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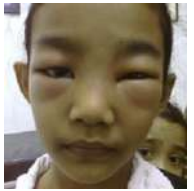
IPNA-AsPNA Junior Master Class, New Delhi 26-27 November 2022

Date: November 27th 2022

Topic: **IPNA Clinical Practice Recommendations for the diagnosis and management of children with steroid-sensitive nephrotic syndrome**

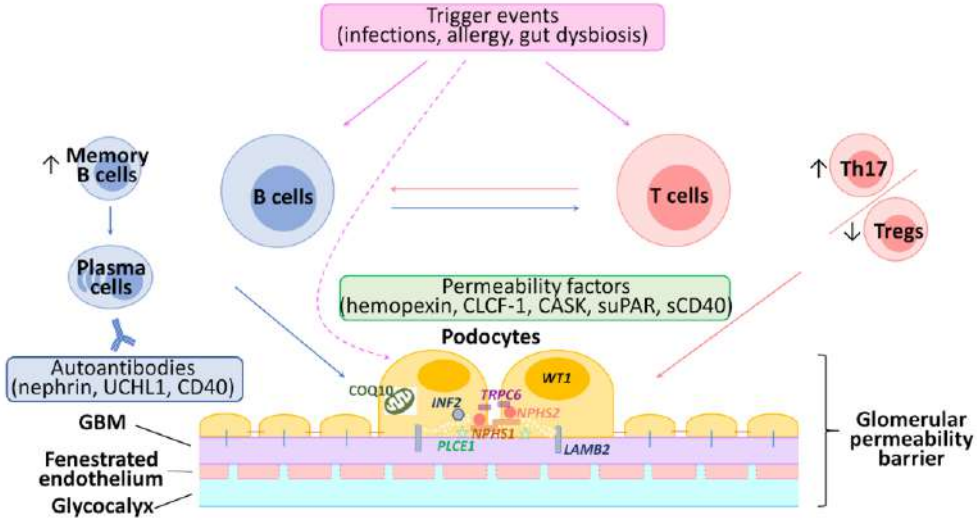
coordinated by the IPNA Best Practices & Standards Committee

Rationale for this guideline



- Idiopathic nephrotic syndrome is the most frequent pediatric glomerular disease affecting from **1.15 to 16.9 per 100,000 children per year globally**

- Unclear pathophysiology involving the **dysregulation of immune cells** and production of **circulating factors** inducing damage to the glomerular filtration barrier.



Trautmann et al, Pediatr Nephrol 2022, epub
Vivarelli, Gipson, Sinha, Boyer. Lancet 2023, in press

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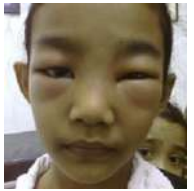
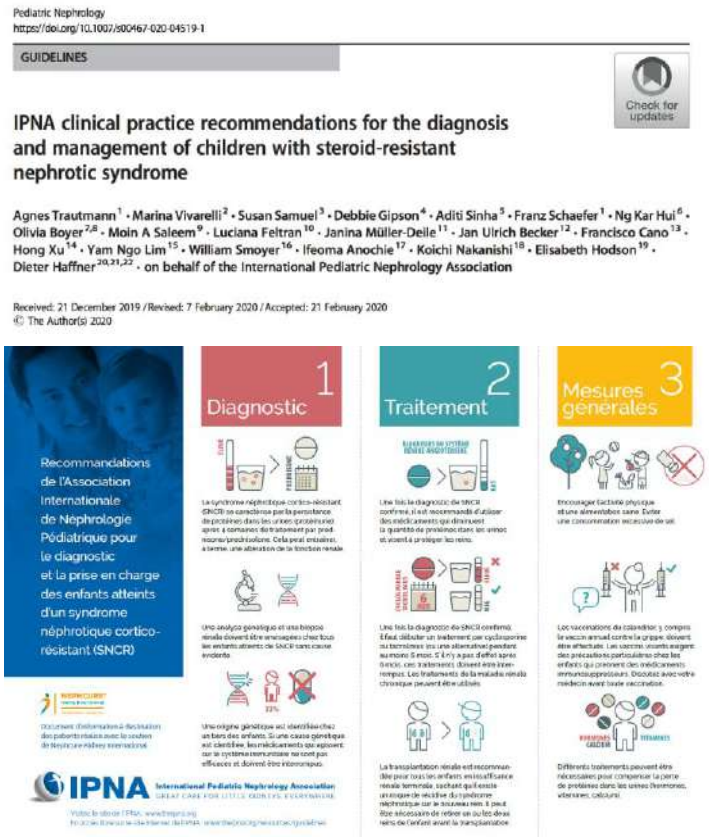


- Idiopathic nephrotic syndrome is the most frequent pediatric glomerular disease affecting from **1.15 to 16.9 per 100,000 children per year globally**
- **85-90% are steroid-sensitive** => SSNS
- **70-80% show at least one relapse** during follow-up
- 50% of these will experience frequent relapses (**FRNS**) or become steroid dependent (**SDNS**)
- **10-30% of patients continue to show relapses as young adults**
- There are no international, evidenced-based, systematically developed recommendations on the diagnosis and management of children with SSNS, except of a focused document from KDIGO

Trautmann et al, Pediatr Nephrol 2022, epub
Vivarelli, Gipson, Sinha, Boyer. Lancet 2023, in press

First IPNA-CPR Project - SRNS

coordinated by the **IPNA Best Practices & Standards Committee**



Pediatric Nephrology
https://doi.org/10.1007/s00467-020-04519-1

GUIDELINES

Check for updates

IPNA clinical practice recommendations for the diagnosis and management of children with steroid-resistant nephrotic syndrome

Agnes Trautmann[1] · Marina Vivarelli[2] · Susan Samuel[3] · Debbie Gipson[4] · Aditi Sinha[5] · Franz Schaefer[1] · Ng Kar Hui[6] · Olivia Boyer[7,8] · Moin A Saleem[9] · Luciana Feltran[10] · Janina Müller-Deile[11] · Jan Ulrich Becker[12] · Francisco Cano[13] · Hong Xu[14] · Yam Ngo Lim[15] · William Smoyer[16] · Ifeoma Anochie[17] · Koichi Nakanishi[18] · Elisabeth Hodson[19] · Dieter Haffner[20,21,22] · on behalf of the International Pediatric Nephrology Association

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Recommandations de l'Association Internationale de Néphrologie Pédiatrique pour le diagnostic et la prise en charge des enfants atteints d'un syndrome néphrotique cortico-résistant (SNCR)

1 Diagnostic

2 Traitement

3 Mesures générales

IPNA International Pediatric Nephrology Association
GREAT CARE FOR LITTLE KIDNEYS, EVERYWHERE

IPNA International Pediatric Nephrology Association
GREAT CARE FOR LITTLE KIDNEYS, EVERYWHERE

توصيات الممارسة السريرية للجمعية الدولية لأمراض الكلى للأطفال (IPNA) لتشخيص ومعالجة متلازمة فقد البروتين الكلوية – المقاومة لأدوية الستيرويد

ipna-online.org/resources/guidelines/

IPNA International Pediatric Nephrology Association

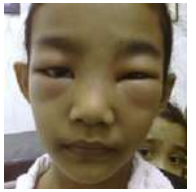
GUIDELINES

Evidence-based clinical management in pediatric nephrology: IPNA Clinical Practice Recommendations

https://ipna-online.org/resources/guidelines/

Second IPNA-CPR Project - SSNS

coordinated by the **IPNA Best Practices & Standards Committee**



Pediatric Nephrology
https://doi.org/10.1007/s00467-022-05739-3

GUIDELINES

IPNA clinical practice recommendations for the diagnosis and management of children with steroid-sensitive nephrotic syndrome

Agnes Trautmann[1] · Olivia Boyer[2] · Elisabeth Hodson[3] · Arvind Bagga[4] · Debbie S. Gipson[5] · Susan Samuel[6] · Jack Wetzels[7] · Khalid Alhasan[8] · Sushmita Banerjee[9] · Rajendra Bhimma[10] · Melvin Bonilla-Felix[11] · Francisco Cano[12] · Martin Christian[13] · Deirdre Hahn[14] · Hee Gyung Kang[15] · Koichi Nakanishi[16] · Hesham Safouh[17] · Howard Trachtman[18] · Hong Xu[19] · Wendy Cook[20] · Marina Vivarelli[21] · Dieter Haffner[22] · on behalf of the International Pediatric Nephrology Association

Received: 15 June 2022 / Revised: 3 August 2022 / Accepted: 22 August 2022
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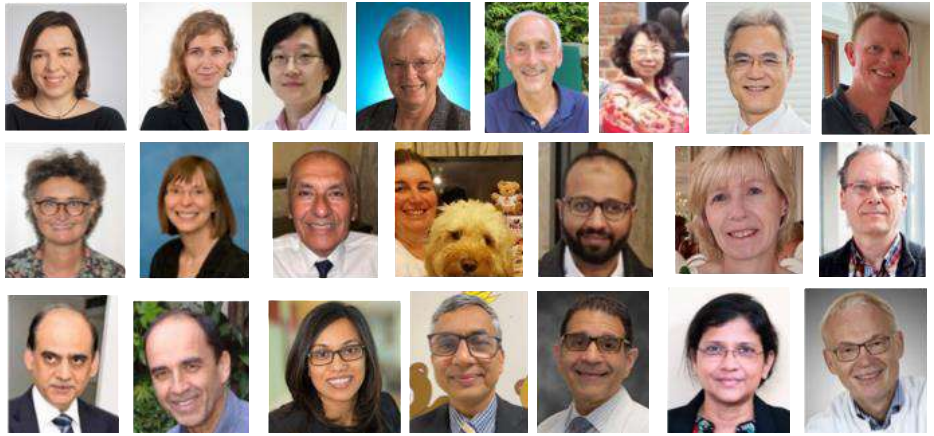
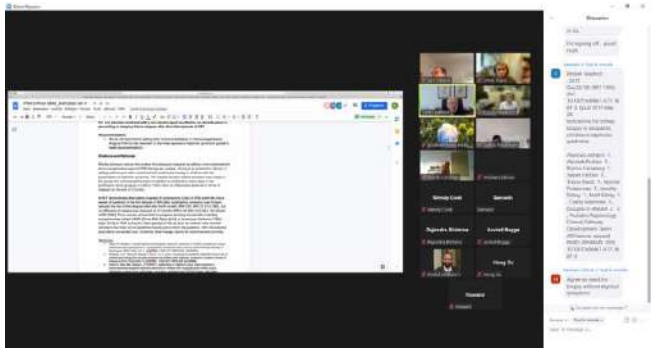




Trautmann et al, Pediatr Nephrol 2022, epub

Methodology

The project used the GRADE method (9 PICO questions) and followed the RIGHT Statement for Practice Guidelines

Core group: Recommendations developed based on evidence from the literature

Strength of recommendations and evidence quality were graded by using the **AAP grading system**

Expert Voting Panel (N=32)

23 pediatric nephrologists including 3–5 representatives of each IPNA Regional Society with expertise in the management of SSNS in children.

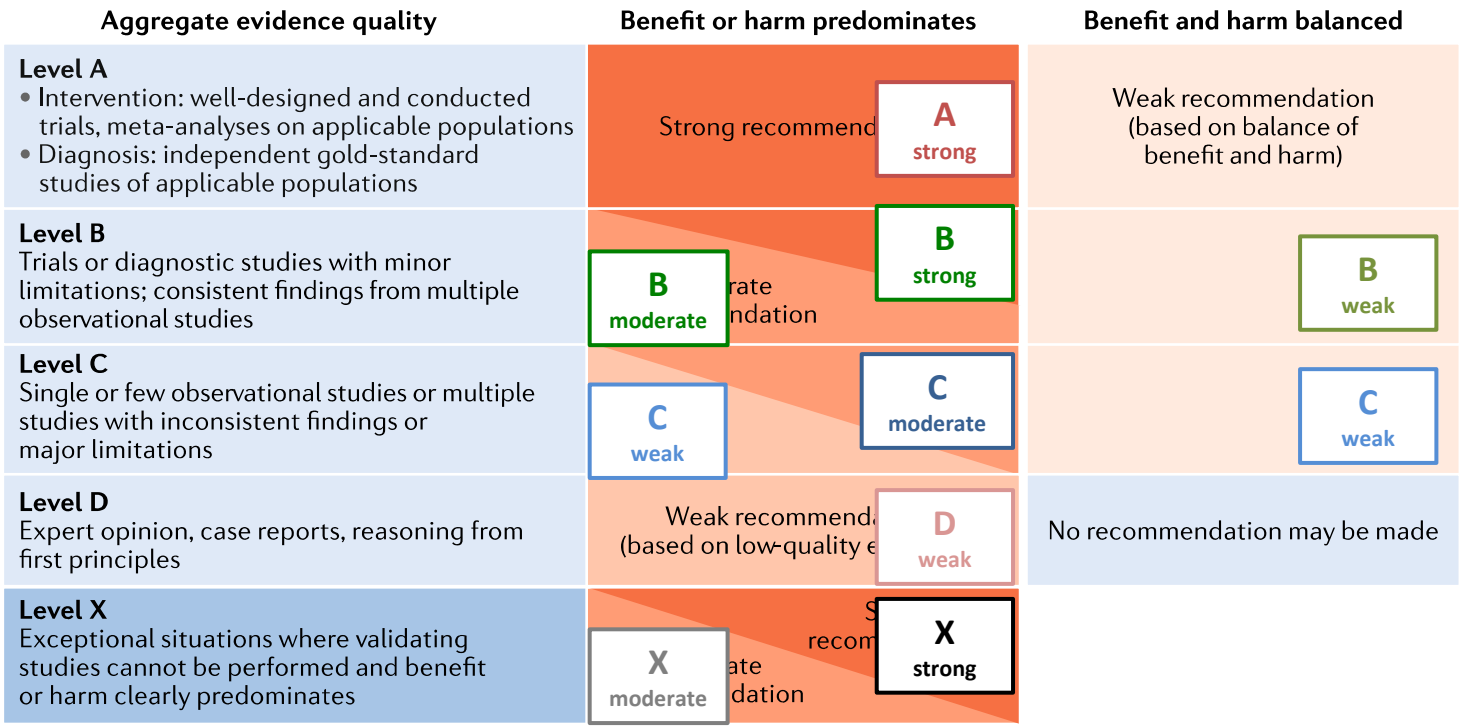
Voting group members were asked by e-questionnaire to provide a level of agreement on a 5-point scale (strongly disagree -> strongly agree) **(Delphi method)**.

<70% consensus: Recommendations discussed and modified by the core group

≥70% consensus
Recommendation accepted

PICO: Patient (or Population), Intervention, Comparison, Outcome; **AAP**: American Academy of Pediatrics; **RIGHT**, Reporting Items for practice Guidelines in HealThcare.

Methodology: **AAP Grading System**

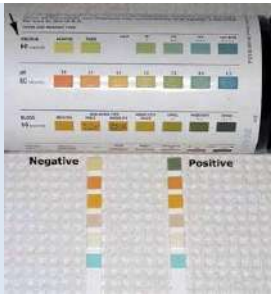


AAP: American Academy of Pediatrics

Definition: **Nephrotic Syndrome**

Nephrotic-range proteinuria

UPCR ≥200 mg/mmol (2 mg/mg) in first morning void
or 24hr urine sample ≥1000 mg/m^2/day
corresponding to 3+ or 4+ by urine dipstick

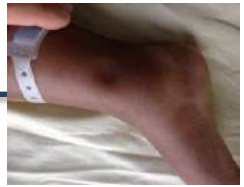


+

Hypoalbuminemia
serum albumin <30 g/l

or

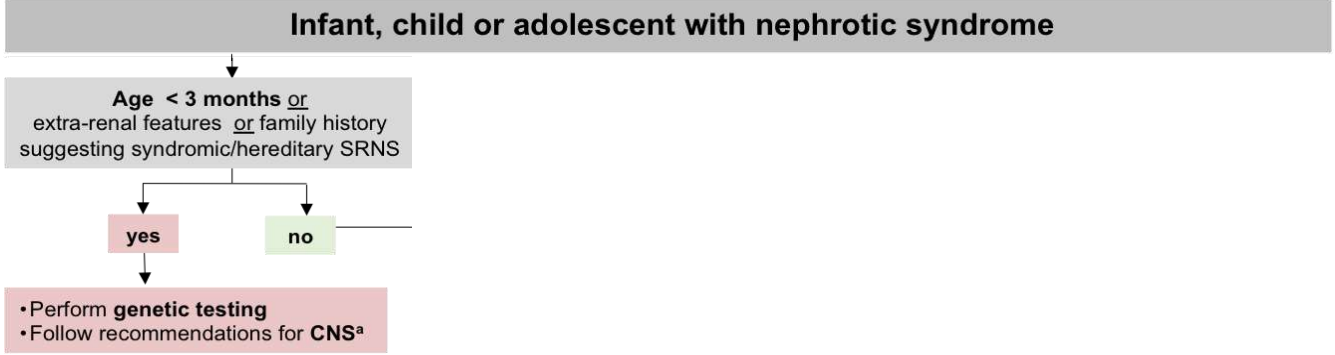
Edema when
serum albumin level is not available



Nephrotic syndrome

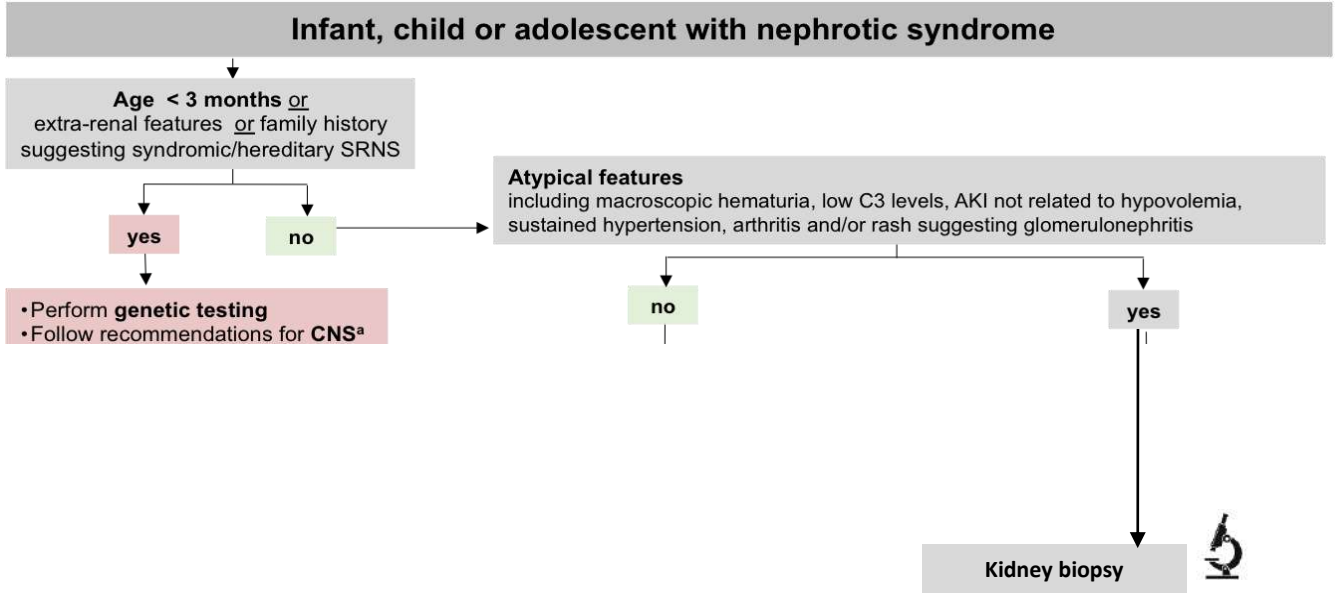
Trautmann et al, Pediatr Nephrol 2022, epub

Diagnostic work-up



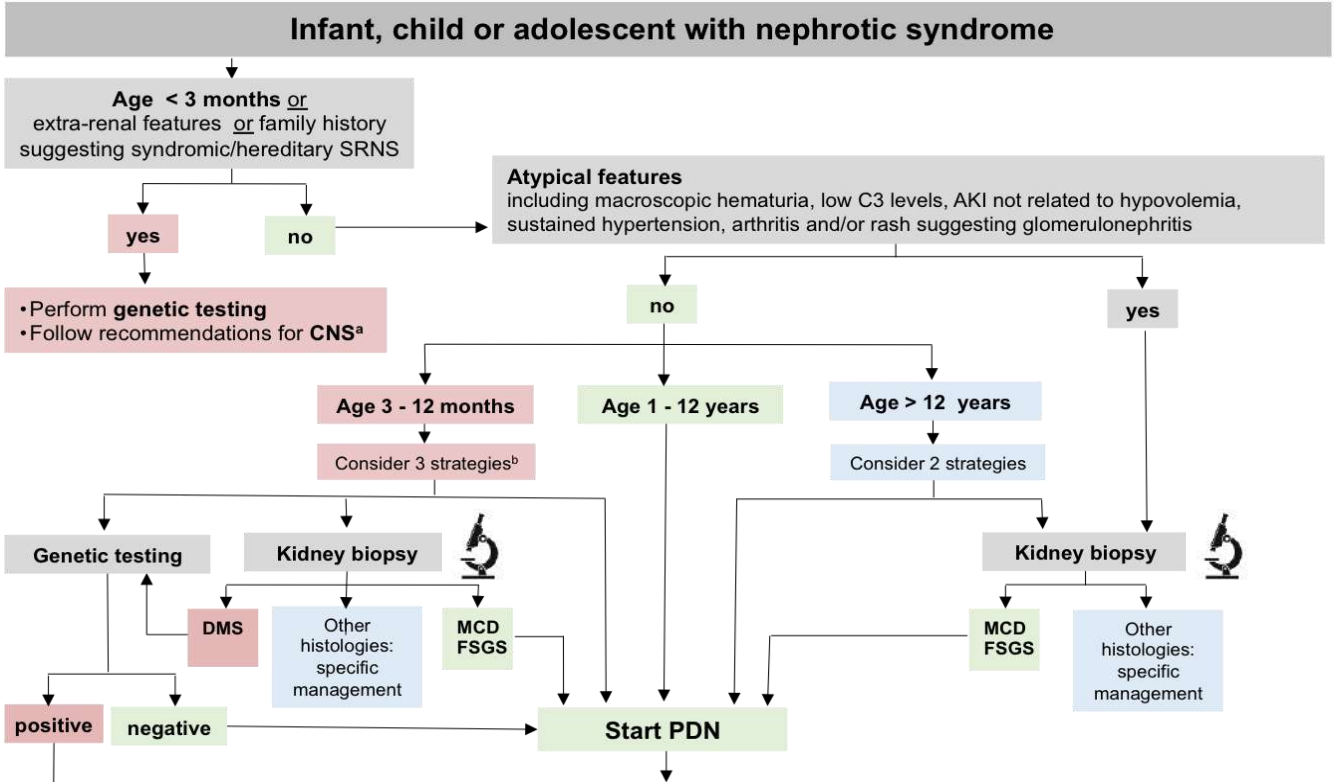
Trautmann et al, Pediatr Nephrol 2022, epub

Diagnostic work-up



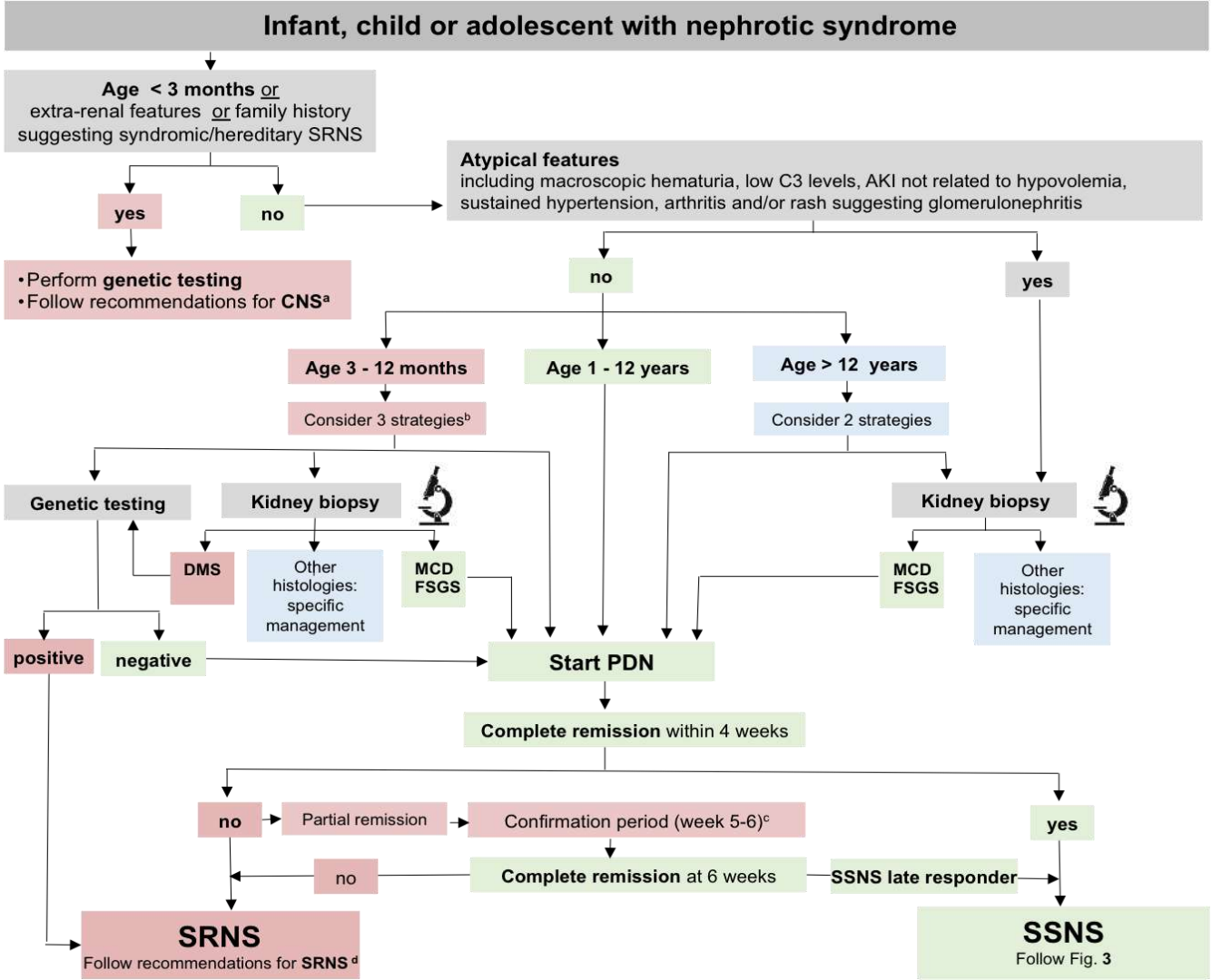
Trautmann et al, Pediatr Nephrol 2022, epub

Diagnostic work-up



Trautmann et al, Pediatr Nephrol 2022, epub

Diagnostic work-up



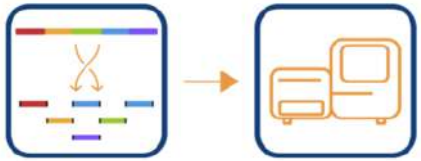
Trautmann et al, Pediatr Nephrol 2022, epub

Histopathology – Kidney Biopsy

B moderate	• **No routine kidney biopsy** in the initial work-up of children with typical NS and age >1 year
A strong	• Recommended in patients with **atypical features** including macroscopic hematuria, low C3 levels, AKI not related to hypovolemia, sustained hypertension, arthritis and/or rash
B weak	• Consider in patients with **infantile onset** NS if genetic screening is not available (age **3-12 months**).
C weak	• Consider in patients **>12 years of age on a case-by-case basis**.
C weak	• Consider in patients with **persistent microscopic hematuria** in specific populations with a high incidence of glomerular diseases such as **IgA nephropathy in East Asia.**
A strong	• Recommended in patients diagnosed with **SRNS**.

Trautmann et al, Pediatr Nephrol 2022, epub

Genetic Testing



A strong

- Recommended in patients
  - with **congenital NS (< 3 months)**
  - **extrarenal features** and/or **family history** suggesting syndromic/hereditary SRNS.

C weak

- Consider in patients with **infantile** onset NS (age 3-12 months).

A strong

- Recommended in patients diagnosed with **SRNS**

B moderate

- **Not recommended if positive family history of SSNS**

Trautmann et al, Pediatr Nephrol 2022, epub

General measures

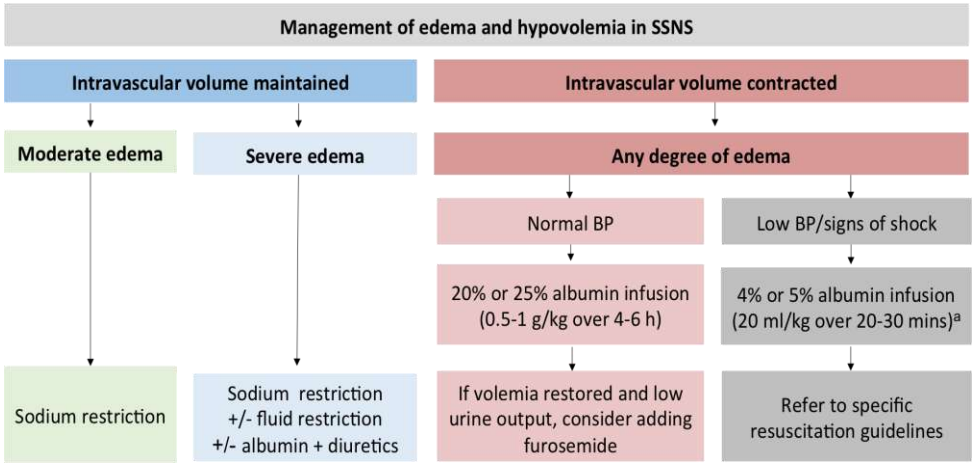
C
moderate

- **Diet:** low salt diet during flares, normal salt intake in remission, low calorie diet on PDN
- Ensure adequate daily calcium intake, vitamin D supplementation in case of deficiency
- **Fluid restriction** only in case of hyponatremia (< 130 meq/L, mind false hyponatremia due to hyperlipemia) and/or severe edema

X
strong

- **No albumin infusion** unless complication: inappropriate use may induce pulmonary edema
- **No routine use of diuretics**: increase the risk of AKI and thrombosis

C
moderate



Trautmann et al, Pediatr Nephrol 2022, epub

General measures

C weak

- **No routine anticoagulation or antiplatelet treatment** unless increased risk for thrombosis

C weak

- **No routine antibiotic prophylaxis**, but prompt antibiotic therapy if suspected bacterial infection

A strong

- **Check vaccination status**

A strong

X strong

A strong

- **Vaccinations** at large with inactivated vaccines including against
  - the flu annually
  - COVID-19
  - with live vaccines when off high-dose immunosuppressive drugs
  - vaccination of the household

Trautmann et al, Pediatr Nephrol 2022, epub

Acute management

EVALUATION




Clinical evaluation: Blood pressure, pulse, assess volume status and extent of edema (ascites, pericardial & pleural effusions); signs of infection (respiratory tract, peritonitis,...), signs of thrombosis (chest pain, headache, neurological signs, abdominal pain, hematuria...)

ACUTE MANAGEMENT

Drug side-effect

Volemia/edema

Hypovolemia: tachycardia, abdominal pain +/- ↑ CRT, ↓ cardio-thoracic index (chest X-Ray)

yes → 4% **albumin infusion** (0.5-1 g/kg over 0,5-1 h), stop diuretics

no

Severe edema: dyspnea, stretched skin...

yes → **sodium restriction +/- fluid restriction +/-** 20% or 25% **albumin infusion** (0.5-1 g/kg over 4-6 h) + **diuretics**

no

Moderate edema

yes → **Sodium restriction**

Thrombosis

Mesenteric ischemia: abdominal pain, tenderness, distension, vomiting/constipation

? yes → Doppler US **Anticoagulation**

Pulmonary embolism: chest pain, tachycardia, +/- fever, abnormal EKG

yes → Angio-TDM Blood Gases **Anticoagulation**

Cerebral artery thrombosis: headache, blurred vision, any neurological sign, may be fluctuant

yes → Angio-MRI **Anticoagulation**

Renal vein thrombosis: abdominal pain, +/- hematuria, HBP, thrombopenia

yes → Doppler US **Anticoagulation**

infections

Peritonitis: fever, abdominal pain, tenderness,

yes → Paracentesis **Antibiotics**

Pneumonia: fever, cough, chest pain, dyspnea, crackles

yes → Chest X-Ray **Antibiotics**

Meningitis: fever, headache, stiff neck, photophobia

yes → Lumbar puncture **Antibiotics**

Cellulitis

yes → Microbial tests **Antibiotics**

Varicella

yes → Skin PCR **IV aciclovir**

PREVENTION

Avoidance of diuretics
Monitoring of labstix
Early treatment of relapses early before complications have occured

Avoidance of diuretics
Labstix monitoring and early treatment of relapses
Early management of hypovolemia and sepsis
Patient mobility
Avoidance of CVL and venipuncture
Preventive anticoagulation if additional risk factor

Inactivated vaccinations at large, during relapses if needed (flu+++, pneumococcus +++, hemophilus)
Live vaccines when off immunosuppressive medications (VZV +++)
In case of exposure to chickenpox in non-immunized immunosuppressed children: specific VZV IVIGs or oral acyclovir or valacyclovir

Vivarelli, Gipson, Sinha, Boyer. Lancet 2023, in press

Dose and duration of PDN (prednisone/prednisolone) in the initial episode of NS

A strong

- After completing the initial diagnostic workup of a child presenting with nephrotic syndrome as outlined above, and a decision is made to start PDN,

  we recommend that **infants > 3 months and children or adolescents (1-18 years)** with their **first episode** of idiopathic NS should receive **daily PDN (prednisone or prednisolone)** for either

A strong

4 weeks at 60 mg/m^2 or 2 mg/kg (maximum dose 60 mg/day), followed by **alternate day PDN** at 40 mg/m^2 or 1.5 mg/kg (maximum dose of 40 mg on alternate days) for **4 weeks**,

or

A strong

6 weeks at 60 mg/m^2 or 2 mg/kg (maximum dose 60 mg/day), followed by **alternate day PDN** at 40 mg/m^2 or 1.5 mg/kg (maximum dose of 40 mg on alternate days) for **6 weeks**.

Trautmann et al, Pediatr Nephrol 2022, epub

Proteinuria – Home Monitoring

X moderate	• We recommend educating families to **monitor urine protein at home** to enable early identification of response to PDN and of relapses.
C weak	• We suggest using the **heat coagulation** or **sulfosalicylic acid test** as alternative methods for home monitoring if dipstick testing for proteinuria is not available.
X moderate	• We recommend **daily home urine dipstick testing until remission**.
D weak	• We suggest home urine dipstick testing, at least **twice weekly** in the first 1-year, individualize thereafter.
X moderate	• We recommend **daily** testing if 1+ or more Or during episodes of **fever**, infections and/or suspected relapse (edema)

Trautmann et al, Pediatr Nephrol 2022, epub

Definition: SSNS versus SRNS

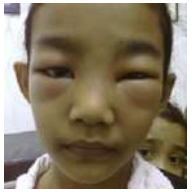
Onset of **Nephrotic Syndrome**: start of oral prednisolone at standard dose (60 mg/m^2/day or 2 mg/kg/day), max. 60 mg/day for 4 to 6 weeks

B moderate

We recommend confirming nephrotic range proteinuria at least once by quantification of proteinuria by UPCR (based on first morning void or 24 hr urine sample) before initiating treatment for the first episode.

Steroid response	Complete Remission	Partial Remission	No Remission
At 4 weeks **Complete remission** within 4 weeks of PDN	**≤ 20 mg/mmol (≤ 0.2 mg/mg)** or negative/ trace dipstick on ≥ 3 consecutive occasions	**> 20 but < 200 mg/mmol (> 0.2 but < 2.0 mg/mg) and,** if available, **serum albumin ≥ 30 g/l**	**≥ 200 mg/mmol (≥ 2.0 mg/mg)** or corresponding to 3+ or 4+ by urine dipstick
	SSNS	**2-wk confirmation period** of oral PDN +/- IV Methylprednisolone and/or + RASB Genetics + KBx	**SRNS**
	Complete remission within 6 weeks of PDN		**Lack of complete remission** within 4 weeks of PDN
At 6 weeks	**SSNS Late Responder**		**SRNS**

Treatment of Relapses



SSNS

Complete the first steroid course by **oral PDN on alternate days**
40 mg/m^2 qod or 1.5 mg/kg qod, max. 40 mg/day
for a **total of 4+4 or 6+6 weeks**

Relapse
Urine dipstick ≥ 3+ or UPCR ≥ 200 mg/mmol (≥ 2 mg/mg) on a spot sample on 3 consecutive days

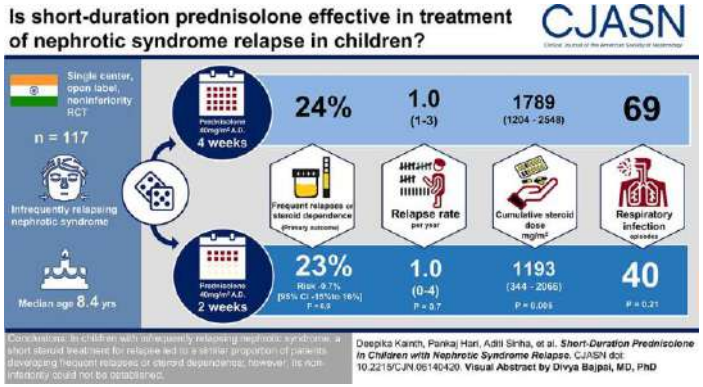
No relapse (20-30%)

Restart oral PDN
60 mg/m^2/day or 2 mg/kg/day, max. 60 mg/day until negative/trace dipstick on **≥** 3 consecutive days, then decreased to **40 mg/m^2 qod** or 1.5 mg/kg qod, max. 40 mg/day for **4 weeks**

B
moderate

A
strong

We do not recommend a tapering schedule during alternate day dosing.



Prevention of Relapse at Onset of Infections

B
moderate

We do **not recommend the routine** use of a short course of low-dose **daily PDN** at the onset of an upper respiratory tract infection (**URTI**) for prevention of relapses

D
weak

We suggest considering a short course of low dose daily PDN at the onset of an URTI in children who are already taking low dose alternate day PDN and have a **history of repeated infection-associated relapses**.

Trautmann et al, Pediatr Nephrol 2022, epub

Definitions: **Forms of SSNS**

Relapse

Urine dipstick ≥ 3+ or UPCR ≥ 200 mg/mmol (≥ 2 mg/mg) on a spot sample on 3 consecutive days

Restart oral PDN

60 mg/m^2/day or 2 mg/kg/day, max. 60 mg/day until negative/trace dipstick on ≥ 3 consecutive days, then decreased to 40 mg/m^2 qod or 1.5 mg/kg qod, max. 40 mg/day for 4 weeks

Frequently relapsing nephrotic syndrome (FRNS)

≥ 2 relapses in the first 6-months following remission of the initial episode

or **≥ 3 relapses in any 12 months**

FRNS

≥ 2 relapses in the first or **≥ 3 relapses** in any 12 months

Low-dose alternate day PDN or first-line steroid-sparing agent

A
strong

InFRNS

< 2 relapses in the first 6 months; < 3 relapses in any subsequent 12 month period

Restart oral PDN

No relapse

Definitions: **Forms of SSNS**

Relapse
Urine dipstick ≥ 3+ or UPCR ≥ 200 mg/mmol (≥ 2 mg/mg) on a spot sample on 3 consecutive days

Restart oral PDN
60 mg/m^2/day or 2 mg/kg/day, max. 60 mg/day until negative/trace dipstick on ≥ 3 consecutive days, then decreased to 40 mg/m^2 qod or 1.5 mg/kg qod, max. 40 mg/day for 4 weeks

SSNS not controlled on therapy:
FRNS despite immunosuppression or significant drug-related toxicity while on immunosuppression
Complicated relapse :
relapse requiring hospitalization

SDNS
≥ 2 consecutive relapses during PDN therapy or within 14 days of its discontinuation
Or SSNS not controlled on therapy
Or complicated relapse

First-line steroid-sparing agent

B
moderate

FRNS
≥ 2 relapses in the first or ≥ **3 relapses** in any 12 months

Low-dose alternate day PDN or first-line steroid-sparing agent

A
strong

InFRNS
< 2 relapses in the first 6 months; < 3 relapses in any subsequent 12 month period

Restart oral PDN

No relapse

Selection of steroid-sparing agent

X
strong

- We recommend that the selection of the steroid-sparing agent be made in **conjunction with patients or guardians** in order **to choose the most appropriate medication for each individual** according to their values and preferences.
  This requires not only information on the **efficacy of these medications**, but also **disclosure of possible side effects** as listed in **Table 5.**

A
strong

- We recommend the introduction of one of the **following-steroid sparing agents** (alphabetical order):
  - calcineurin inhibitors (CNIs)
  - cyclophosphamide (CYC)
  - levamisole (LEV)
  - mycophenolate mofetil (MMF)/ mycophenolic sodium (MPS)

Trautmann et al, Pediatr Nephrol 2022, epub

Selection of steroid-sparing agent – side effects

First-line steroid-sparing agent

Levamisole (all transient): leucopenia, elevated transaminases, ANCA vasculitis after 2 years

MMF/MPS (all transient): abdominal pain, diarrhea, weight loss, leucopenia, anemia and elevated transaminases

CNIs: nephrotoxicity, hypertension, posterior reversible encephalopathy syndrome, diabetes mellitus (TAC), hirsutism (CsA)

Cyclophosphamide: transient leucopenia and/or thrombocytopenia, alopecia, hemorrhagic cystitis, infections, cancer, infertility

2nd-line: Rituximab (>7-9 yo): transient infusion reactions, prolonged hypogammaglobulinemia, neutropenia, infections

C
weak

Boyer et al, NDT 2022, in press

Selection of steroid-sparing agent – second line

B
moderate

- We recommend using **RTX** as a steroid-sparing agent in children with FRNS or SDNS who are not controlled on therapy **after a course of treatment with at least one other steroid-sparing agent** at adequate dose especially in case of non-adherence.

C
weak

- This is especially preferable, both in terms of safety and of effectiveness, **above the age of 7-9 years**.

X
strong

- We recommend **switching to a different steroid-sparing** agent when a patient is **not controlled on therapy** with the initial agent.

Trautmann et al, Pediatr Nephrol 2022, epub

Steroid-sparing agents – clinical tips

First-line steroid-sparing agent

X moderate	**Levamisole** : monitor transaminases and CBC/3-4 months Monitor ANCA at baseline and /6-12 months
B moderate	**MMF/MPS** : monitor transaminases and CBC/3-4 months AUC > 50 mg·h/L in patients not controlled on MMF/MPS
B moderate	**CNIs:** monitor T0, lowest effective dose, avoid prolonged use of CNIs for > 2-3 years, otherwise perform KBx
B moderate	**Cyclophosphamide**: single course of 2 mg/kg/d (max 150 mg) for 12 weeks or 3 mg/kg/d for 8 weeks (or 6 monthly pulses) + low-dose PDN qod, monitor CBC/2 wks – stop if cytopenia
B strong	**2nd-line: Rituximab: target** absolute CD19 cell count < 5 cells/mm3 or < 1% lymphocytes, monitor IgG and CBC

X strong

Steroid-sparing agents- clinical tips

First-line steroid-sparing agent

Levamisole : monitor transaminases and CBC/3-4 months
Monitor ANCA at baseline and /6-12 months

C
weak

MMF/MPS : monitor transaminases and CBC/3-4 months
AUC > 50 mg·h/L in patients not controlled on MMF/MPS

→ Taper off PDN and IS in 1.5 -2 months

CNIs: monitor T0, lowest effective dose, avoid prolonged use of CNIs for > 2-3 years, otherwise perform KBx

Cyclophosphamide: single course of 2 mg/kg/d (max 150 mg) for 12 weeks or 3 mg/kg/d for 8 weeks (or 6 monthly pulses) + low-dose PDN qod, monitor CBC/2 wks – stop if cytopenia

B
strong

2nd-line: Rituximab: target absolute CD19 cell count
< 5 cells/mm3 or < 1% lymphocytes, monitor IgG and CBC

→ Taper off PDN and IS in 2-3 months

Monitoring of steroid-sparing agents

First-line steroid-sparing agent

Levamisole : monitor transaminases and CBC/3-4 months
Monitor ANCA at baseline and /6-12 months

C weak

MMF/MPS : monitor transaminases and CBC/3-4 months
AUC > 50 mg·h/L in patients not controlled on MMF/MPS

→ Taper off PDN and IS in 1.5 -2 months

CNIs: monitor T0, lowest effective dose, avoid prolonged use of CNIs for > 2-3 years, otherwise perform KBx

B moderate

Cyclophosphamide: single course of 2 mg/kg/d (max 150 mg) for 12 weeks or 3 mg/kg/d for 8 weeks (or 6 monthly pulses) + low-dose PDN qod, monitor CBC/2 wks – stop if cytopenia

B strong

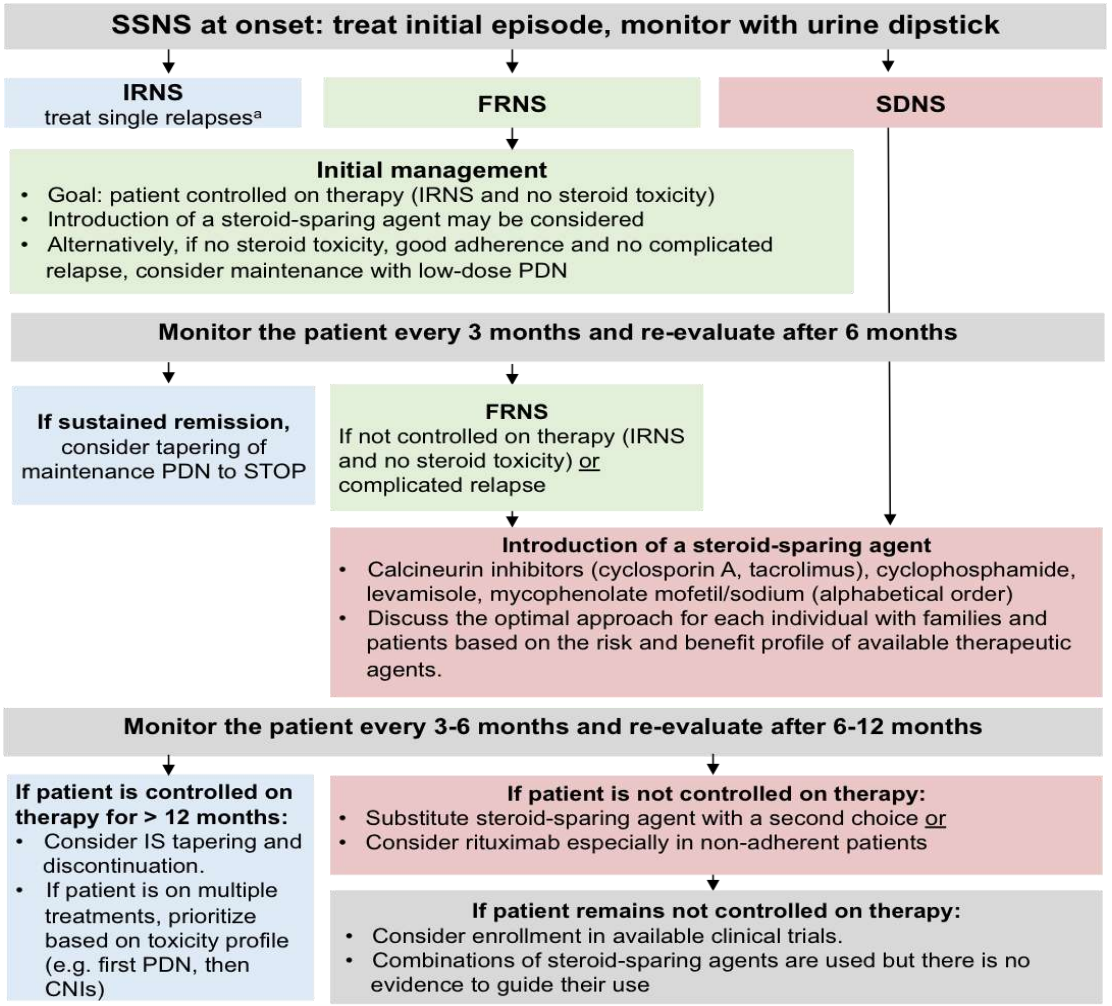
2nd-line: Rituximab: target absolute CD19 cell count
< 5 cells/mm3 or < 1% lymphocytes, monitor IgG and CBC

→ Taper off PDN and IS in 2-3 months

X strong

Tapering and discontinuation of maintenance treatment in children if sustained remission for at least 12 months

Management of children with SSNS



Trautmann et al, Pediatr Nephrol 2022, epub

Acknowledgements

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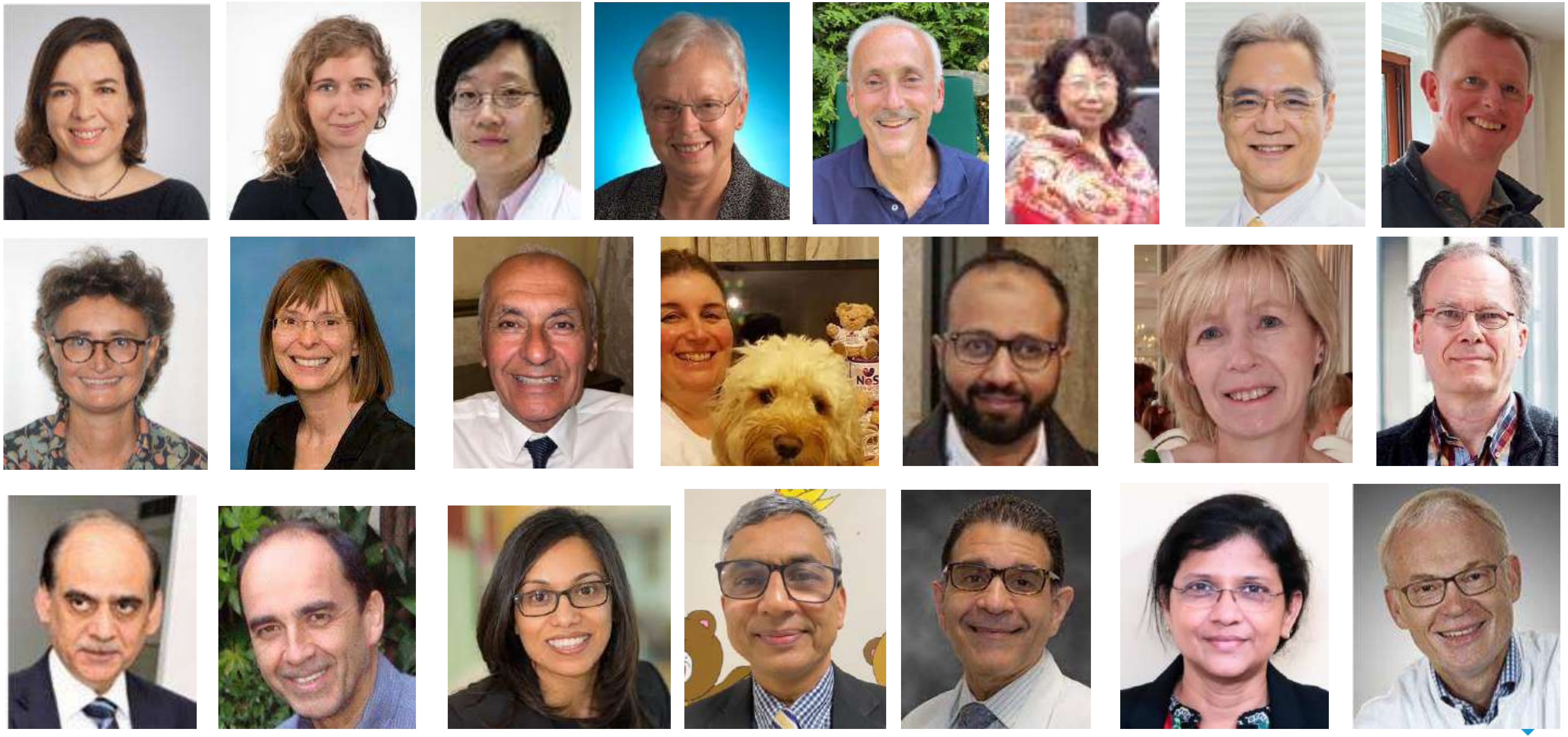
Core group members: SSNS guideline



Acknowledgements: IPNA SSNS guideline

Core group (n=22)

20 Pediatric Nephrologists from IPNA regional societies
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Core group continued

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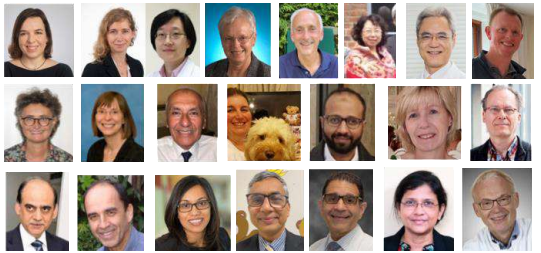

External expert group (n=12)

Pediatric endocrinologists: Agnes Linglart (Paris, France), Dirk Schnabel (Berlin, Germany);
General pediatrician: Adamu Sambo (Gloucestereshire, UK)
Transition: Marjo van Helden (Nijmegen, Netherlands), Ben Sprangers (Leuven, Belgium);
Dieticians: Stefanie Steinmann (Hannover, Germany), Sheridan Collins (Sydney, Australia), Katie Byrne (Michigan, United states)
Patient representatives: Clemens and Juliane Brauner (Hannover, Germany), Chandana Guha (Sydney, Australia), Stephane Serre (Toulouse, France).

Voting Panel (n=32)

Experts from IPNA regional societies:
ESPN, ANZPNA, JSPN, ASPN, ALANEPE, AsPNA, AFPNA

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