

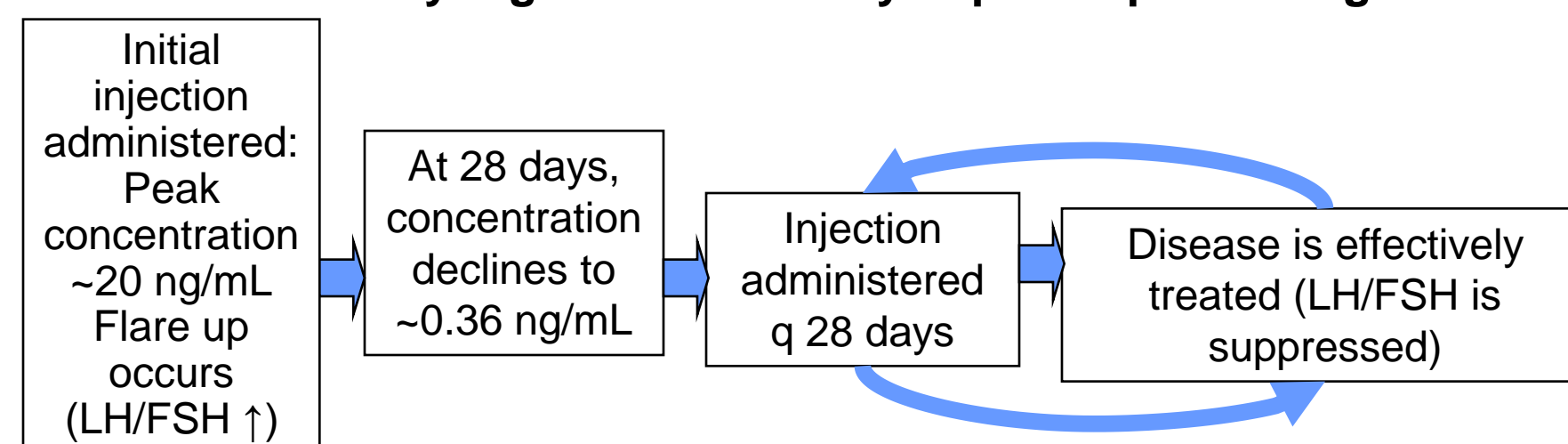
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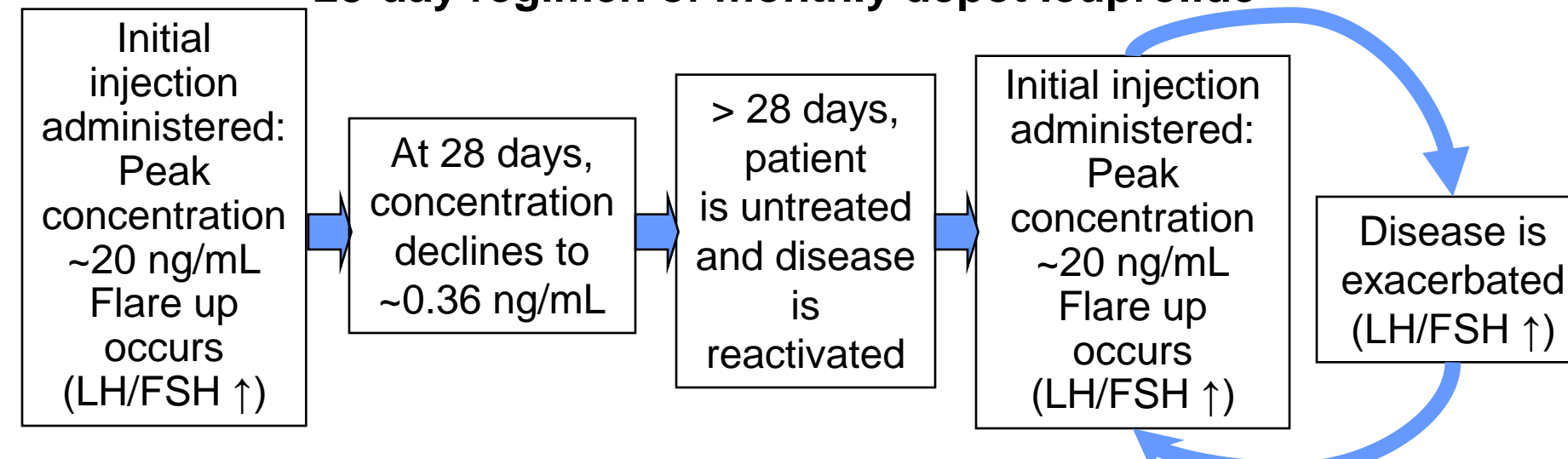
BACKGROUND

- Central precocious puberty (CPP) is a rare disorder caused by premature activation of the hypothalamus-pituitary-gonadal (HPG) axis, causing development of secondary sexual characteristics, accelerated growth, and accelerated bone maturation.¹
- Untreated CPP is associated with:
 - Psychosocial and behavioral problems²⁻⁵ (e.g., early sexual behavior, early pregnancy, substance abuse, depression, conduct problems).
 - Early preemptive growth spurt⁶ (early closure of epiphyseal growth plates, compromised adult stature).
- Treatment
 - Gonadotropin releasing hormone (GnRH) agonists are the mainstay treatment.
 - GnRH initiation causes an initial paradoxical stimulatory effect ("flare up") that remits following continuous administration.
 - Consequences of interrupted therapy, which can lead to multiple flare ups, may include returned pubertal signs (e.g., menses, breast development, testicular growth, and compromise of adult stature).
 - In the U.S., the most commonly used GnRH agonist is an intramuscular injection of depot leuprolide acetate given once every 28 days ("monthly depot leuprolide").

Efficacy is dependent upon adherence to a 28-day regimen of monthly depot leuprolide regimen



Exacerbation of disease occurs when patients do not adhere to a 28-day regimen of monthly depot leuprolide



OBJECTIVE

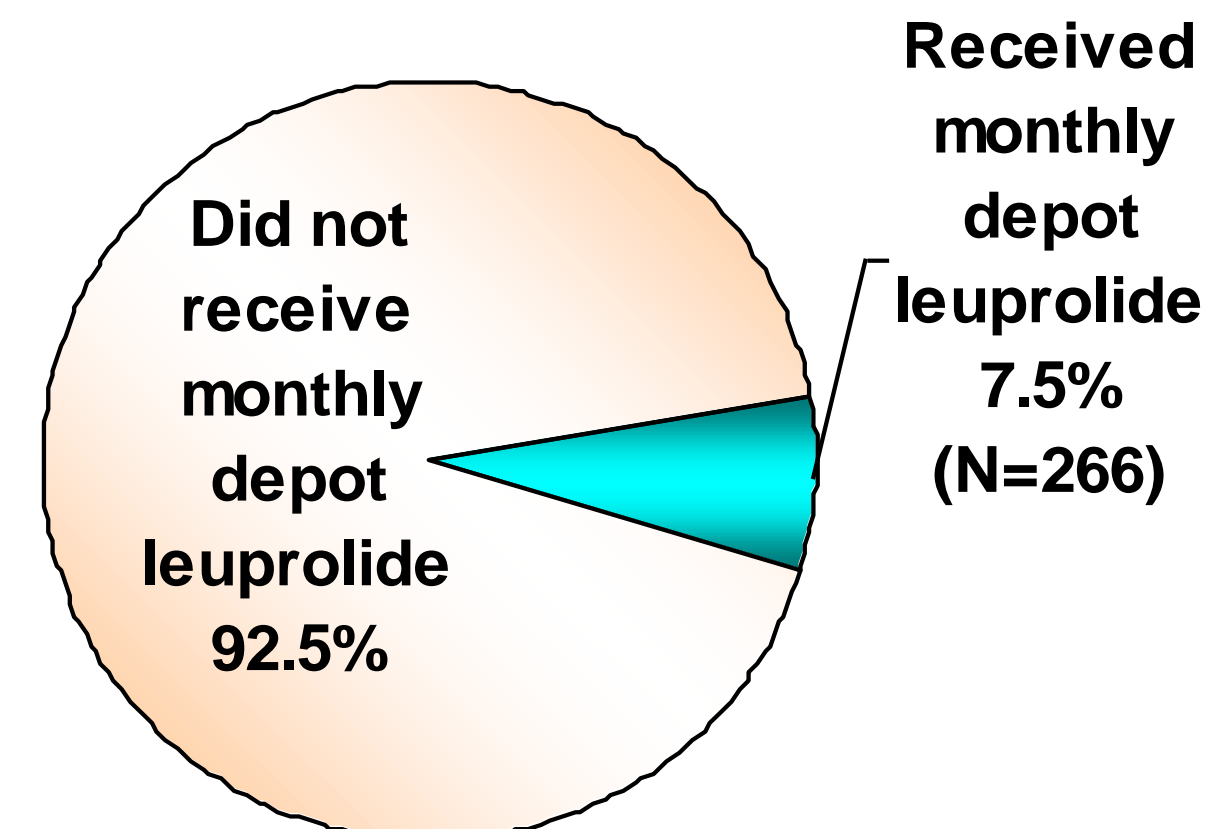
- Because complete suppression of hormones is dependent on continuous delivery of GnRH agonists, we examined the extent to which patients adhered to the prescribed monthly depot leuprolide regimen.

METHODS

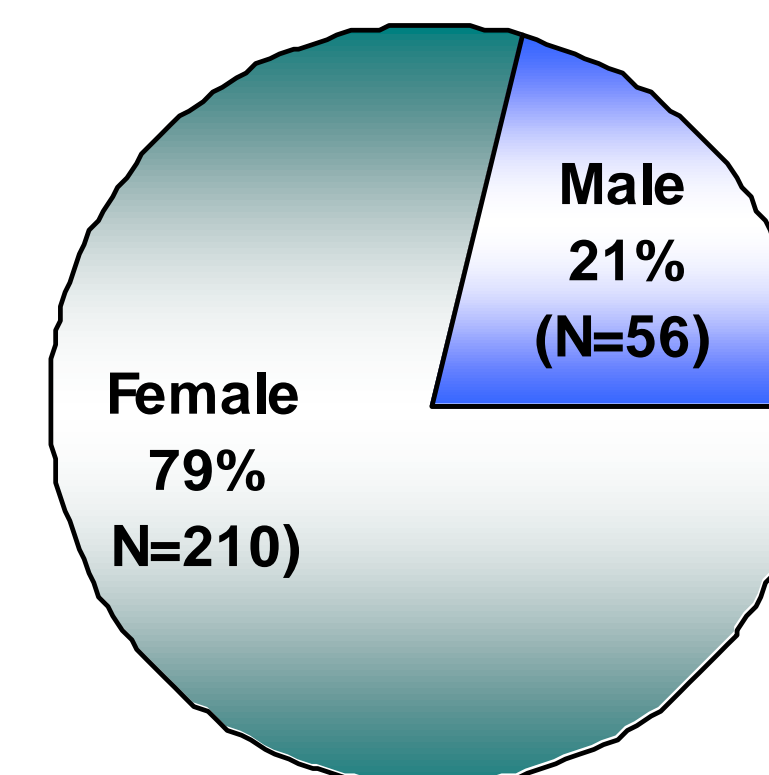
- We conducted a 7-year (1997-2004) retrospective analysis of Florida Medicaid-enrolled children age 2-11 years with CPP (ICD-9 259.1, precocious sexual development and puberty, including premature thelarche and adrenarche) to examine the frequency with which children received monthly depot leuprolide. Patients who received at least one administration of monthly depot leuprolide were identified. All data were patient de-identified and HIPAA compliant.

RESULTS

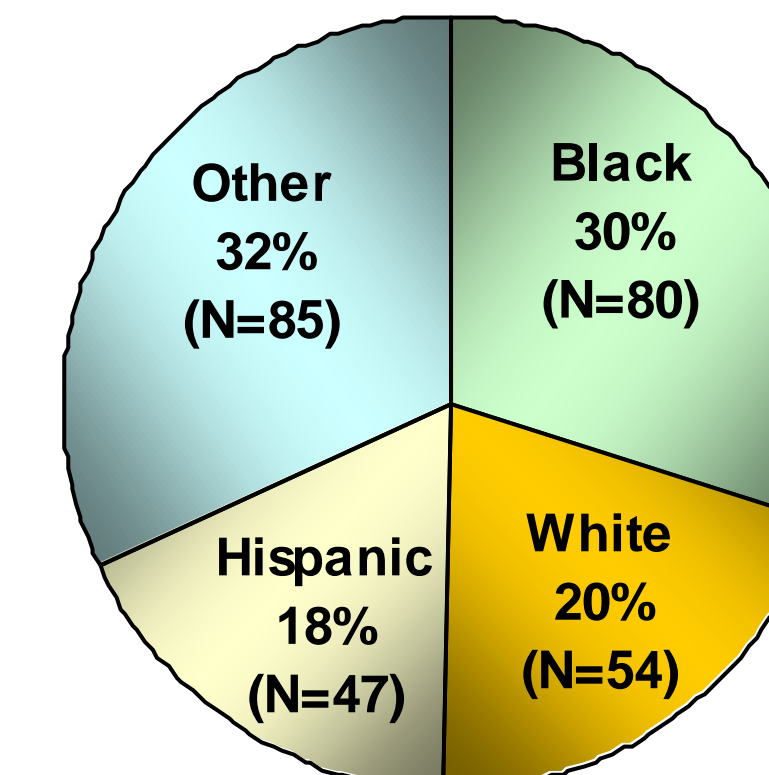
Among 3,530 children with CPP, 266 (7.5%) received monthly depot leuprolide administrations during the index period.



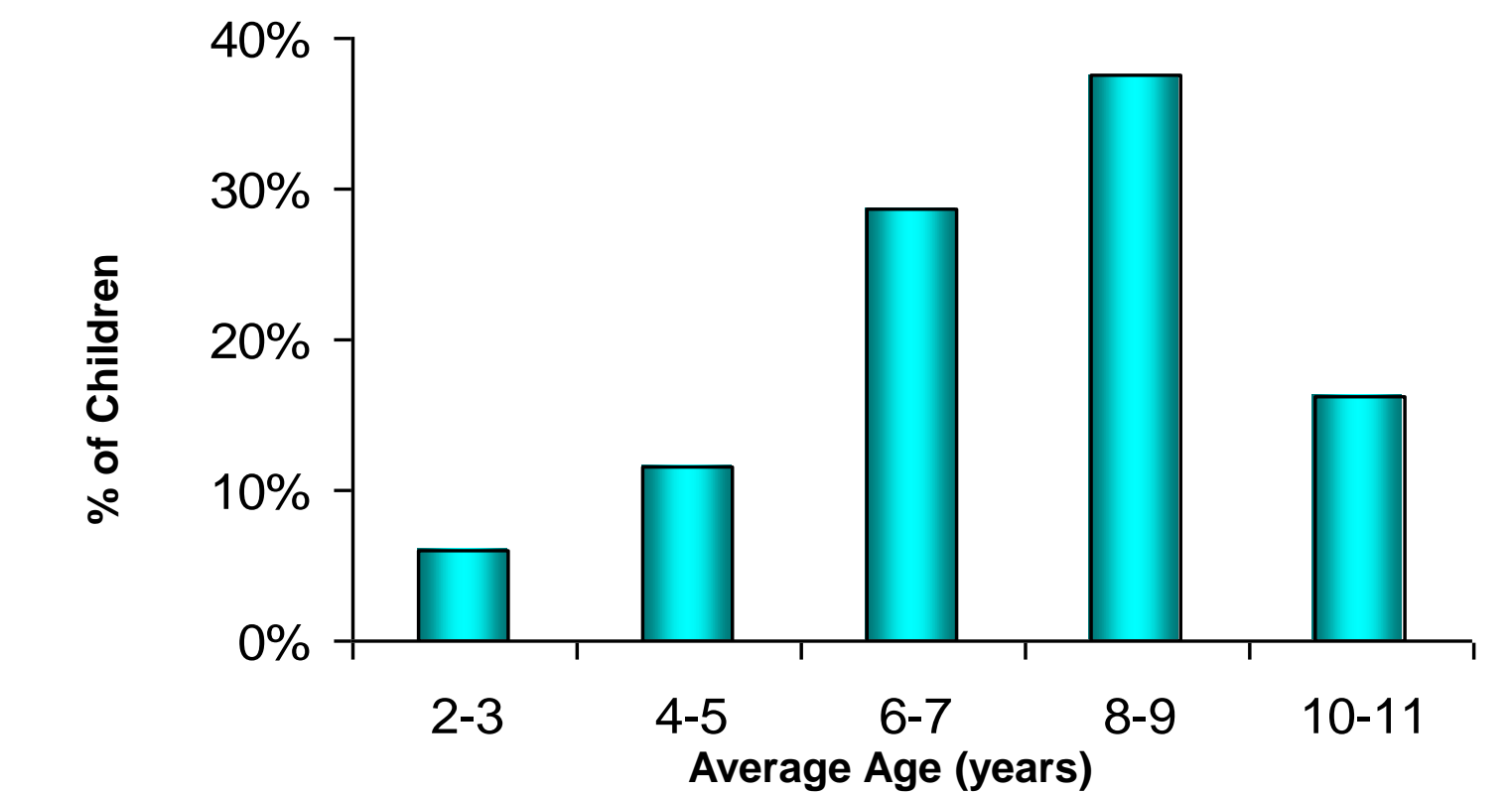
Sex distribution among those receiving monthly depot leuprolide administrations during the index period (N=266)



Racial/ethnicity distribution of those receiving monthly depot leuprolide administrations during the index period (N=266)

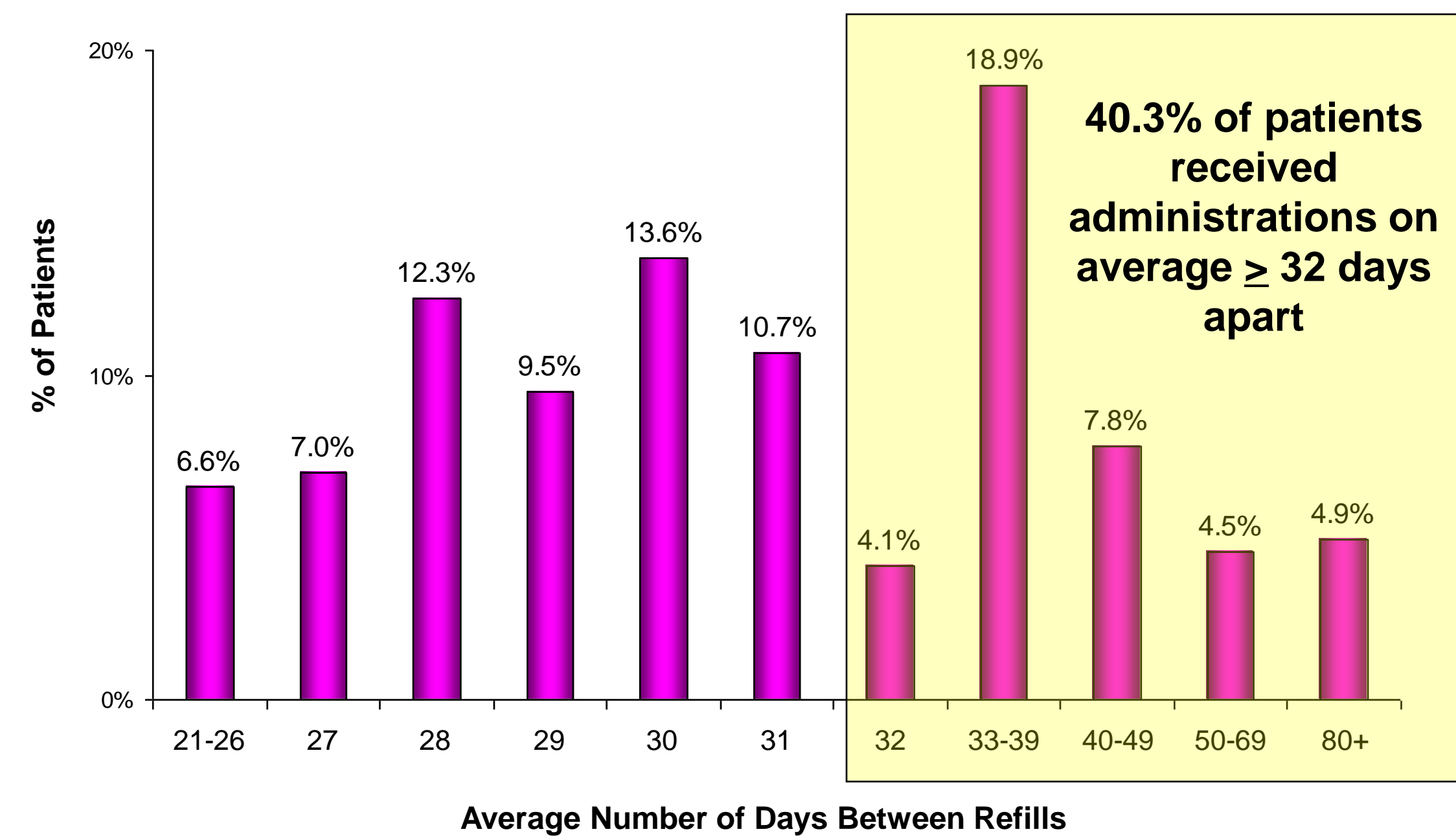


Average age distribution at 1st diagnosis among those receiving monthly depot leuprolide administrations during the index period (N=266)



Average age at 1st CPP diagnosis was 7.4 (SD 2.2).

Among patients who received at least two administrations (N=243), average number of days between administrations



Among patients who received at least two administrations (N=243), the average number of days between administrations was 37 (SD 17.6), with a range of 21 to 156 days.

CONCLUSIONS

Among Florida Medicaid-enrolled children diagnosed with CPP who received at least 2 administrations of monthly depot leuprolide, only (25.9%) received treatment within the 28-day recommended administration period.

Our findings suggest that the majority of children with CPP who receive monthly depot leuprolide may be inadequately controlled and are therefore at risk for the return of pubertal signs such as menses, breast development, testicular growth and long-term compromise of adult stature.

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FOR FURTHER INFORMATION

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DISCLOSURES

Authors of this presentation have the following to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation:

Cheryl Hankin, Amy Bronstone, and Zhaohui Wang are Consultants to Indevus Corporation
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