

# Health Care Practitioner Knowledge About Dosing And Side Effects Of Fluticasone Propionate Metered-Dose-Inhaler For Children With Asthma

Joseph A Sforza, B.S. (1), Amanda R Skoner, B.S. (1), David P. Skoner, M.D. (2)

(1) Juniata College, Huntingdon, PA, (2) West Virginia University School of Medicine, Morgantown, WV

## Abstract

**RATIONALE:** A 6 year-old child developed Cushing's Syndrome after 16 months of treatment with an FDA-unapproved dose (110mcg) of the inhaled corticosteroid (ICS) fluticasone propionate metered-dose-inhaler (FP-MDI) for asthma. The objective was to assess health care practitioner (HCP) knowledge about FP-MDI dosing and side effects. **METHODS:** Anonymous and interactive polling was conducted using TurningPoint software and hand-held devices before and after PowerPoint presentation of the case during live meetings of HCPs across the United States. During the presentation, education about FDA-approved FP-MDI doses and side effects was provided. **RESULTS:** Presentations (n=40) were delivered to 790 HCPs, including asthma specialists. Before the presentation, only 26% of HCPs knew the dose of FP-MDI that is FDA-approved for children <12 years of age (44mcg only), and only 28% were confident in their ability to detect and diagnose growth and adrenal suppression secondary to ICS in a child with asthma. After the presentation, the respective values were 97% and 89% (p<0.05). FP-MDI was the ICS with which 43% were most experienced, yet only 11% knew the Asthma Guideline-recommended medium dose of FP-MDI for 5-11 year old children (>176-352mcg daily). A high percentage (49%) indicated that between 21% and 80% of 5-11 year old children that they treat with FP-MDI receive the 110mcg dose. **CONCLUSIONS:** HCPs are deficient in knowledge about FDA-approved FP-MDI doses and side effects and use FDA-unapproved doses, placing children at risk for developing serious systemic side effects. The reasons are unclear, but better methods to educate HCPs about ICS dosing and side effects are needed.

## Introduction

A 6 year-old child developed Cushing's Syndrome after 16 months of treatment with an FDA-unapproved dose (110mcg) of the inhaled corticosteroid (ICS) fluticasone propionate metered-dose-inhaler (FP-MDI) for asthma. The objective was to assess health care practitioner (HCP) knowledge about FP-MDI dosing and side effects.

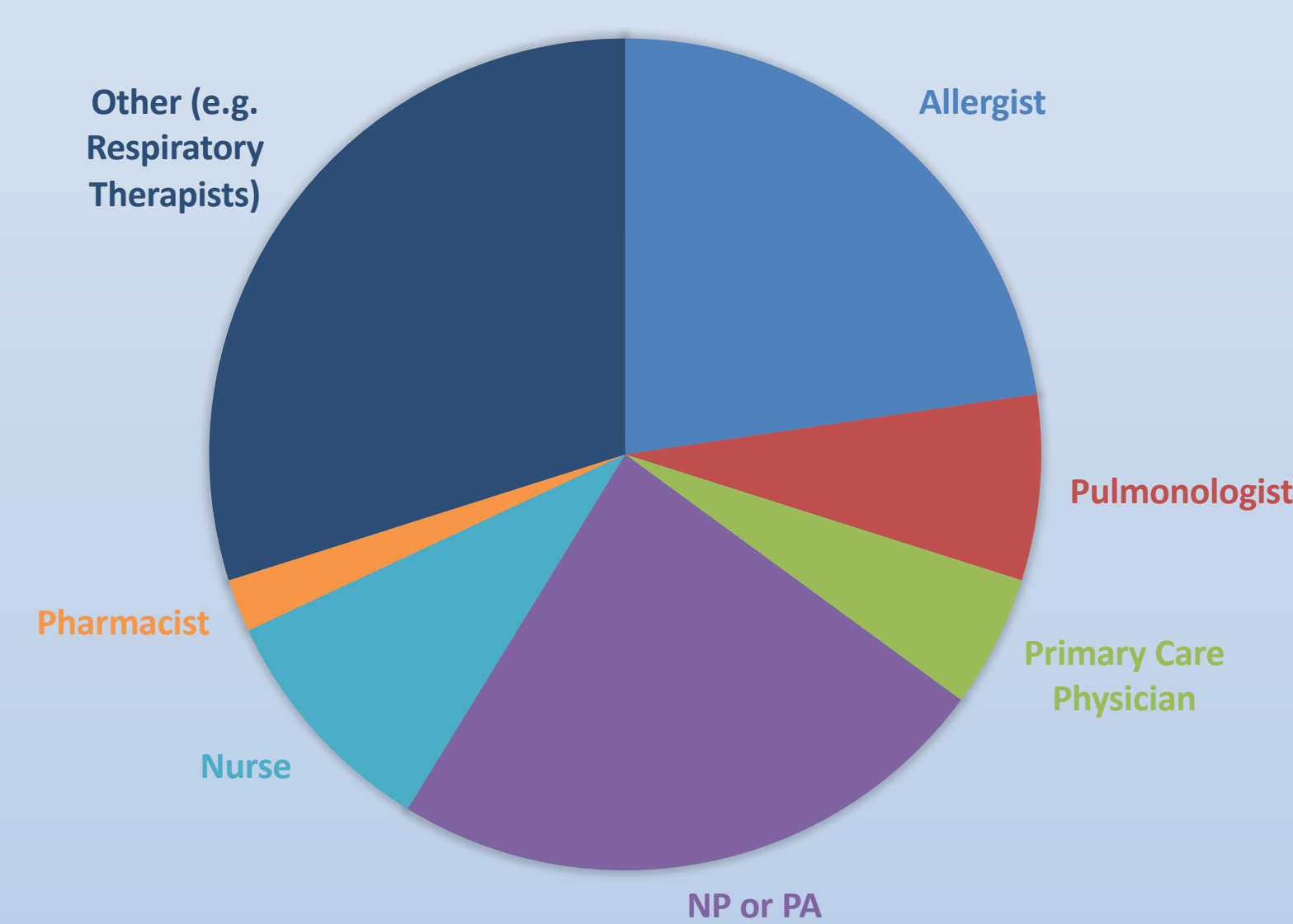
## Materials & Methods

### Methods

Anonymous and interactive polling was conducted using TurningPoint software and hand-held devices before and after PowerPoint presentation of the case during 40 live meetings of HCPs across the United States. During the presentation, education about FDA-approved FP-MDI doses and side effects was provided.

### Participants

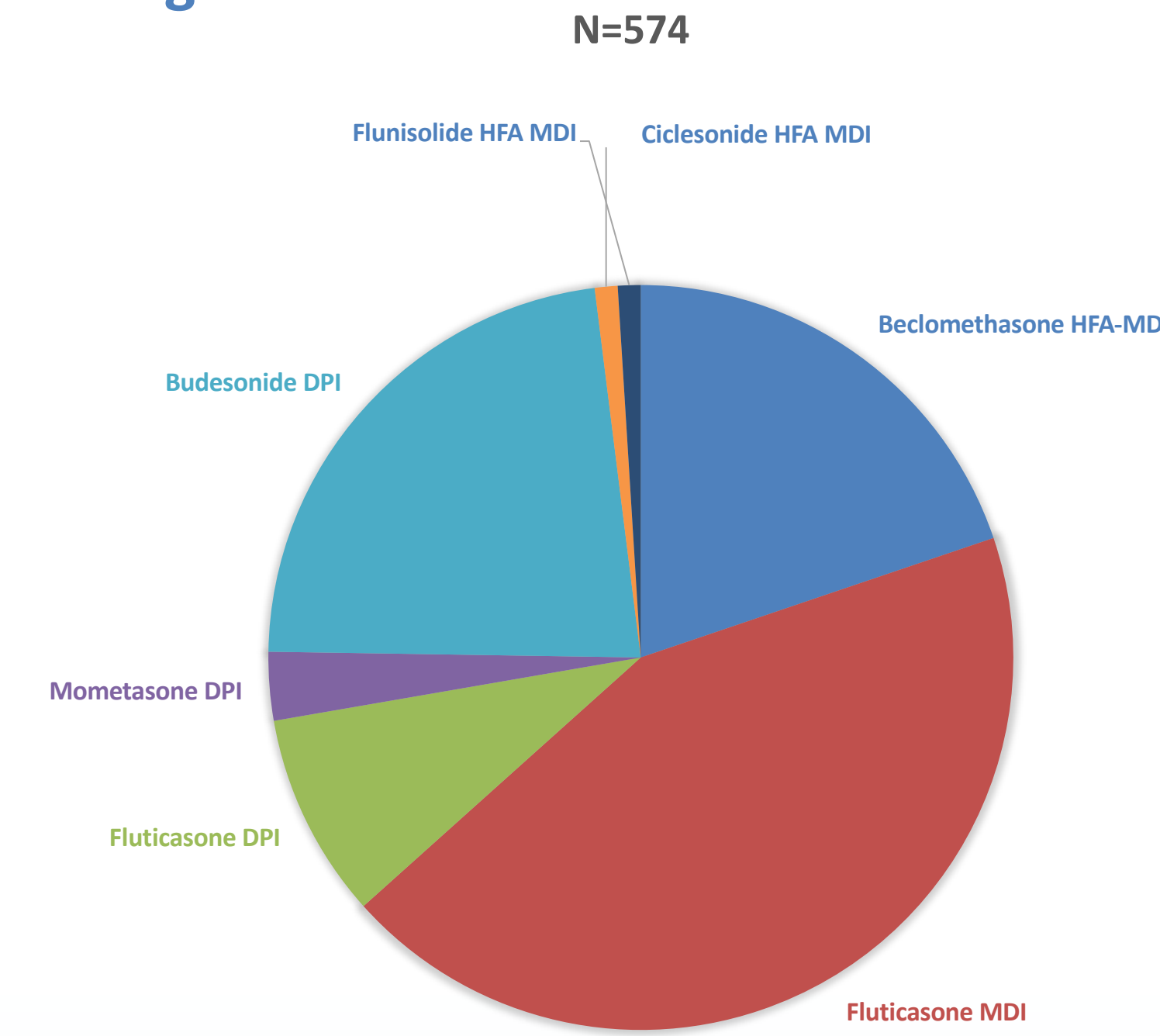
Background of Meeting Attendees (%)  
N=728



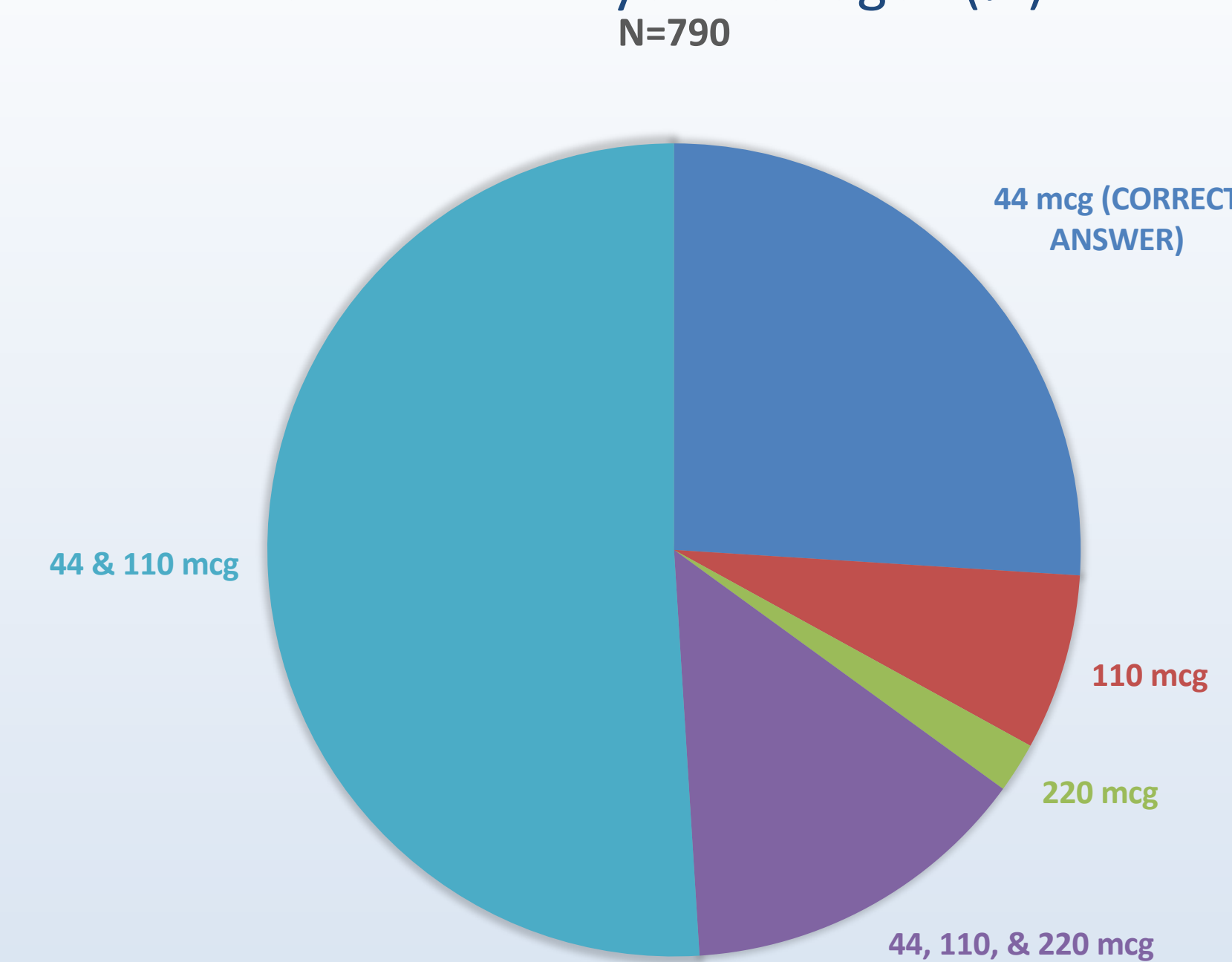
## Results

Presentations (n=40) were delivered to 790 HCPs, including asthma specialists. Before the presentation, only 26% of HCPs knew the dose of FP-MDI that is FDA-approved for children <12 years of age (44mcg only), and only 28% were confident in their ability to detect and diagnose growth and adrenal suppression secondary to ICS in a child with asthma. After the presentation, the respective values were 97% and 89% (p<0.05). FP-MDI was the ICS with which 43% were most experienced, yet only 11% knew the Asthma Guideline-recommended medium dose of FP-MDI for 5-11 year old children (>176-352mcg daily). A high percentage (49%) indicated that between 21% and 80% of 5-11 year old children that they treat with FP-MDI receive the 110mcg dose.

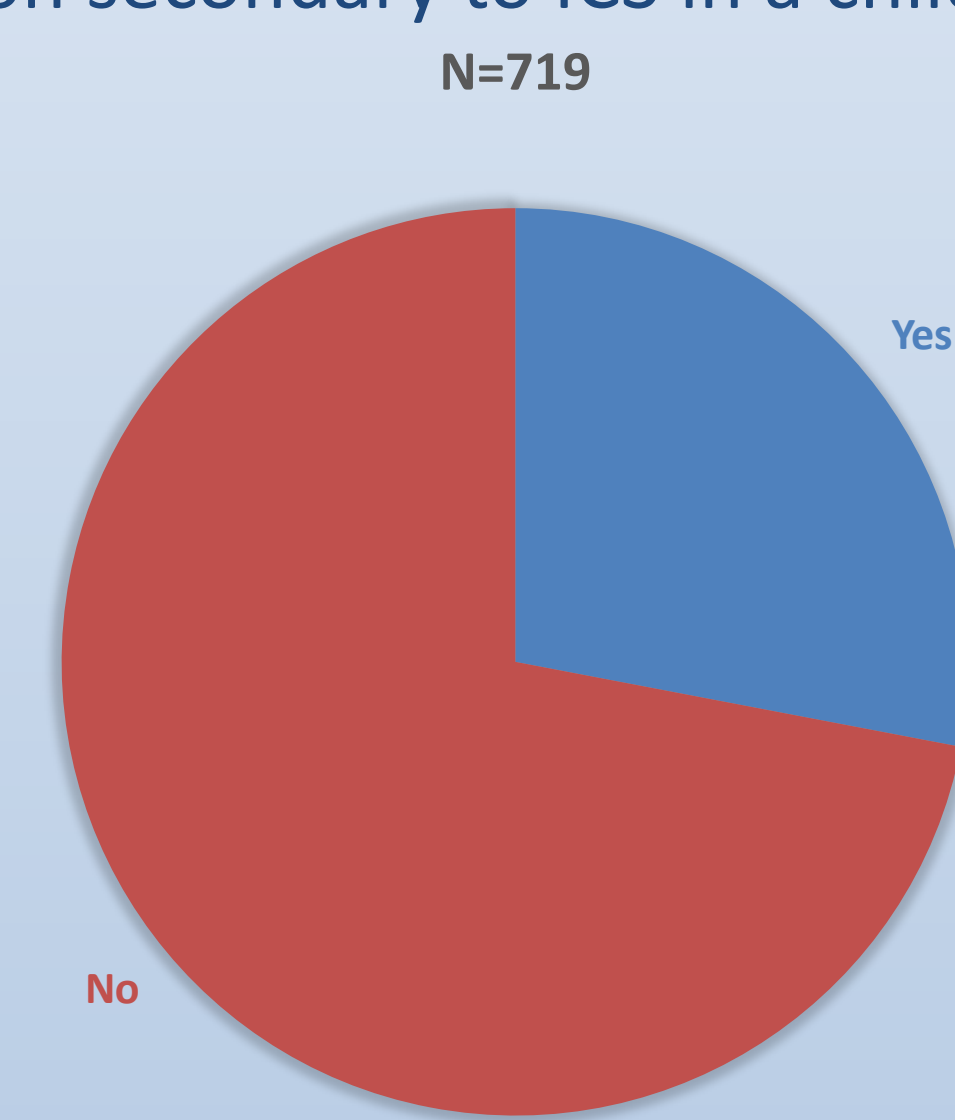
### With Which ICS Do You Have the Greatest Level of Experience in treating 5-11 Year-Old Children with Asthma? (%)



### Which fluticasone MDI dosages are FDA-approved for asthma in children <12 years of age? (%)

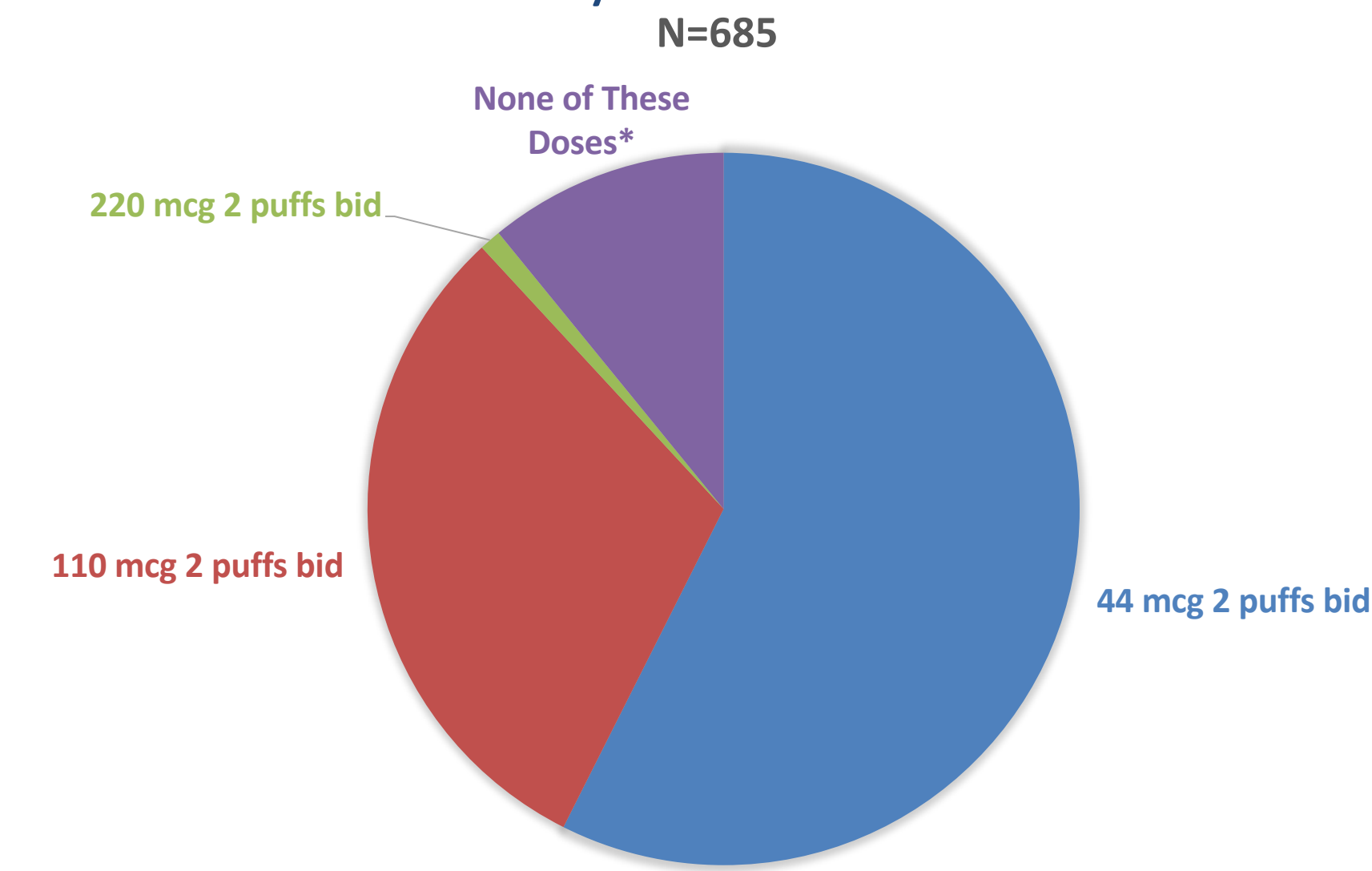


### Do you feel confident in your ability to detect and diagnose growth and adrenal suppression secondary to ICS in a child with asthma? (%)



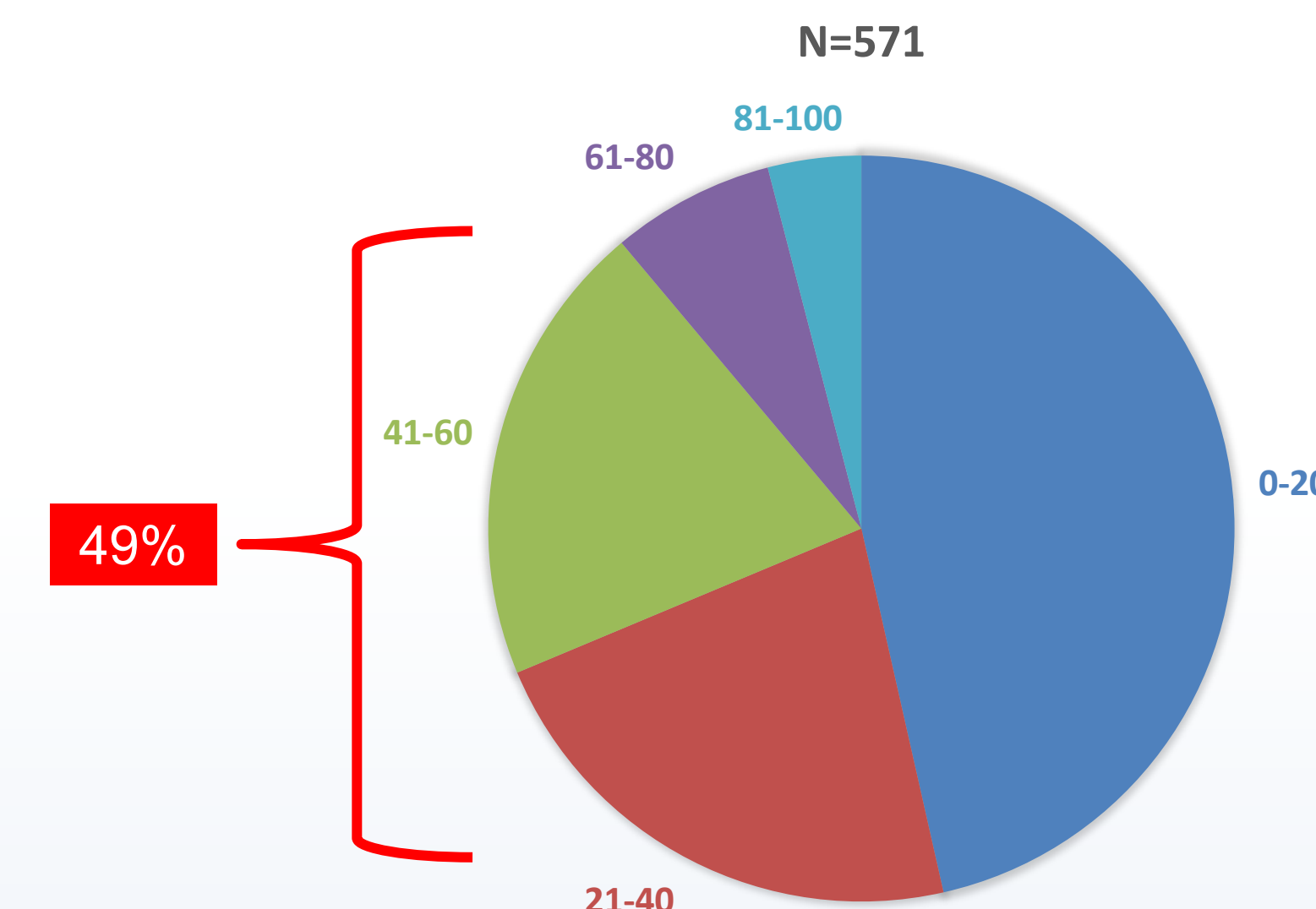
## Results

### What is the NHLBI Guideline-recommended "medium dose" of fluticasone MDI for 5-11 year old children with asthma? (%)

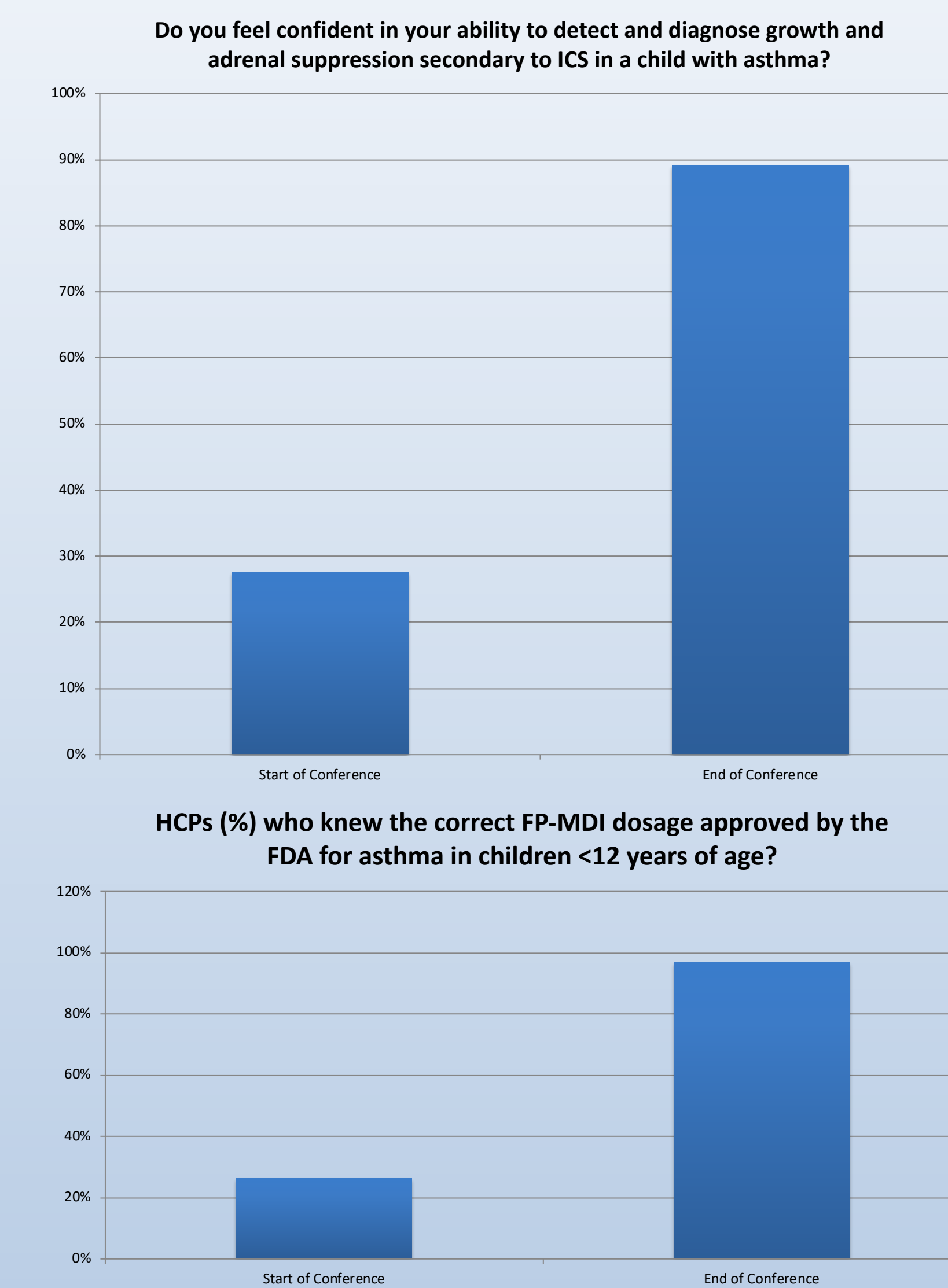


\* Correct answer is >176-352mcg daily

### Of all the 5-11 year old children with asthma that you treat with FP-MDI, what percentage receive the 110 mcg strength?



### COMPARISON OF RESPONSES BEFORE AND AFTER PRESENTATION OF THE CASE (p<0.05)



## Conclusion

HCPs are deficient in knowledge about FDA-approved FP-MDI doses and side effects and use FDA-unapproved doses, placing children at risk for developing serious systemic side effects. The reasons are unclear, but better methods to educate HCPs about ICS dosing and side effects are needed.

### Limitations

- Findings are limited to HCP knowledge about one ICS in one age group. Future studies should focus on other drugs, including non-steroids, and other age groups, including adults.
- Did not investigate the reasons for the deficiencies in knowledge about FDA-approved FP-MDI doses and side effects.

## Discussion

- The FDA approved all three FP-MDI doses (44, 110, 220 mcg) for adults, but did not approve the 110 mcg and 220 mcg doses for children because the dose-related risk of HPA axis suppression outweighed benefit.
- Most HCPs are unaware of the age-dependence of the FP-MDI FDA indication and use the higher unapproved doses "off-label".
- FP-MDI is the ICS most commonly associated with "off-label" prescribing and adrenal crisis in children in other countries.
- "Off label" prescribing is common, legal, often unknown by the prescribing physician, and unregulated by the FDA.
- Some of the most commonly prescribed "off-label" medications for children are used for allergy and asthma.
- Additional concerns are present when using inhaled corticosteroids and nasal or topical corticosteroids in the same children, which has not been well-studied.
- HCPs must be re-educated and better systems must be put into place to protect children, including at the levels of the FDA, pharmaceutical company, pharmacy, and electronic medical records.

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### Contact Information

dskoner54@gmail.com