

SEISMIC: A Multi-StakeholdEr Summit to Address the DiagnosiS, TreatMent, and Access to Novel Therapies for C3G and IC-MPGN

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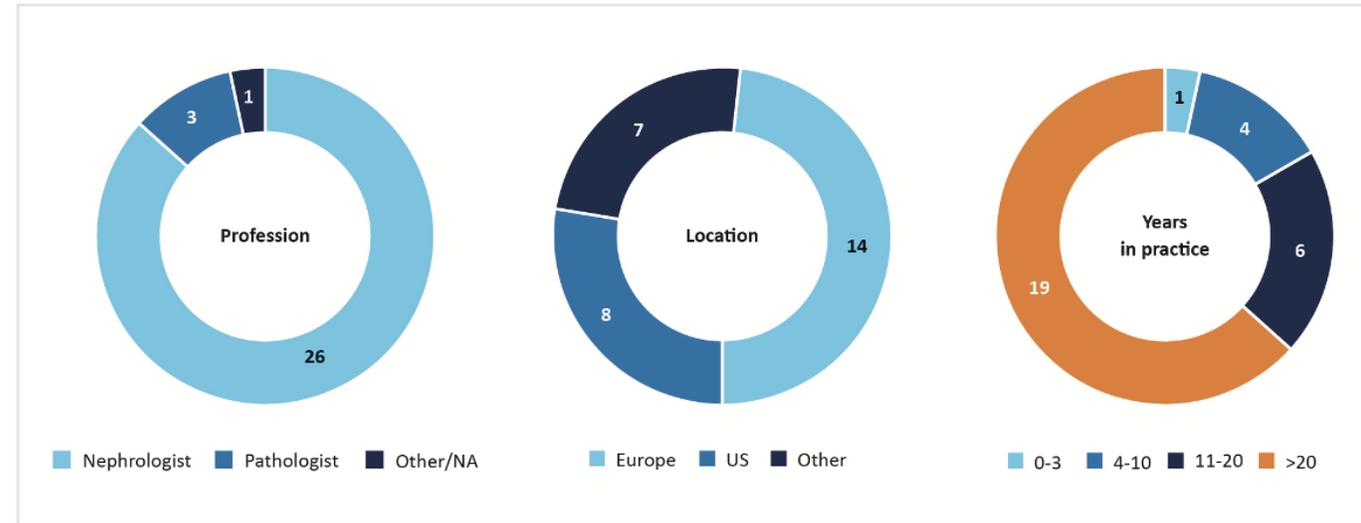
Introduction

- High Disease Burden
 - ESKD in <10 years from diagnosis
 - High recurrence in transplant
- Availability of Targeted Therapeutics in 2025
- Opportunities
 - Accurate and Timely Diagnosis
 - Efficacious Approach to Management
 - Issues of Access

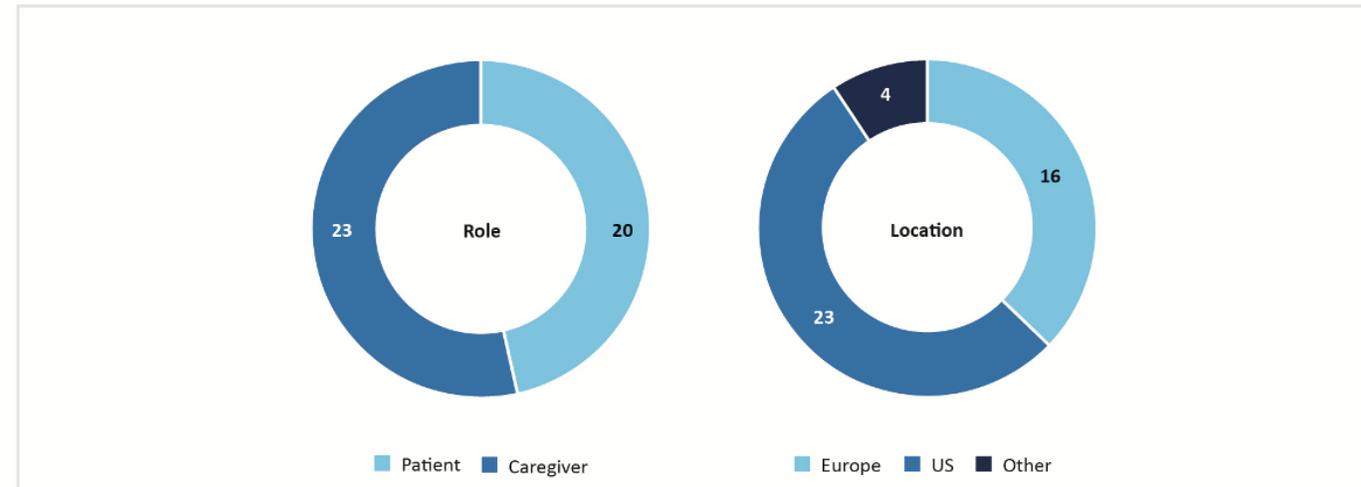
Methodology

- Meeting
 - 99 stakeholders from 20 countries
 - 63 in person
 - Stakeholders: caregivers (12), clinicians (61), research scientists (3), industry representatives (14), regulators (7), and payer delegates (2).
 - Survey prior to meeting to identify issues
 - 3 Sessions: Diagnosis, Management and Access

a. Physicians



b. Patients & Caregivers



Results - Diagnosis

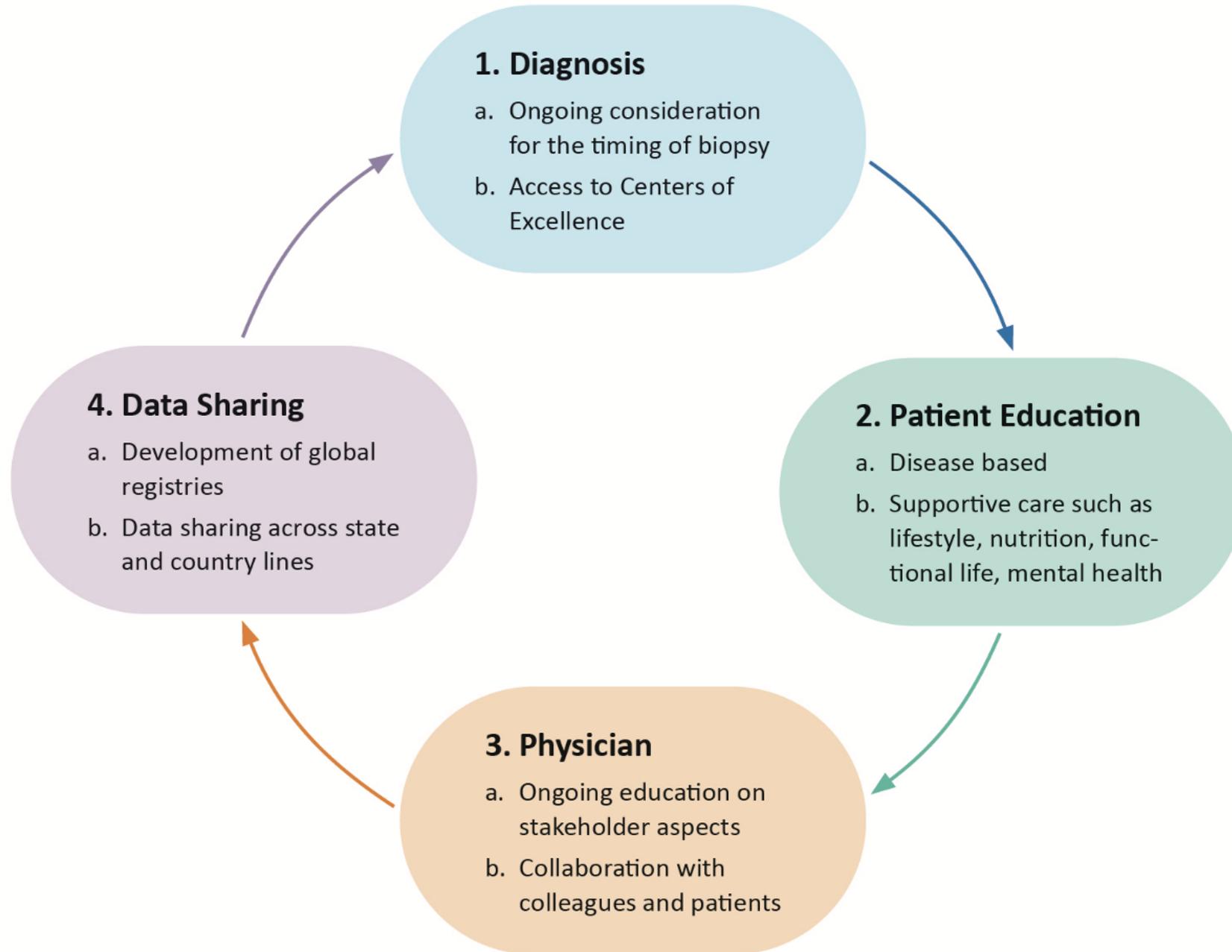
- Recognized Diagnostic Delay: Survey results showed <40% of patients received a biopsy within 6 months of symptoms; 21% waited over 5 years.
- Triggers: Proteinuria is the primary trigger for biopsy (>0.5 mg/mg creatinine in children; similar standard in adults taking into consideration chronicity and comorbidities).
- Pathology: Light microscopy and immunofluorescence studies represent the minimum biopsy requirements for appropriate diagnosis; with the need for a unified, disseminated diagnostic approach to shorten the time to biopsy.
- Improving Systems: multidisciplinary teams and referral to glomerular disease centers of excellence would promote greater disease awareness and facilitate early diagnosis.

Results - Management

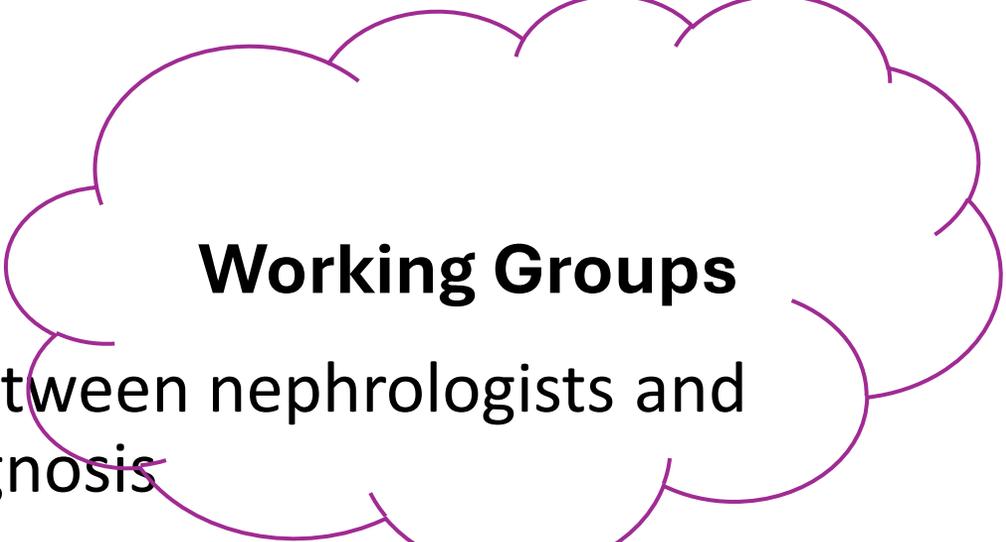
- Current SOC: Survey results showed 70% of patients receive glucocorticoids as first-line therapy, yet only ~14% reported satisfaction with results.
- The Paradigm Shift: Stakeholders unanimously supported the use of targeted therapeutics as first-line therapy for active disease, “as long as expense was not an issue”.

Results - Access

- Standard of Care: Need to define and disseminate a standardized SOC to prevent clinician roadblocks to access.
- Payer Acceptance: Collaboration with regulators to refine efficacy criteria (proteinuria reduction, eGFR stabilization) to ensure insurance coverage.
- Equity: Access should be based on medical need, independent of geography or economic status.



Conclusions



Working Groups

- Improve communication/collaboration between nephrologists and renal pathologists to ensure accurate diagnosis
- Define the minimum viable diagnostic workup for suspected C3G or IC-MPGN
- Develop guidelines on when to perform a biopsy, considering age, comorbidities, and other risk factors
- Establish a systematic patient cohort to collect longitudinal data and inform evidence-based practice guidelines.

Thank You