

The Humanistic Burden of Rare Kidney Diseases: Understanding the Impact of Focal Segmental Glomerulosclerosis (FSGS) and Immunoglobulin A Nephropathy (IgAN) on Patients and Caregivers Study (HONUS): Preliminary Results for IgAN in the United States (US)

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Demographics

- 89 patients and care-partner pairs were included in this analysis (**Table 1**).
- The average age for patients was 37.3 years, half were male (51.7%). The majority were Caucasian (86.5%) and around two-thirds (68.5%) had full-time jobs at the time of the survey.
- The average age of care-partners for IgAN patients was 39.6 years, nearly half (44.9%) were male. The majority were Caucasian (88.9%) and 86.5% had full-time jobs at the time of the survey.
- Most of the care-partners were partners of the patients (87.6%), and the rest were friends (4.5%), parents (2.3%), siblings (2.3%), or other relatives (3.4%) of the patients.

Table 1. Demographics for patients and care-partners

	Patients (N=89)	Care-partners (N=89)
Age		
Mean ± SD	37.3 ± 8.1	39.6 ± 11.0
Median	35.0	36.0
Sex, N (%)		
Male	46 (51.7)	40 (44.9)
Female	42 (47.2)	48 (53.9)
Other/Unknown	1 (1.1)	1 (1.1)
Race, N (%)		
Caucasian	77 (86.5)	79 (88.9)
African American	7 (7.9)	7 (7.9)
Hispanic	3 (3.4)	3 (3.4)
Asian and Pacific Islander	2 (2.3)	2 (2.3)
Native American	1 (1.1)	0 (0.0)
Prefer not to answer	1 (1.1)	0 (0.0)
Employment status, N (%)		
Full time	61 (68.5)	77 (86.5)
Part time	5 (5.6)	6 (6.7)
Self employed	0 (0.0)	1 (1.1)
Looking for work	12 (13.5)	1 (1.1)
Not looking for work	6 (6.7)	0 (0.0)
Retired	0 (0.0)	1 (1.1)
Disability	2 (2.3)	0 (0.0)
Student	1 (1.1)	1 (1.1)
Homemaker	2 (2.3)	2 (2.3)

SD, standard deviation.

Patient Disease Characteristics

- Patients had IgAN for an average (SD) of 6.5 (5.2) years. The mean (SD) time from first symptoms to diagnosis was 1.8 (5.6) months, with a median of 0.3 months.

- While immunoglobulin A nephropathy (IgAN) has been shown to be associated with significant clinical and economic impact, less is known about the humanistic burden associated with the disease.
- HONUS (**H**umanistic Burden of Rare **N**ephrotic Diseases: **U**nderstanding the impact of FSGS and IgAN on Patients and Caregivers **S**tudy) is a multi-national, cross-sectional survey designed in consultation with IgAN and focal segmental glomerulosclerosis (FSGS) patients and clinical community members. The HONUS study aims to quantify the humanistic burden of rare kidney diseases from both patient and caregiver (care-partner) perspectives.¹
- The current analysis focused on a subset of IgAN adult patients and their care-partners in the United States (US) who participated in HONUS before September 2022.

Patient Disease Characteristics (Continued)

- Around one-third patients were in CKD stage 1 or 2 (29.2%), 42.7% were in CKD stage 3, and 20.2% were in CKD stage 4. Five patients (5.6%) had experienced kidney failure and received a kidney transplant. The most common comorbidities reported were hypertension (30.3%), anemia (24.7%) and depression (20.2%).

Health-Related Quality of Life (HRQoL)

- For adult patients with IgAN, the mean SF-12 Physical Component Summary (PCS) score was 46.8 (7.0) and Mental Component Summary (MCS) score was 40.4 (8.5), lower (reflecting worse HRQoL) than previously published mean scores (MCS and PCS of 50) for the US general population.⁸
- As assessed by the KDQoL-36, the average scores for burden of kidney disease, symptom/problems, and effects of kidney disease for patients were 44.6 (22.0), 59.6 (14.0), and 64.0 (15.9) respectively (**Table 2**).
- 30.3% and 1.1% of the patients had moderate and severe anxiety, respectively (**Figure 1A**) and more than half had moderate (55.1%), moderately severe (2.3%), or severe depression (1.1%) (**Figure 1B**).
- For the care-partners, the mean SF-12 PCS and MCS scores were 50.0 (6.6) and 42.7 (9.6), respectively (**Table 2**) with lower mean MCS score than previously published US general population mean MCS score of 50.⁸
- None of the care-partners reported severe anxiety, and only 14.6% reported moderate anxiety (**Figure 1C**). Less than half of the care-partners reported moderate (38.2%) or moderately severe (5.6%) depression (**Figure 1D**).

Table 2. HRQoL for patients and care-partners

	Patients (N=89)	Care-partners (N=89)
SF-12 PCS		
Mean ± SD	46.8 ± 7.0	50.0 ± 6.6
Median	47.5	49.4
SF-12 MCS		
Mean ± SD	40.4 ± 8.5	42.7 ± 9.6
Median	40.1	41.1
Burden of kidney disease (KDQoL-36)		
Mean ± SD	44.6 ± 22.0	-
Median	37.5	-
Symptom/problems (KDQoL-36)		
Mean ± SD	59.6 ± 14.0	-
Median	56.3	-
Effects of kidney disease (KDQoL-36)		
Mean ± SD	64.0 ± 15.9	-
Median	62.5	-

KDQoL, kidney disease quality of life instrument; MCS, mental component summary; PCS, physical component summary; SD, standard deviation; SF-12, 12-item short form survey.

- To quantify the humanistic burden of IgAN adult patients in the US.
- To understand the burden and impact of IgAN from the care-partner perspective.

OBJECTIVE

METHODS

Patients and care-partners were recruited from two patient advocacy groups (NephCure Kidney International and the IGA Nephropathy Foundation of America) and one medical center (University of North Carolina Kidney Center) in the US. The survey was approved by the Pearl Institutional Review Board (IN, USA) and is Health Insurance Portability and Accountability Act (HIPAA) compliant.

Study Population

Inclusion criteria

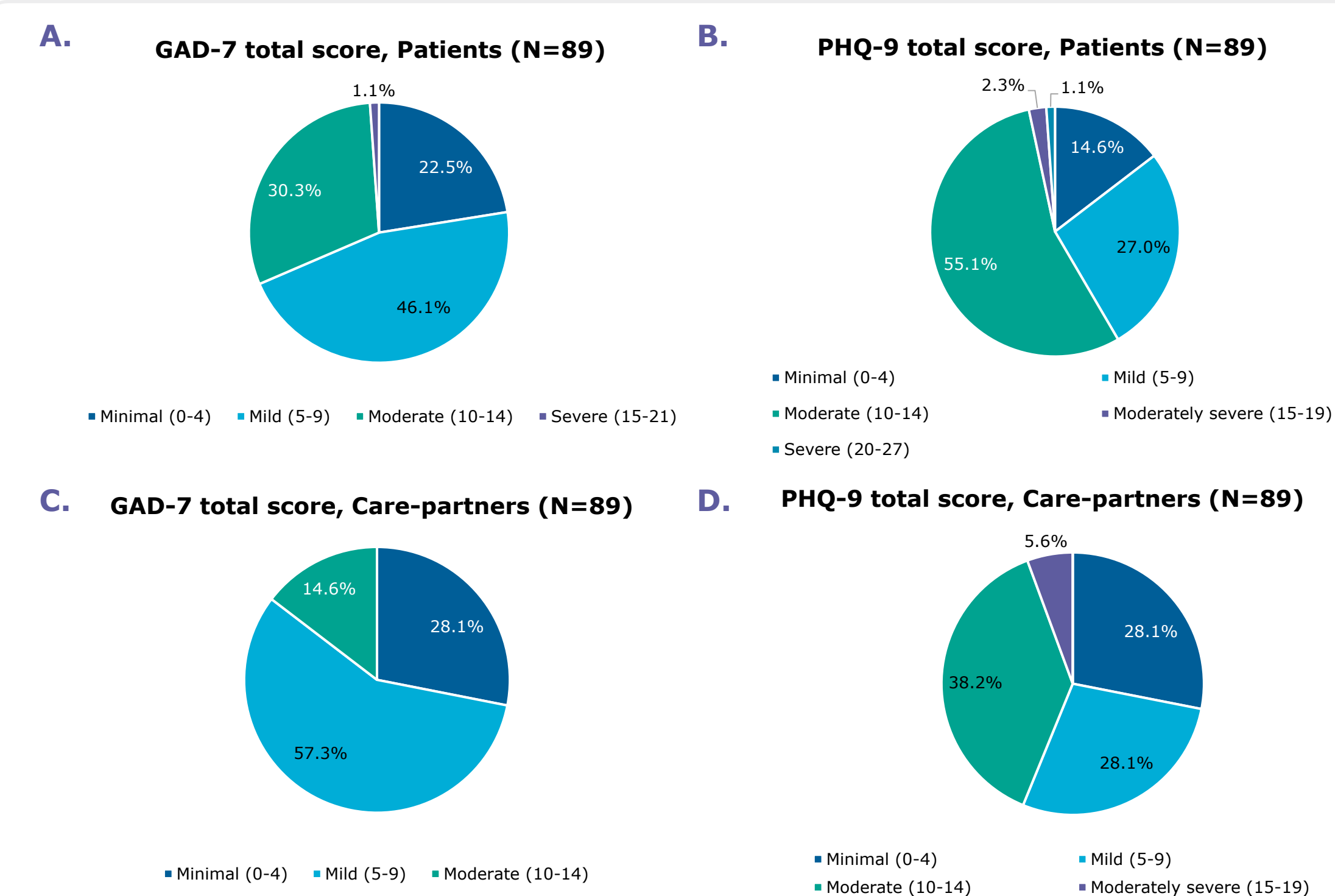
- Adult patients (ie, ≥18 years old) and their paired adult care-partners in the US who had a physician-provided diagnosis of IgAN (with renal biopsy confirmation of the diagnosis), and were able to provide informed consent.

Exclusion criteria

The following patients (their care-partners) were excluded from the study:

- Had IgAN secondary to another condition
- Had a history of malignancy other than adequately treated basal cell or squamous cell skin cancer
- Had a co-existing glomerular disease (eg, membranous nephropathy or lupus nephritis)
- Participated in a kidney disease clinical trial, and potentially have received active treatment as part of the trial at the time of recruitment

Figure 1. GAD-7 and PHQ-9 total scores



GAD-7, general anxiety disorder-7; PHQ-9, patient health questionnaire-9.

1. GAD-7 is calculated by assigning scores of 0, 1, 2, and 3 to the response categories, respectively, of "not at all," "several days," "more than half the days," and "nearly every day." GAD-7 total score for the seven items ranges from 0 to 21. 0-4 indicates minimal anxiety, 5-9 indicates mild anxiety, 10-14 indicates moderate anxiety and 15-21 indicates severe anxiety. The recall period is the past 2 weeks.

2. PHQ-9 scores are calculated based on how frequently a person experiences these feelings. Each "not at all" response is scored as 0; each "several days" response is 1; each "more than half the days" response is 2; and each "nearly every day" response is 3. The sum value of these responses gives the total score. 0-4 indicates minimal depression, 5-9 indicates mild depression, 10-14 indicates moderate depression, 15-19 indicates moderately severe depression, and 20-27 indicates severe depression. The recall period is the past 2 weeks.

Most Burdensome Symptoms and Fear of the Future

- The top three most burdensome symptoms reported by patients were constipation (85.4%), lower back pain (80.9%), and bone or joint pain (79.8%).
- All but one patient reported (98.9%) feeling of fear and uncertainty for the future due to their disease.
- All care-partners reported somewhat feelings of fear and uncertainty for the future due to the disease of their cared ones.

Work Productivity

- Work productivity results for patients and their care-partners are summarized in **Table 3**.
- Around three fourths of patients (73.0%) had worked in the past 7 days.

Work Productivity (Continued)

- Among employed patients, a mean of 6.7% reported absenteeism, 28.0% reported presenteeism, 32.2% reported overall work impairment and 37.8% reported activity impairment due to IgAN-related reasons.
- The majority of care-partners (94.4%) had worked in the past 7 days. Among those who were employed, a mean of 10.5% reported absenteeism, 29.2% reported presenteeism, 35.4% reported overall work impairment and 34.0% reported activity impairment due to IgAN-related reasons.

Table 3. WPAI:SHP

	Patients (N=89)	Care-partners (N=89)
Number of people with working hours in the past 7 days, N (%)	65 (73.0)	84 (94.4)
Percent absenteeism		
Mean ± SD	6.7 ± 8.1	10.5 ± 15.0
Median	4.8	5.1
Percent presenteeism		
Mean ± SD	28.0 ± 22.4	29.2 ± 22.6
Median	30.0	30.0
Percent overall work impairment		
Mean ± SD	32.2 ± 23.7	35.4 ± 25.9
Median	31.8	33.3
Percent activity impairment		
Mean ± SD	37.8 ± 22.6	34.0 ± 24.7
Median	30.0	30.0

SD, standard deviation; WPAI:SHP, work productivity and activity impairment:specific health problem.

1. Percent absenteeism, percent presenteeism, and overall work impairment were only assessed among respondents who were employed at the time of survey.

2. One patient is employed, but worked 0 hours in the past week, so percent work time missed, impairment while working, and overall work impairment were not available for that patient.

3. The recall period is the past 7 days.

LIMITATIONS

- Lack of a control group and use of historical US general population estimates for reference.
- Selection bias may exist as participants who voluntarily participated in the survey may differ from those who did not.
- The study relied on self-reported survey responses and could be subject to biases resulting from concerns common to all self-reported measures. Patients' self-reported diagnosis and disease history of IgAN may differ from a clinician's assessment.
- Participant responses may be influenced by the COVID-19 pandemic. This broader circumstance may impact socioeconomic status, accessibility of care, health outcomes, and HRQoL.

Study Outcomes

The following data were collected among patients and care-partners:

Patient	Care-partner
<ul style="list-style-type: none"> KDQoL-36 GAD-7 PHQ-9 Most burdensome symptoms Fear and uncertainty for the future Productivity impairment: WPAI:SHP 	<ul style="list-style-type: none"> SF-12 GAD-7 PHQ-9 Fear and uncertainty for the future Productivity impairment: WPAI:SHP

Kidney Disease Quality of Life Instrument (KDQoL-36) is a short form that includes the SF-12 as generic core plus the burden of kidney disease, symptoms/problems of kidney disease, and effects of kidney disease scales from the KDQoL-SF™-12.³

12-Item Short Form Survey (SF-12) is a general health questionnaire that assesses the impact of health on everyday life²

Generalized Anxiety Disorder Assessment (GAD-7) is a seven-item instrument that is used to measure or assess the severity of generalized anxiety disorder⁴

Patient Health Questionnaire-9 (PHQ-9) is the 9-item depression module from the full PHQ and measures the severity of depression⁵

Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI:SHP)⁶

Analysis

- All outcomes were summarized descriptively. Continuous variables were summarized as mean, median, and standard deviation (SD); categorical variables were summarized as count and proportion.

CONCLUSIONS

Adult patients with IgAN in the US experienced impaired mental and physical health compared with the general population. The disease negatively impacted their work productivity.

Care-partners for adult patients with IgAN had considerably worse mental health compared with the general population. Their work productivity was also impaired due to the disease.

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DISCLOSURES

JS, UF, DG, KG, KK-Z, KH, DR, BS, PS, KT, MB: Received consultancy fees from Travere Therapeutics, Inc.
BH: Employee, Travere Therapeutics, Inc.
WT, MZ, Z-YZ: Employees of Analysis Group, which received consultancy fees from Travere Therapeutics, Inc.

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