



Analysis of affordability of negotiated pediatric drugs by category in China's National Reimbursement Drug List

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INTRODUCTION

Background

Pediatric medicines possess unique attributes, such as dose sensitivity, specialized administration methods, and stringent applicability requirements. China, with approximately 253 million children aged 0–14 (accounting for 17.95% of the total population), plays a critical role in global child health. **The National Drug Price Negotiation (NDPN) policy** has reshaped China's drug market access rules, while its impact on **pediatric medicines** is understudied.

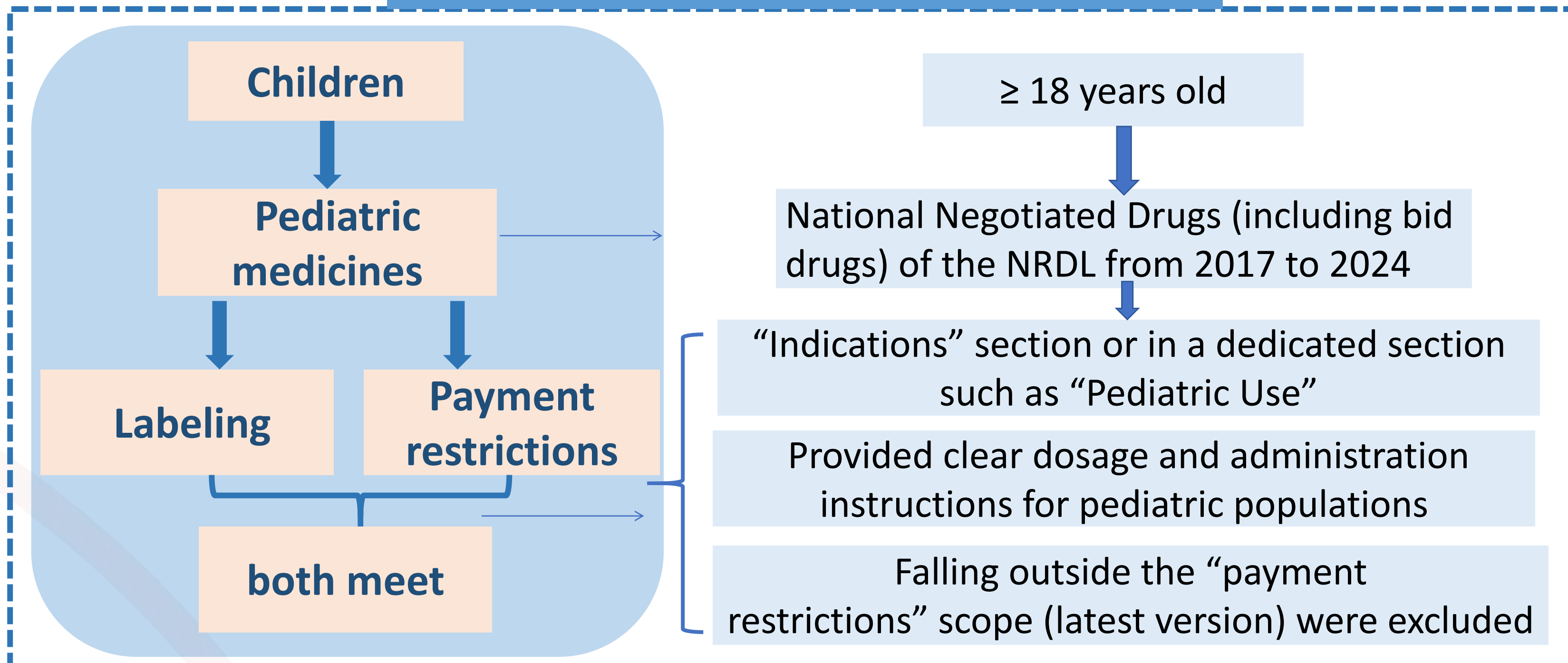
- The 2024 NRDL adjustment plan explicitly stated that **priority** will be given to adjusting and including pediatric medicines in China.
- From 2021 to 2023, the number of pediatric medicines **covered increased** from 47 to 58 and then to 77 through NDPN policy.

Objective

This study aims to analyze the **affordability** of pediatric medicines in the **National Reimbursement Drug List (NRDL)** through negotiation **from 2017 to 2024**, and provide evidence to support decision-making.

METHOD

Inclusion/Exclusion criteria



Referring to the WHO/HAI calculation methodology

- Calculated the average **DDC** (cost per defined daily dose) for each category separately, using negotiated prices from the Yaozhi Database and DDD values from the WHO ATC/DDD Index or drug package inserts.
- Assessed the **statistical relationship** between each categorical variable and DDC ($p < 0.05$).
- Affordability** was assessed by DDC, considering the proportion of China's household disposable income required to cover annual treatment costs, with a ratio of ≤ 1 being considered affordable.

RESULTS

Key findings

- Fig1.** A total of **108 pediatric medicines** were included, covering 12 ATC classes except classes G and P, with a mean launch-to-NRDL delay of **2.03 years** (SD=0.87).
- Fig2.** Mean DDC **varied significantly by ATC class** ($F=2.043$, $p=0.029$), with class B highest (1045.09, SD=1653.67) and class S lowest (9.90, SD=0.00).
- Fig3.** Mean DDC also **differed significantly by negotiation year** ($F=32.122$, $p=0.000$), peaking in 2021 (310.54) and bottoming in 2019 (37.36).
- Fig4.** Before reimbursement, 23 medicines (21.30%) were unaffordable, mainly in **class L** ($n=11$). After reimbursement, 4 remained unaffordable (class L:2, B:1, M:1).

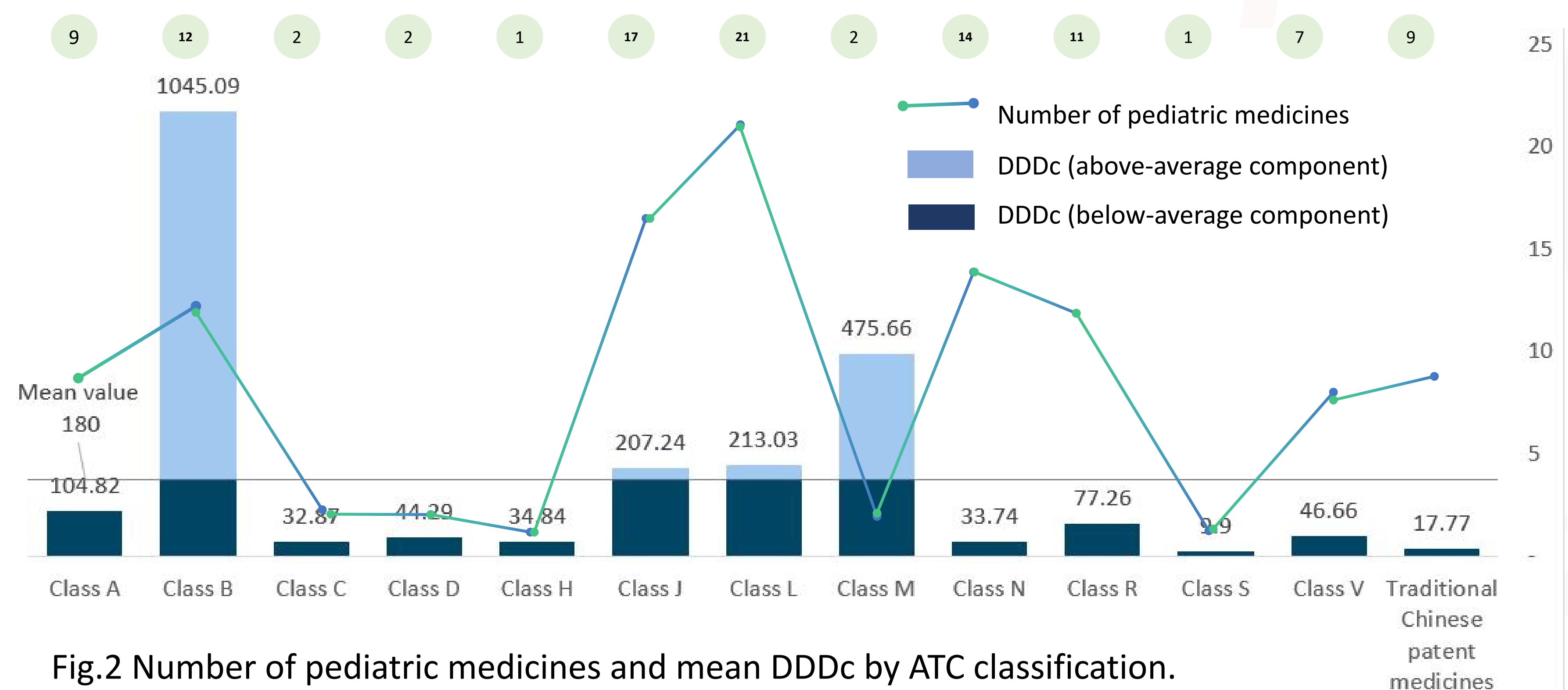


Fig.2 Number of pediatric medicines and mean DDC by ATC classification.

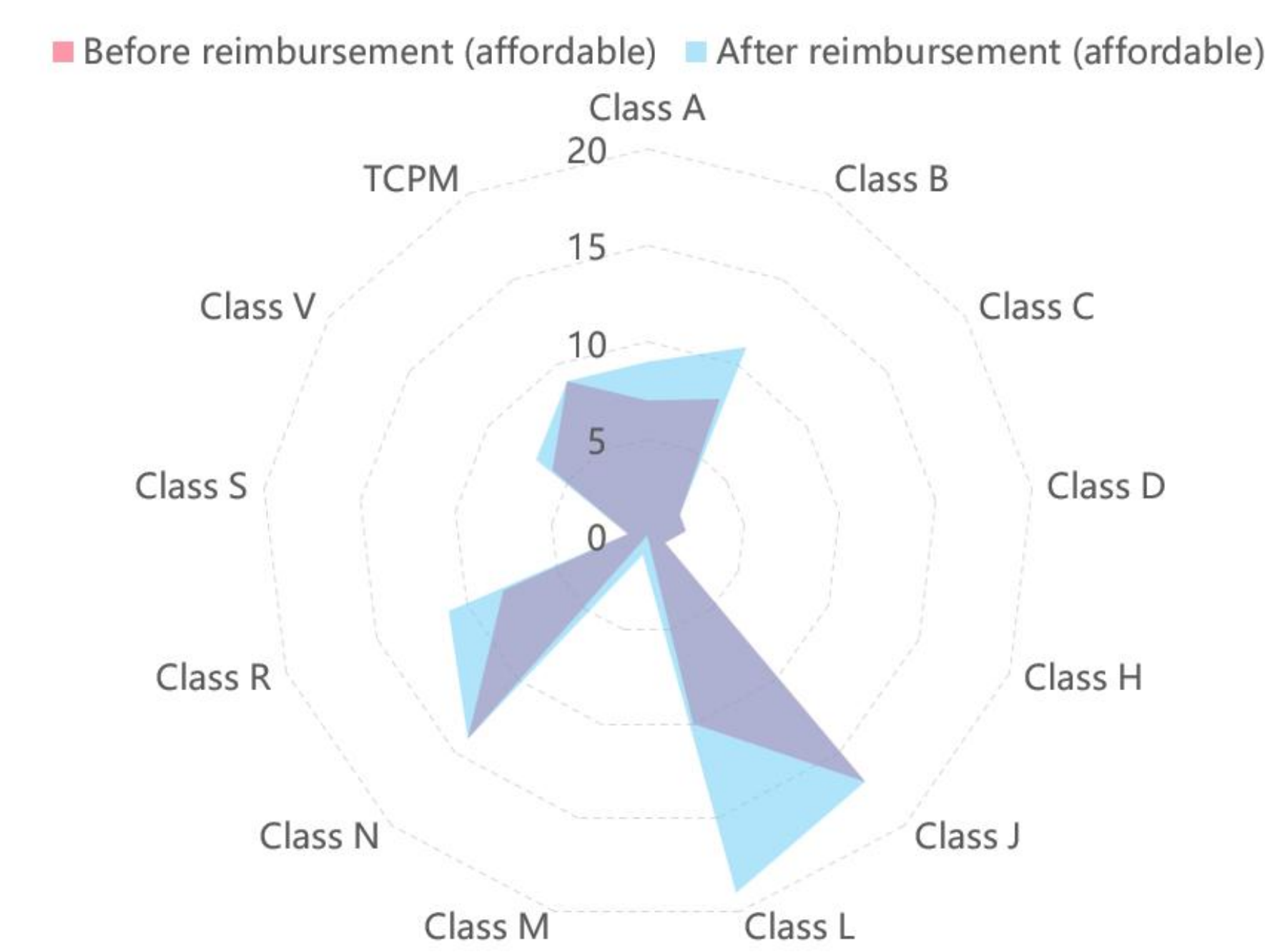


Fig.3 Affordable pediatric medicines counts (pre/post-reimbursement) by ATC classification.

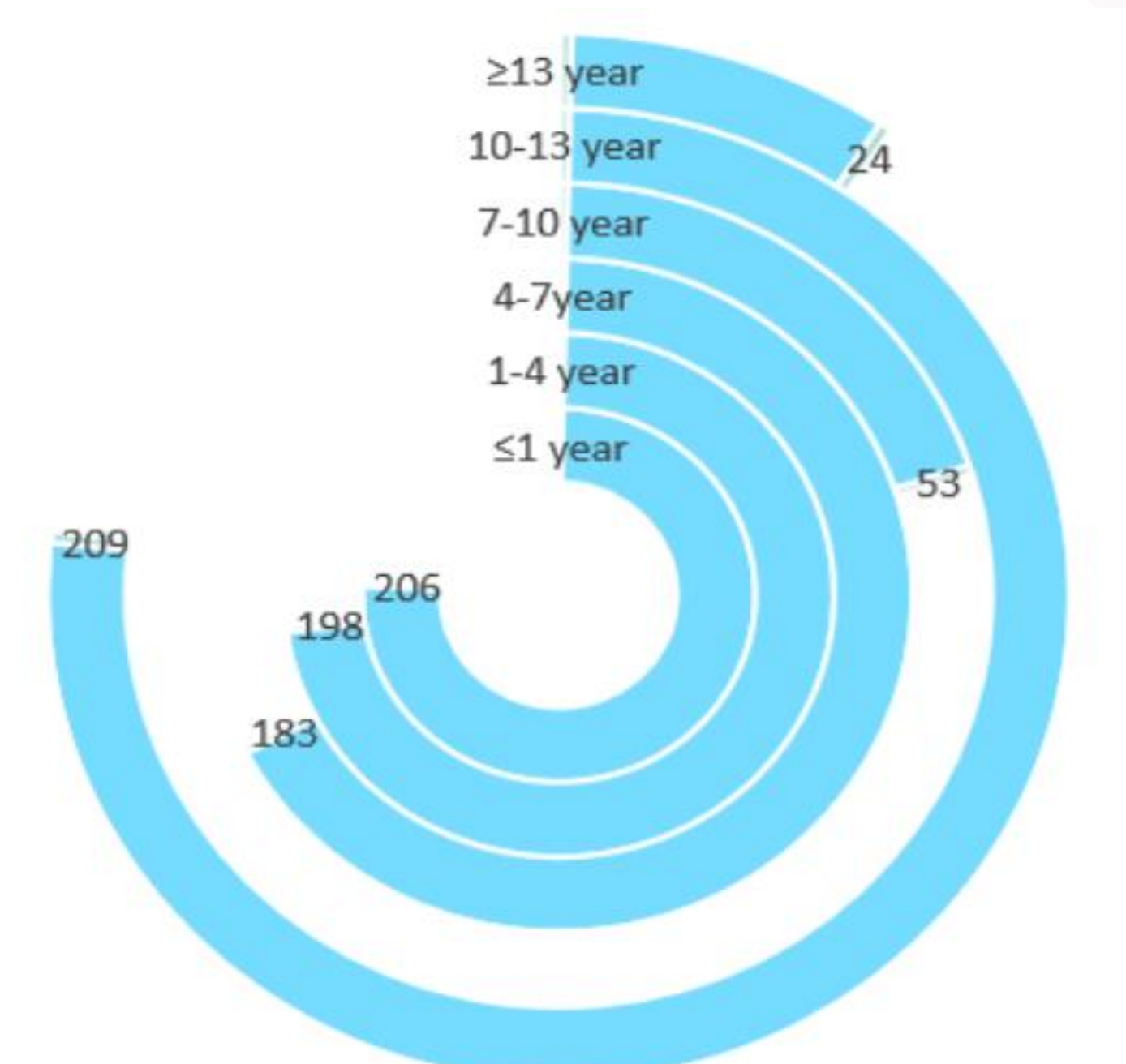


Fig.4 Mean DDC of pediatric medicines by delay between market launch and inclusion in NRDL.

CONCLUSION

- Mean DDC of included pediatric medicines varied significantly by ATC class and negotiation year, classification is discriminative for pediatric medicines.
- The NDPN policy has substantially reduced prices for novel drugs and improved the affordability of pediatric treatments, notably for Class L.
- However, targeted strategies are needed to address inequities across therapeutic categories and negotiation cycles.