

Consensus Statement from the International Society of Glomerular Disease for Certification of Glomerular Disease Centers of Excellence

Draft for Public Review: 2025-03-28

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Abstract

In 2022, the International Society of Glomerular Disease (ISGD) was created to be a professional hub for the worldwide community of physicians, researchers, and other stakeholders interested in understanding, treating, and improving the outcomes of glomerular diseases. The Peer Support Committee within ISGD seeks to provide support for ISGD members and the broader nephrology community in order to improve the care of patients with glomerular diseases (GD), assisting in diagnosis and treatment. In this context, the identification and certification of centers with the capability and capacity to provide comprehensive care for patients with glomerular diseases, train the next generation of GD experts, conduct impactful research on glomerular biology and medicine, and advocate for GD as a field of study and practice is a key deliverable for this committee. An additional goal of ISGD is to facilitate mentorship and resource sharing programs to aid in the formation and development of additional centers of excellence. ISGD welcomes collaboration from allied organizations with shared goals, and it is committed to collect metrics of success of existing centers towards renewal of certification. In this article, we present the Consensus Statement of the International Society of Glomerular Disease for the Certification of Glomerular Disease Centers of Excellence.

Introduction

Kidney disease is a major public health concern, affecting more than 850 million people worldwide [1]. According to the 2019 Global Burden of Disease (GBD) Study, chronic kidney disease (CKD) accounted for 41.5 million disability-adjusted life years (DALYs) (95% UI: 38.3–45.0) and 1.43 million deaths [2]. Following diabetes and hypertension, glomerular diseases (GD) represent a major cause of CKD, constituting approximately 20%–25% of prevalent CKD cases [3]. Furthermore, GD is estimated to account for 17% of total DALYs and 13% of all deaths due to CKD [4].

A striking finding from the 2019 GBD study is the significant increase in the global burden of GD over the last three decades [4]. This likely reflects improved access to kidney biopsies and other diagnostic modalities. This trend underscores the critical impact of GD, which contributes substantially to disability, hospitalization, and premature death [4, 5].

The burden of GD is particularly significant in many low- and lower-middle-income countries (LMICs), where it is the most common cause of CKD and end-stage kidney disease (ESKD), especially in regions such as Asia and sub-Saharan Africa [6]. This is largely due to limited resources for managing GD [7]. Additionally, the burden of acute GD is disproportionately higher among populations with lower socioeconomic status, partly due to the greater prevalence of acute post-infectious glomerulonephritis [8]. Furthermore, LMICs often lack the infrastructure and resources to participate in clinical trials, as highlighted by a recent systematic review on the representation of LMICs in CKD drug trials [9]. This disparity contributes to marked inequities in outcomes based on race, ethnicity, geography, and socioeconomic status. The establishment of centers of excellence supported by collaboration with centers throughout the ISGD can help address these inequities.

The management of GD is challenging due to the heterogeneous nature and unpredictable course of GD. Proper diagnosis and treatment relies on a timely initial disease recognition, kidney biopsy, ancillary testing, familiarity with risk evaluation and mitigation (REM) strategies, and access to evidence-based therapies. Major system-level barriers impede the implementation of guideline-driven approaches for diagnosis and treatment of patients with GD in resource-limited countries [7]. Even patients with adequate access to care may experience significant morbidity due to the toxicity of immunosuppressive therapy. Treatment decisions require comprehensive understanding of the benefits and relevant harms at an individual patient level. Standardized protocols and a team with expertise are essential components for administering therapy with the fewest possible side effects.

It is likely that the magnitude of the burden of GD is underestimated due to lack of data on those who do not have access to hospital care and so never have a diagnosis made, or those who present too late for GD to be diagnosed as the underlying cause of their CKD. The lack of established networks and referral pathways to centers with GD expertise exacerbates the problem.

Pooling data on GD incidence, prevalence, and other outcomes is challenging because data may be collected differently in various practice settings (biopsy reports versus ICD codes). Furthermore, studies often focus on a specific GD subtype (e.g., lupus) [10] rather than reporting on all GD categories. Certain

geographic locations are underrepresented in research, and guidelines may not be fully applicable to patients in these regions. Centers of Excellence would facilitate clustering of these patients and enhance the opportunity to establish disease registries. Where registries do exist, they can be transformative in providing long-term data on outcomes that informs priorities and approaches to treatment [11]. Similarly, no data are available on the number of eligible patients with GD that are enrolled in existing clinical trials.

The Importance of Developing Glomerular Disease Centers of Excellence

Many patients with GD are diagnosed late in the course of their disease, often when kidney function has already declined. Frequently, patients with GD will carry the lifelong burden of CKD disease and are at high risk of progression to ESKD. The management of GD requires a multidisciplinary team effort and involves collaborating with providers in primary care and specialists in pathology, pharmacy, rheumatology, immunology, oncology, transplant, and genetics. The nephrologist caring for patients with GD must have a comprehensive understanding of GD pathophysiology, kidney pathology, pharmacology of immunosuppressive medications, and knowledge of the risk of adverse effects from medications and from disease progression [12]. Patients with GD often experience barriers and delays accessing a GD specialist. It can be difficult for patients and referring providers to gauge the level of expertise at a center and to learn about its available diagnostic and therapeutic resources, allied health services, and clinical trials. Defining the criteria for certification as a Glomerular Disease Center of Excellence (GD CoE) and reporting their services will provide patients and referring providers with greater transparency into the resources and expertise available. This information is anticipated to facilitate earlier diagnoses, improve access to targeted state-of-the-art treatments, promote superior kidney outcomes, lessen morbidity and mortality, and improve quality of life.

It is also expected that GD CoEs will benefit research into GDs. Successful GD CoEs would rapidly build up a rich clinical database of the demographics and clinical attributes of patients in their region along with how patients respond to therapy. Voluntary sharing of data from CoEs would provide a resource for epidemiological studies of GDs in diverse populations. In rare and ultra-rare disease, data sharing among multiple entities makes it possible to assemble sufficient cohorts for statistically valid analysis; the PARASOL project examining the predictive value of proteinuria in FSGS [13] is one recent example. Translational studies would be facilitated if CoEs establish biorepositories of urine, blood and tissue. Such biorepositories would provide critical validation populations for much of the single center research published in GDs. Besides offering a hub for natural history studies and biorepository, GD CoEs are expected to help facilitate the enrollment of patients in clinical trials and, when possible, to match the right patient to the right drug, setting the basis for precision medicine approaches to patients with GD. One of the main problems in clinical trials of novel therapeutics for GDs is that many recruiting sites are needed and most only enroll a handful of patients. CoEs with large prevalent and incident populations of GD patients would positively impact the feasibility of successful recruiting for clinical trials.

Over the past decade, there have been profound developments in the field of GD through advances in basic and translational research, discovery of novel antigens, clinical trials, and newly approved and targeted therapies. GD previously fell into the category of rare kidney diseases and orphan diseases, which historically had few clinical trials and required many years of follow-up time to determine the efficacy of

new therapeutics. The field of nephrology has now been identified as an emerging development opportunity for the pharmaceutical industry. Several factors have played a role in this development including greater recognition of the unmet need for therapeutics in nephrology, more practical surrogate endpoints for clinical trials, and faster approval pathways [14]. The ability to use proteinuria as an FDA-accepted surrogate endpoint for kidney outcomes for some GDs has dramatically accelerated the development and approval of new therapeutics.

The increase in clinical studies of glomerular diseases over the recent decade has been significant. A recent study found a 123% increase in clinical studies of rare kidney diseases in the years 2013 to 2022 compared to the years 2003 to 2012. This consisted of a 283% increase in observational studies, 93% increase in interventional studies, and a significant rise in early phase studies [15]. The increase in interventional trials, which includes traditional trials as well as umbrella and basket trials, in particular trials with biologic agents, reflects the growth and investment in development of this medication class. Biologic agents are designed to specifically target the complex pathways that are key in the pathophysiology of GD. This is an exciting time in the field of GD with newly approved targeted therapeutics for GD as well as an expanded spectrum of supportive therapies for CKD in general, and a growing pipeline for novel therapeutics in nephrology. New therapeutic options can also increase the complexity of clinical decisions, for example regarding patient-specific treatment selections or polypharmacy as real-world evidence is under development. As the therapeutic options in GD are likely to continue to expand in the future, it is important for patients to have access to specialists with expert current knowledge, for GD CoE to provide access to these promising therapeutics, and to provide transparent information on the therapeutics available at GD CoE.

A recent international survey of nephrology fellows reported a wide variation in GD educational experiences during nephrology training. The survey reported 51% of trainees had experienced a dedicated GD curriculum, 45% had exposure to a specialized GD clinic, and 77% had exposure to an on-site nephropathologist during fellowship. Importantly, higher trainee competency scores in GD diagnosis and treatment were associated with increased number of days spent in a specialized GD clinic per year, years of fellowship, and dedicated kidney pathology didactics [16]. These findings indicate how vital it is that trainees have adequate training in GD during fellowship and highlights the positive impact dedicated GD education has on trainee competency in the diagnosis and management of patients with GD. Thus, it is important for GD CoE to help formalize GD training experiences available and to provide exposure to nephropathology and specialized GD clinics. Providing these educational features at a GD CoE are important to ensure the next generation of nephrologists are well versed in the management of GD.

Consensus Statement: The Four-Part Mission of Glomerular Disease Centers of Excellence

This consensus statement is the culmination of a project undertaken by a work group of the International Society of Glomerular Disease. This international work group is made up of experts in glomerular disease tasked with development of the criteria deemed important for a GD CoE. Along with a CoE designation, the certification process will also transparently indicate the level and depth of services that can be found in an individual CoE or partner center. Such transparency will be informative to the

stakeholders looking for a GD CoE and will facilitate collaboration and resource sharing in the development of future CoEs. To be designated as a GD CoE, the center will contribute to the four-part mission of clinical expertise, research, education, and advocacy in GD (see Fig. 1).

Provide Clinical Expertise in GD. GD CoE will offer patients comprehensive care from providers with expertise in glomerular diseases, including diagnostics and treatment of GD. GD CoE will serve as hubs for second opinion, thus serving the community of providers desiring support in developing a specific plan of care for their patients affected by GD. In addition, GD CoE are expected to participate in collaborative co-management with referring physicians outside their own center to support the quality of care available to patients within broader networks.

Kidney pathologists will be available at the GD CoE, or readily available through external partners, for review of glomerular disease cases. A regular multidisciplinary biopsy meeting to view and discuss kidney biopsies is desirable and would contribute to fulfilling the educational mission of the CoE. Ideally, CoEs should include access to allied health and support services to ensure disease education, shared decision making and drug monitoring. Such support is expected to vary between centers, and gaps will be identified and need to be filled. Cohorting patients in specialized clinics is desirable, especially to establish biorepositories of clinical data and biological specimens. The providers at GD CoE should be knowledgeable about prescribing the treatments for GD that are readily available regionally, and prepared to develop expertise in using new drugs that become available. Genetic counseling provided on site or through the entities providing genetic testing will be implemented. When feasible GD CoEs will ensure implementation of current care guidelines within their local communities. GD CoEs should provide patients with opportunities to interact with similarly affected individuals at the institution or within the community. The GD CoE provides opportunities for patients to participate in clinical research, including trials, commensurate with local resources (Table 1).

Contribute to Research in GD. GD CoE will move the field forward by actively conducting clinical, translational, and/or basic research. While GD clinical trials are not currently available in all regions, one of the benefits of establishing a GD CoE is expected to be attracting attention of trial sponsors to CoE as well-qualified potential clinical trial sites. Ultimately GD CoE will participate in the recruitment of patients for clinical trials and/or observational studies. GD CoE with research capabilities will serve as a training hub of network participants.

GD CoE will disseminate research results through peer-reviewed publication and will make the research data, samples, and resources available to the community as able (Table 1). Dissemination of research and expert information through additional means is also encouraged, e.g., research conferences, collaborations with local nephrology communities and/or patient advocacy groups, etc.

Advance Education in GD. GD CoE will provide educational resources for all levels of learners interested in glomerular diseases. These learners may include students, residents, fellows, attending physicians/faculty, allied health professionals, patients, and caregivers. Some GD CoEs will offer an advanced training program in glomerular disease management for clinicians and scientists, commensurate with available resources. Such programs may include multi-institution collaborative programs or consortia

in order to enhance training capacities (Table 1). Additionally, patient/caregiver education in GD through written and online resources, patient care symposia, and support groups is equally important.

Advocate for Research and for Healthcare Equity and Accessibility for Patients with GD. GD CoE will advocate for patients with GD and endeavor to lower barriers to healthcare access within their center. They should support healthcare equity and healthcare accessibility as relevant and feasible in their local context, and advocate for glomerular disease research funding through work with patient panels, government agencies, private foundations, traditional and/or social media. Advocacy may be done by individual centers or through collaboration between centers (Table 1).

Conclusions and Future Directions

This consensus statement from the International Society of Glomerular Disease lays out recommendations for certification as a GD CoE. A certified GD CoE will contribute to the four-part mission of patient care, research, education, and advocacy in GD.

Short term goals of this statement include disseminating and implementing the standards for certification of GD CoE. In the first half of 2025, we will launch a review and certification process, and centers will be able to apply through the International Society of Glomerular Disease to obtain the distinction as a GD CoE. Additionally, a website with the list of certified GD CoE and their available services and resources will be made publicly available. The International Society of Glomerular Disease looks forward to collaboration with all like-minded entities to achieve our shared goals.

Longer term goals of developing GD CoE include fostering collaboration among centers through both a formal mentorship program, resource sharing through ISGD. By partnering established CoE with newer centers or centers with differing resources available, our goal is to facilitate the development of additional CoE over time. Collaborations among CoE will also enable centers to standardize data collection and develop shared resources, such as clinical, teaching, and research resources, and clinical and research databases. It is hoped that collaborations across GD CoE will promote development of clinical trial networks across GD CoE and clinical trial matching tools for patients. These shared resources and networks would improve the understanding of GD pathophysiology, which could lead to identification of better biomarkers for diagnosis, prognosis, and targeting of disease-specific pathways for treatment. Additionally, the GD CoE can also help establish patient and family support groups, which are critical for the physical and emotional well-being of patients. The goal for GD CoE is to bring together physicians, patients, educators, researchers, and advocates from across diverse practice areas with the shared interest to improve care for patients with GD, increase transparency of the available resources at GD CoE, and advance knowledge in the field of GD through education and research.

Fig. 1. Goals and Four Mission Areas of Glomerular Disease Centers of Excellence

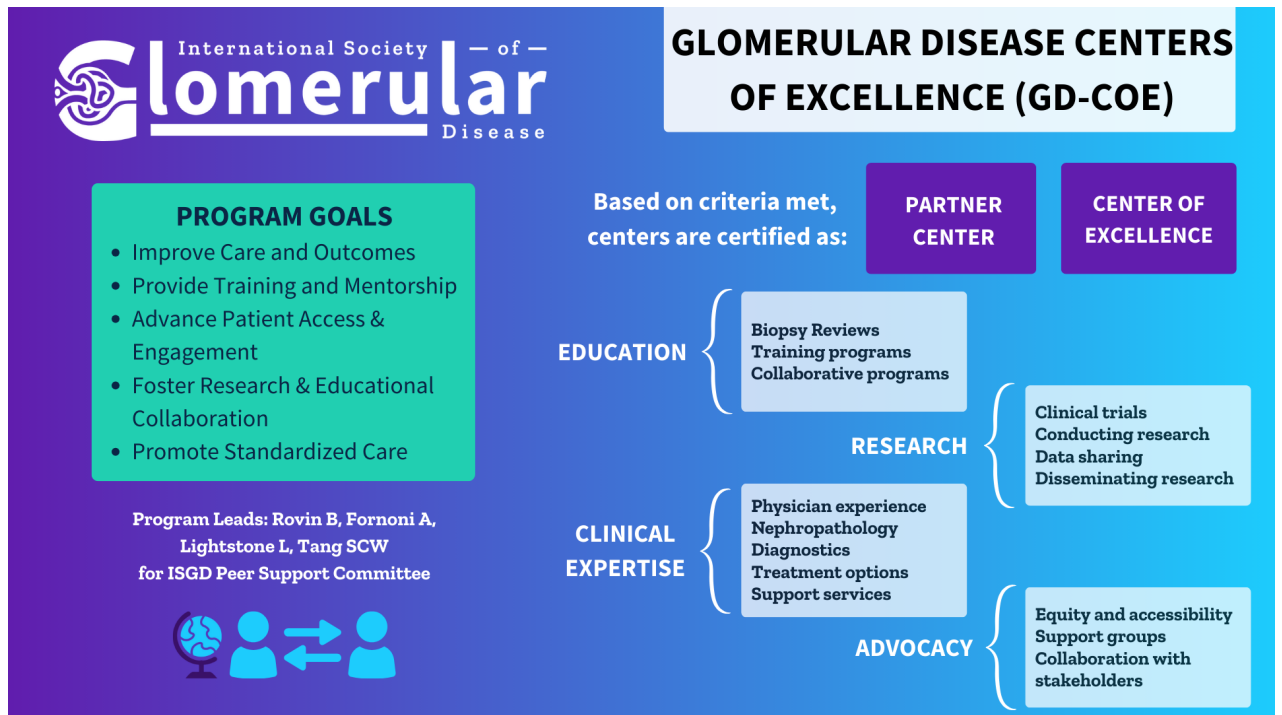


Table 1. Glomerular Disease Centers of Excellence: Criteria, Mission Areas, and Level of Service

<i>Criteria</i>	<i>Mission Area</i>	<i>Glomerular Disease Center of Excellence</i>	<i>ISGD Partner Center</i>
<i>Level of physician experience in GD</i>	Clinical Expertise	Cohorted specialized GD clinics. Manages GD patients referred from other nephrologists.	Physicians with GD specialist interest. Manages GD patients referred from other nephrologists; or Initiates treatment and manages per guidelines but may refer for second opinion.
<i>Kidney pathologist(s) in-house or readily accessible through external partners</i>	Clinical Expertise	Kidney pathologist is available with regular “biopsy rounds” for diagnostic and educational purposes (necessary).	Kidney pathologist available in-house or virtually for discussion of challenging cases; or Kidney pathologist opinion available virtually or through referral to an external center
<i>Diagnostics: biopsy practices</i>	Clinical Expertise	In addition to light microscopy (LM), immunofluorescence (IF), and electron microscopy (EM), has access to advanced biopsy diagnostics (specialized staining, mass spectroscopy, transcriptomics, etc.).	Able to perform LM, IF, and/or EM, when indicated.
<i>Diagnostics: genetic testing available to patients</i>	Clinical Expertise	Genetic testing and genetic counseling is available for applicable clinical scenarios	Genetic testing may be available in special cases.

<i>Treatment options</i>	Clinical Expertise	Access to investigational medications; regular MDTs with frequent off-label use of novel medicinal products.	regular local MDTs with use of novel, in label licensed medicinal products; or comfortable using in label immunosuppression e.g. cyclophosphamide, rituximab and other DMARDs
<i>Treatment options: availability of IV infusions</i>	Clinical Expertise	Available within the clinic or at the same geographic location (e.g. same hospital campus or medical office building). GD clinic staff can schedule appointments for patients.	Available within the same system (hospital, clinical network, etc.) but at a different geographic location. Patients must schedule appointments separately; or Patients must be referred outside the system of your clinic for infusions.
<i>Allied health/additional support services</i>	Clinical Expertise	At least 5 support services are required. The clinic has on staff, or has regular access to, specialized allied health and support services: <ul style="list-style-type: none"> - kidney nurses, - pharmacists, - dietitian, - social worker, - patient navigator, - other services/providers (genetics, etc.) 	1-3 of the listed support services.

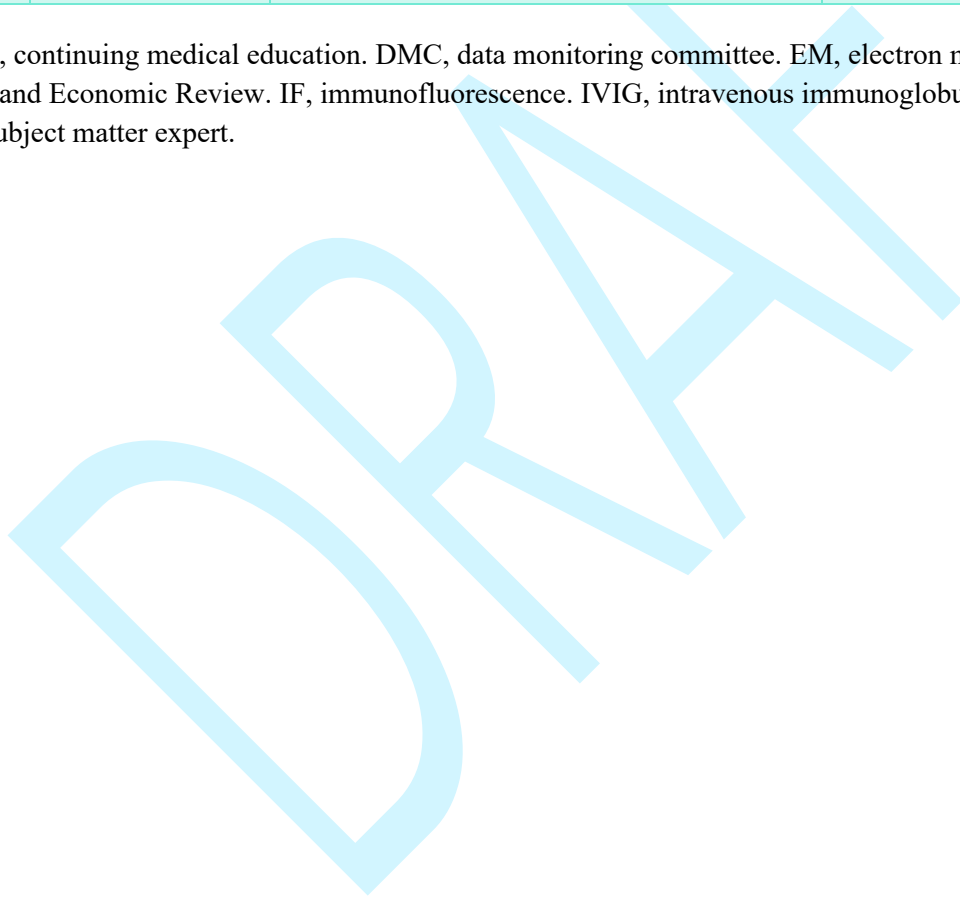
<p><i>Opportunities for patients to participate in clinical trials</i></p>	<p>Research</p>	<p>Physicians are leading (nationally or internationally) clinical trials in GN, or designing, on DMCs or trial steering committees.</p>	<p>Familiar with current interventional clinical trial options and have at least one glomerular disease trial available to patients in the last 3 years and have a standing plan for referring patients to centers who participate in clinical trials.</p>
<p><i>Conducting clinical, translational, and/or basic research</i></p>	<p>Research</p>	<p>Actively conducting translational and/or basic research on glomerular diseases; at least 2 projects, in which the PIs are from your center.</p>	<p>Actively conducting clinical research on glomerular diseases; at least 1 project, in which the PI is from your center.</p>
<p><i>Disseminating research results</i></p>	<p>Research</p>	<p>At least one peer-reviewed original research paper led by investigators from the center.</p>	<p>Two or more peer-reviewed original research papers that investigators from the center contributed to.</p>
<p><i>Research data sharing & collaboration</i></p>	<p>Research</p>	<p>The center maintains a biorepository, clinical database, cell lines, mouse lines, novel reagents, and data analytic techniques that are available to the community.</p>	<p>The center collaborates with investigators across institutions and disciplines using data and/or resources from your center combined with data and resources from other centers.</p>

<i>Opportunities to review kidney biopsies with kidney pathologists</i>	Education	Regular educational sessions with a pathologist specializing in kidney pathology and attended by trainees and fellows.	On-demand educational sessions with a kidney pathologist to educate trainees.
<i>Advanced training program in glomerular disease management for clinicians and scientists</i>	Education	Has a dedicated GD-focused fellowship, and trains external nephrologists and/or researchers, or provides CME in GD.	Has a general nephrology fellowship that offers specialized training in GD, and trains external nephrologists, or provides CME in GD.
<i>Participation in multi-institution collaborative programs and/or consortia for education</i>	Education	Formal collaborative program(s) in place	No formal program, but collaborates informally with other institutions

<p><i>Support healthcare equity and healthcare accessibility</i></p>	<p>Advocacy</p>	<p>Publicly endorses healthcare equity (e.g. in center policies, on website, etc.) and has specific programs/projects in place to improve access for underserved patient populations (depending on local context, this could include minoritized racial populations, patients in poverty, rural patients, etc.). Has demonstrated success in reaching underserved patients. Engages in regular self-evaluation and analytics to characterize success of equity programs.</p>	<p>Endorses healthcare equity/accessibility and has some degree of policies or programs in place.</p>
<p><i>Work with patient panels, private foundations, government agencies, and traditional and social media</i></p>	<p>Advocacy</p>	<p>Works with governmental agencies and private foundations for approval of new medications and/or works with ICER or similar organizations, and/or holds leadership role or frequently participates in SME capacity with patient advocacy groups.</p>	<p>Works with patient advocacy groups, or takes referrals from foundations who help patients in their area connect with experts for care.</p>

<i>Opportunities for patients to interact with other similarly affected individuals</i>	Advocacy	In-house patient support programs and referral of patients to disease foundations and patient advocacy groups. Proactively inform patients of these resources.	Patient support groups are available upon occasion at our institution, or we refer patients to other resources in the community.
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Abbreviations: CME, continuing medical education. DMC, data monitoring committee. EM, electron microscopy. GD, glomerular disease. ICER, Institute for Clinical and Economic Review. IF, immunofluorescence. IVIG, intravenous immunoglobulin. LM, light microscopy. PI, primary investigator. SME, subject matter expert.



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