healthcare as well as specific health disparities present throughout various communities. In recognition of the apparent negative consequences of the healthcare system, the NIDDK developed a set of initiatives aimed at mitigating health disparities with regards to the institute's mission diseases of diabetes, digestive diseases, and kidney diseases. The four initiatives are as follows: to recruit diverse study cohorts inclusive of those most affected, to amplify the opportunities available for underrepresented groups to receive training and support in research-oriented careers, to promote participant engagement in all aspects of clinical studies, and to support research that identifies the causes of health disparities with testable hypotheses (Roberts & Rodgers, 2020).

Diversification of Clinical Study Cohorts

The continued lack of diversification of clinical trials and cohort composition within medical studies can only be understood upon historical examination of trial composition including the industrialization of randomized controlled trials (RCTs) as well as the lack of data transparency legislation. In discussing the inherent pressures brought about by the pharmaceutical industry, Dr. Bothwell et al. propose that RCTs have inherent limitations in regards to perceived generality due to their potential unjustified benefits acquired via data manipulation. The value and standardization of RCTs came to fruition as a result of pharmaceutical growth occurrent post World War II within the United States in combination with continued promotion within clinical epidemiology. The combination across industry and medicine set forth recognition of regulations internationally, establishing RCTs as a common metric. Despite its perceived impartiality, RCTs have inherent social and economic holdings that disrupt their perceived unbiased appeal (Bothwell et al., 2016). The limitations of RCTs are apparent in their disregard for dynamic factors of influence including SDOHs.

Challenging the historical composition of clinical trials including the narrative of the unbiased use of RCTs, the National Academies of Science, Engineering, and Medicine (NASEM), in conjunction with other agencies, have set forth a comprehensive set of assessments addressing how the lack of representation inducts harmful consequences. The inclusive list addresses topics including how the lack of representation comprises generalizability, incurs significant financial loss, as well as disrupts the progression of innovation and access to medical interventions (National Academies of Sciences et al., 2022). In speaking on the RCTs and diversification of trial models, NASEM definitively affirms the NIDDK initiatives through

reference of the multi-faceted aspects of health including genetic composition in combination with social, environmental, and economic factors.

Aside from standardized composition of cohort models, the recording and transparency of clinical trials holds significance with regards to the lack of diversification. Prior to 2007, there was no function protocol codified under the Food and Drug Administration (FDA) in reference to registration of clinical trials within the United States. Section 801 of the Food and Drug Administration Amendments Act of 2007 (FDAAA 801) became functional protocol for clinical trials and defined prominent terms and rulesets for developing and continuing a clinical trial. The FDAAA 801 was expanded upon through the Final Rule for Clinical Trials Registration and Results Information Submission in 2017 and offered further clarity on aspects such as quality control and data acquisition (FDA, 2023). The history of the development and inclusion of these policies is notable as it reveals an apparent artifact of the NIH. Prior to 2007, the NIH, and by extension the NIDDK, demonstrate an incomplete perspective on medical trial composition as the associated database was not accurately reflective of previous or ongoing trials (Wood & Perosino, 2008).

The Educational Capacity of the NIDDK

The NIDDK is a world-renowned governmental medical research agency with notable expansiveness to its organizational capacity and educational composition. Through this authority, the second initiative of the NIDDK seeks to develop a resilient community of researchers necessary in promoting renal health. To properly examine this initiative, it is paramount to consider the history of nephrology including current workforce composition and technological innovation. As discussed previously, CKD in addition to other kidney diseases have had drastically increasing prevalence amongst Americans over the course of the past few decades.

Despite the widespread epidemic, the current workforce composition within the medical field among healthcare professionals lack nephrology focused careers. Responding to this absence in staffing, Dr. Linde et al. developed an inventory of the current organizations that compose the Kidney Health Initiative (KHI) as well as an actionable plan of integration (Linde et al., 2016). Within the research, Dr. Linde et al. suggests similar initiatives to that of the NIDDK; however, with the additional focus towards improved efforts and recognition between stakeholders. This call to action is notable as not only would it ensure diversification of thought but would also enable for a more robust understanding of those that compose the functional healthcare system.

In response to the growing absence of nephrology focused careers, the NIDDK has developed specific programs coincided with their set initiatives. A prime example of such educational programs includes the Diversity Summer Research Training Program (DSRTP) as well as the Short-Term Research Experience for Underrepresented Persons (STEP-UP). DSRTP and STEP-UP provide high school and undergraduate students the opportunity to learn, receive mentorship, and aid in research focused towards the goals of the NIDDK (NIDDK, 2023d). Although, these educational programs are extremely beneficial in developing the next generation of a nephrology focused workforce, such programs fail to encapsulate non-traditional students or those seeking to pivot into the nephrology space.

Aside from opportunities centered towards careers in research, the NIDDK has also developed numerous educational sources to be utilized by patients, healthcare professionals, and researchers. These resources are classified by their accessibility and generic focus. The resources directly composed by the NIDDK and available to patients include basic outlines of diseases of focus, common diagnostic tests used in evaluation of such diseases, weight management tips, health statistics, and diet and nutritional aides. Although these sources of information are useful

in developing a broad understanding of a given disease or condition, these resources lack depth and applicability to direct implementation and improvement of SDOHs. Additionally, the NIDDK previously had conducted an evidence-based intervention and education program known as the National Kidney Disease Education Program (NKDEP) from 2000 to 2019. NKDEP works specifically to elevate the disparities affecting communities due to a lack of knowledge and support with a particular interest in patients with CKD. Although the official programming developed under the title of the NKDEP has ceased, the NIDDK has affirmed that the content of the program will still be provided to fulfill specific needs (NIDDK, 2023c).

Participant Engagement

The third initiative of the NIDDK seeks to address the lack of inclusivity present within evaluation, design, and discussion of clinical trials and disease progression. The most prominent examples of programs directly linked to the NIDDK's third initiative include the Stakeholder Engagement Innovation Centers as well as the Chronic Renal Insufficiency Cohort Study. The Stakeholder Engagement Innovation Center for Type 1 Diabetes (SEIC-T1D) and the Stakeholder Engagement Innovation Center for Type 2 Diabetes (SEIC-T2D) seeks to provide a platform for communities affected by diabetes to engage with other stakeholder's and formulate a discussion around areas of interest with regards to renal care. Additionally, the programs offer an opportunity for these communities that are often overlooked to receive specialized education and support through a network of multi-disciplined researchers and investigators. SEIC-T1D and SEIC-T2D are both within the preliminary stages with projects currently completing the grant application process (NIH, 2022). The Chronic Renal Insufficiency Cohort Study (CRIC) is a clinical investigation conducted in analysis of risk factors associated with the progression of CKD and cardiovascular disease with the aim to develop modeling systems addressing high-risk

groups. CRIC is currently within Phase IV of clinical trials and has identified numerous associated factors contributing to increased risk.

Contextualization and feedback are extremely important in regards to patient health. By extending the concepts of design and human factors examination into the realm of clinical investigations, many academics believe that SDOHS can be further conditioned and evaluated through the contextualization of behavioral principles. Seeking to develop a novel framework for the construction of trials, Dr. Brehaut et al. conducted a study focused on evaluating a patient-focused Theoretical Domains Framework (TDF) model in relation to patient groups. The results indicate a broader range of factors for trial participation typically not considered in conventional medical trial models. The results of the study conducted by Dr. Brehaut et al. further confirm the necessity for the implication of the NIDDK's third initiative as it emphasizes the fundamental and dynamic nature of patient experience.

Research into Health Disparities

Building upon the fundamentals of SDOHs, the fourth initiative of the NIDDK seeks to eradicate health disparities through actionable and testable research. Established in 2021, the Inaugural Health Disparities and Healthy Equity Working Group serves as a fundamental representation of the fourth initiative of the NIDDK. Developed in response to the NIDDK Council Forum on Underrepresented Investigators and Science, the Health Disparities and Healthy Equity Working Group seeks to develop action-oriented recommendations and opportunities for high-priority groups with specific research needs and varying health disparities. The group is divided into a series of five subgroups each with varying sub-focus and objectives centered around SDOHs and healthy equity. The plan of action concerning the research proposed by the group is to be released in the Spring of 2023 (NIDDK, 2023b).

Constructing Political Artifacts of Knowledge

The programs constructed with regards to the initiatives of the NIDDK are sources of technological artifacts of power. With the authority as a world-renowned medical research agency, the NIDDK offers a plethora of institutional medical knowledge. Utilizing Foucault's theory of knowledge as power, the NIDDK, and by extension its associated programs, in possessing such vast knowledge assume a position as a source of power. Additionally, through the application of Langdon Winner's Theory of Technological Politics, the programs developed in response to the established initiatives of the NIDDK are redefined as political artifacts constructed with intent of using its power to disrupt and eradicate health disparities surrounding communities most affected.

Combining the two frameworks in application to the NIDDK, the programs developed are inherent political artifacts of knowledge that reflect authority and responsibility of the institute by which they were conceived. Recognizing the severity and associated power, the programs previously reviewed are elevated to a new standard and should be examined accordingly. The programs developed in hopes of diversification of clinical trials are significant as their construction reflect not only the absence of equitable testing standards but also display a commitment to equitable research. The educational resources and programs provided by the NIDDK, although useful in development of younger nephrology-focused careers, lack depth and specificity in application. The programs set forth with the intent to achieve greater participant engagement reflect a novel appreciation for SDOHs whereby health is a dynamic and everchanging condition with an abundance of factors. Lastly, the development of actionable research of health disparities emphasizes further the contextualization of healthcare systems.

Limitations

There is a significant limitation with respect to the investigation and research reviewed. One of the most apparent limitations of the research conducted is the lack of transparency of institutional history. The analysis conducted surrounding developed and emerging artifacts of the NIDDK is limited as the institute was originally instated as the National Institute of Arthritis and Metabolic Diseases (NIAMD) in 1950 (NIDDK, 2015). Although major organizational reframing and policy overhaul eventually brought about the current form and function of the NIDDK, such historical events have generated a level of obscurity surrounding previous initiatives and programming. Future research projects could investigate the complex history and programming of past eras of the NIDDK in order to develop a deeper understanding of current and past artifacts.

Conclusion

The responsibility of the NIDDK stems from its functional capacity as a federal medical research institute. Although the programs developed in response to the initiatives set forth by the NIDDK aim to disrupt the detrimental effects of health disparities, the form and function of the associated programming suggest actionable results. In being political artifacts of knowledge, the programs have a definitive obligation to uphold the duties and responsibilities of the institute by which the programs represent. In order to fulfill the outlined initiatives to their entirety, the NIDDK should further refine and expand the programs to reflect equity for those experiencing health.

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