

Inhaled Corticosteroids in Asthma: The Balance Between Safety and Efficacy

OUTCOMES SUMMARY REPORT

Live Educational Activity Series

May 5, 2016 – December 15, 2016

Grant Number: 1950

MEDA

Executive Summary:

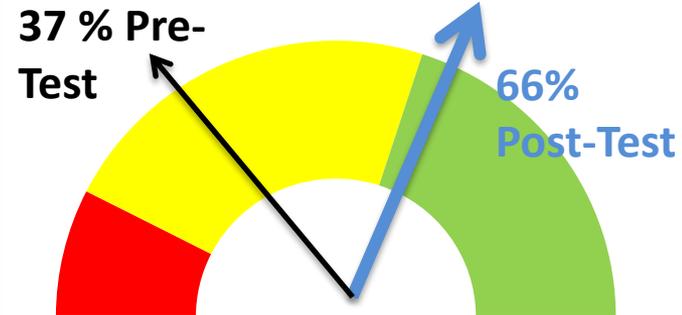
Project Scope

With the goal of improving patient care, National Jewish Health implemented an educational initiative designed to address identified professional practice gaps and educational needs related to the physician and medical staff's understanding and comfort related to the efficacy, safety and bioavailability of inhaled steroids in asthma. This multi-component initiative featured the following initiatives:

- ✓ **A panel discussion with eleven national key opinion leaders** discussing the safety, efficacy and bioavailability of various molecules; how safety is and should be measured; and how steroids affect HP axis, growth and the eye.
- ✓ **A peer-reviewed journal** based on the panel discussion findings, published in the *Annals of Allergy, Asthma and Immunology*, and disseminated to a national audience of 20,000 (nearly 5,000 direct mail) physicians treating allergic or immunologic disorders.
- ✓ **A national series of eleven two-hour evening workshops** summarizing the consensus panel outcomes and featuring an expert faculty presenter leading an interactive, case-based discussion

Activity Impact & Anticipated Reach

- ✓ A panel discussion with (11) national key opinion leaders
- ✓ A peer-reviewed journal
- ✓ Completed national series of (11) evening workshops (only 10 were proposed)



Over **20,000**

participants, learners and readers in the live activities and journal dissemination



Overall relative knowledge gain from pre- to post-Activity



78%

Executive Summary:

Panel Discussion

Panel Discussion:

Eleven national key opinion leaders and a faculty facilitator served on a panel in Denver, CO on November 14, 2015. The panel discussed and debated the following topics:

- Safety, efficacy and bioavailability of various molecules
- How safety is and should be measured
- How steroids, specifically inhaled steroids, and concomitantly nasal steroids, affect HP axis, growth and the eye

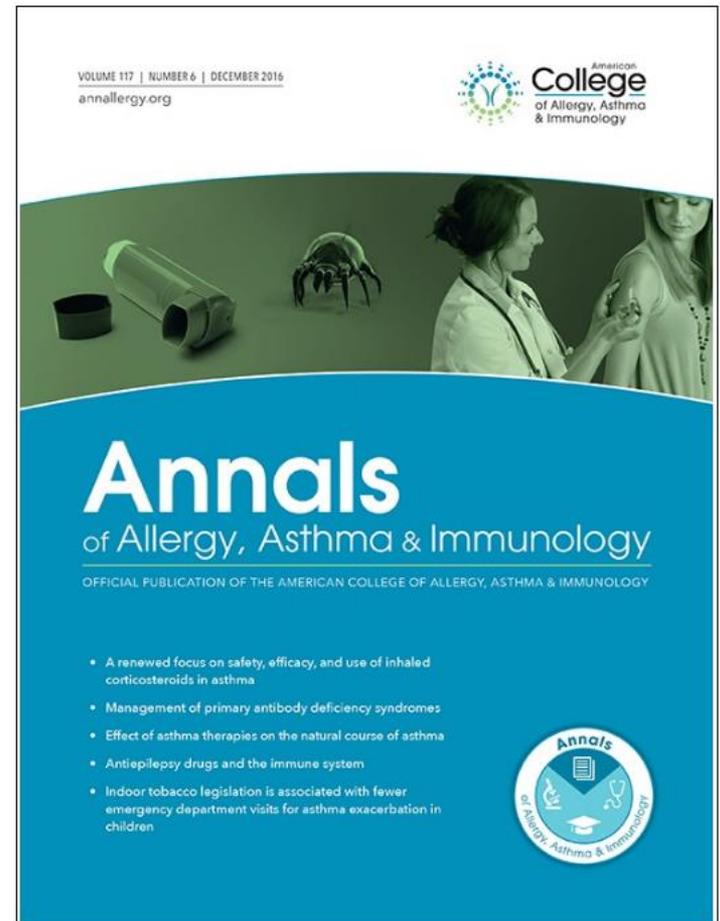
The consensus manuscript was prepared based on the presentations, questions and statements from meeting discussants during open discussion periods, deliberations and recommendations by the panel. A draft statement was circulated to the participants for comment, at which time the panel considered the comments and released a revised statement.

Executive Summary: Medical Journal

Journal:

The results of the live panel were developed into eight different manuscripts. While originally written to be a supplement, the Editors at the *Annals of Allergy, Asthma & Immunology* decided the topic was relevant and important enough to include in an issue of the journal.

The *Annals of Allergy, Asthma & Immunology* is a scholarly medical journal published monthly by the American College of Allergy, Asthma & Immunology. The purpose of the Annals is to provide clinical and research information that is readily applicable to both the clinician and the researcher. Each issue of the Annals is mailed to **4,130 allergy and immunology physicians** and is also available online at www.annallergy.org, which boasts an impressive **12,000 unique visitors per month**.



Executive Summary: Live Activity Details

Live Activity

Although proposed as only (10), this live, interactive series consisted of (11) workshops. The activities featured case-based learning, multi-media approaches, and written materials to engage participant learners. The workshops were held between May and December 2016 throughout the United States.



Total number of attendees: **741**
Average number per meeting: **67**

City	Attendee #s
San Diego (5/5/16)	51
Houston (5/10/16)	51
Scottsdale (5/31/16)	71
Orlando (5/31/16)	52
Atlanta (6/1/16)	61
Washington, DC (6/2/16)	27
New York (6/6/16)	119
Las Vegas (6/8/16)	63
Philadelphia (6/9/16)	47
Denver (6/22/16)	132
San Francisco (12/15/16)	67

Executive Summary:

Live Activity Details

Program Design: The Office of Professional Education at National Jewish Health (NJH) developed the CME/CE activity in collaboration with expert faculty from NJH and across the United States. An Audience Response System (ARS) was utilized in each location to facilitate active engagement by participants and maximize learning opportunities by incorporating interaction, discussion, and real-time feedback from faculty presenters.

Target Audience: Allergists, pediatricians, pulmonologists, primary care providers, registered nurses, allied health professionals, and other healthcare providers involved in the treatment of patients with asthma were the target audience for this educational initiative.

Educational Outcomes Strategy: National Jewish Health aimed at measuring knowledge, competence and performance for this activity. The success of the program was measured by the following:

- Pre-test
- Post-test
- Evaluation
- 45-day follow-up survey

Accreditation

The eleven programs were each certified for:

- 2.0 AMA PRA Category 1 Credits™
- 2.4 Nursing Contact Hours (California Board of Registered Nursing)

Faculty

Faculty presenters included:

- **Rohit Katial MD, FAAAAI, FAAAAI, FACP**, Professor of Medicine
Associate Vice President of Clinical Research & Industry Relationships
Co-Director of the Cohen Family Asthma Institute at National Jewish Health
Helen Wohlberg & Herman Lambert Chair in Pharmacokinetics
National Jewish Health, Denver, CO
- **Anthony Gerber, MD, PhD**, Associate Professor of Medicine
Division of Pulmonary, Critical Care and Sleep Medicine
Department of Biomedical Research
National Jewish Health, Denver, CO
- **David Skoner, MD**
Director, Division of Allergy, Asthma and Immunology, Department of Medicine
Allegheny Health Network, Pittsburgh, PA
Professor of Medicine - Temple University, Philadelphia, PA
Professor of Pediatrics - West Virginia University, Morgantown, WV



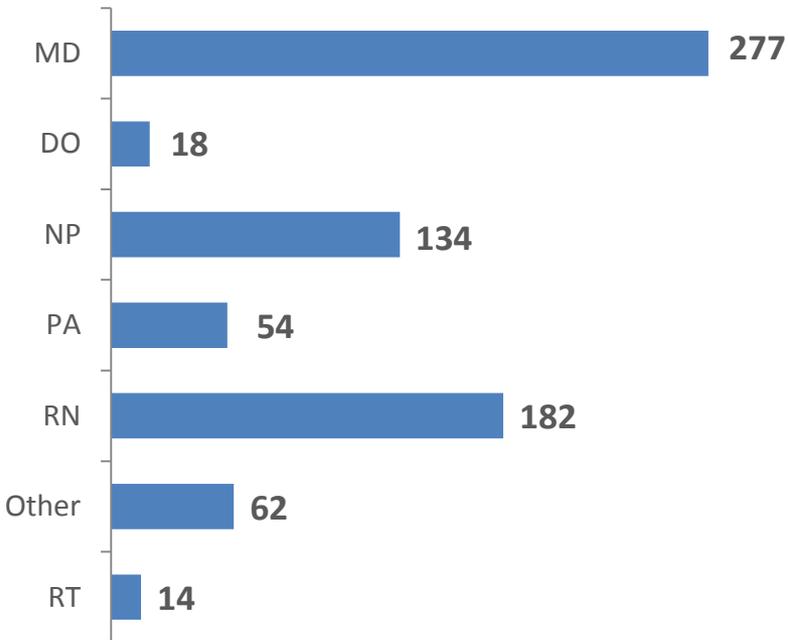
Learning Objectives

Upon completion of this activity, participants will be able to:

1. Discuss the pivotal studies of ICS efficacy.
2. Review steroid mechanism of action and how to best assess safety specifically in assays versus end organ effects.
3. Describe the clinical relevance of steroid properties in relation to safety and efficacy.
4. Discuss approaches to shared decision making between patients and providers to balance safety and efficacy.
5. Review the safety of the combination of intranasal and inhaled corticosteroids.

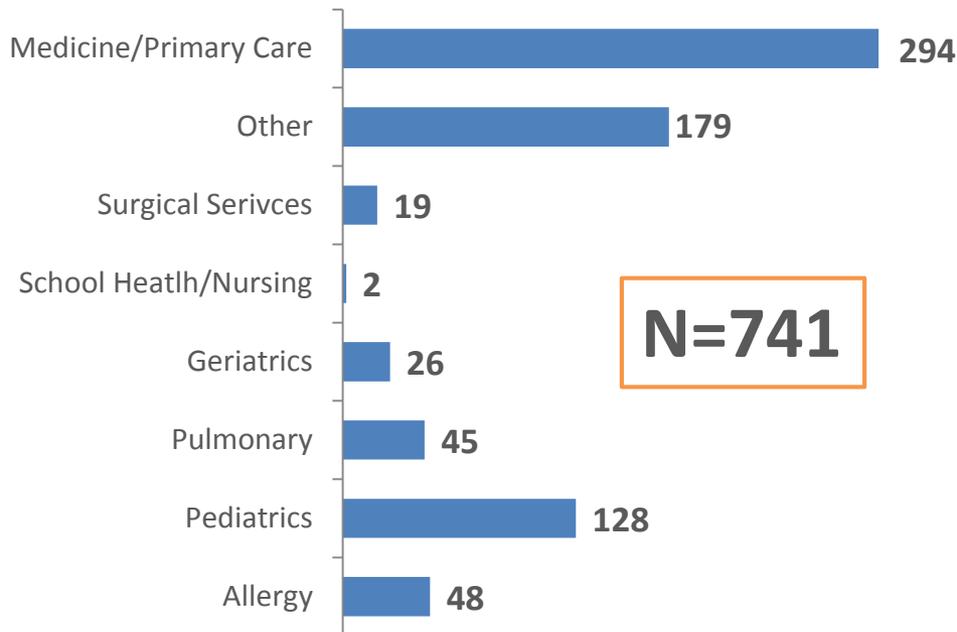
Level 1 Outcomes: Participation

Designation



*Other: PharmD, CRNA, PhD, MBA, MA, CNS, CNMT, CPHQ

Specialty



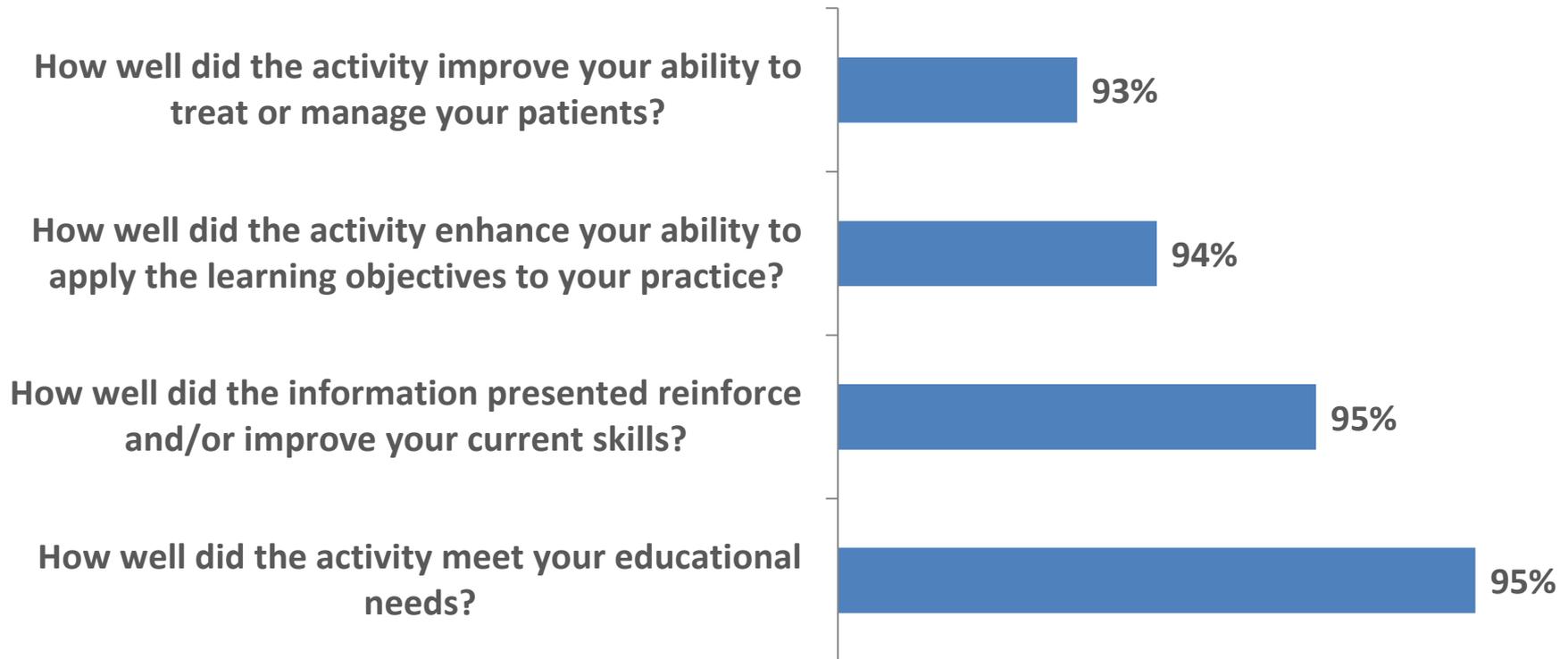
N=741

*Other: Acute Care, ENT, Hospice, Dermatology, Nephrology, Endoscopy, Oncology, Hematology, Nuclear Medicine, Anesthesia

65% of attendees were prescribers

Level 2 and 3 Outcomes: Satisfaction and Learning

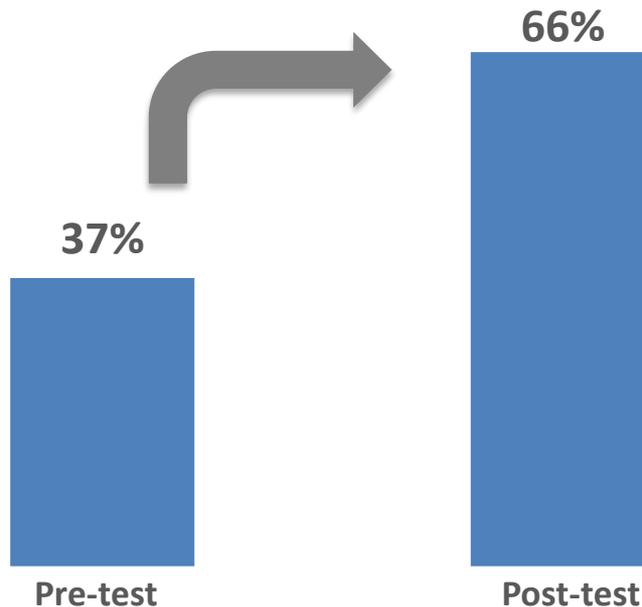
Analysis of Participants' Responses Related to Educational Needs



Level 3 and 4 Outcomes: Learning (Knowledge and Competence)

Level 3 and 4 outcomes were measured by comparing participants' pre- and post-test answers. The attendees' responses to these questions demonstrated that **participants gained knowledge as a result of the activity.**

Overall, participants demonstrated an average **78% increase in declarative and procedural knowledge and competence** as a result of this activity.



Overall increase in knowledge: **78% from baseline to post-test.**

Knowledge gain was marked by an increase in correct responses from pre- to post-activity.

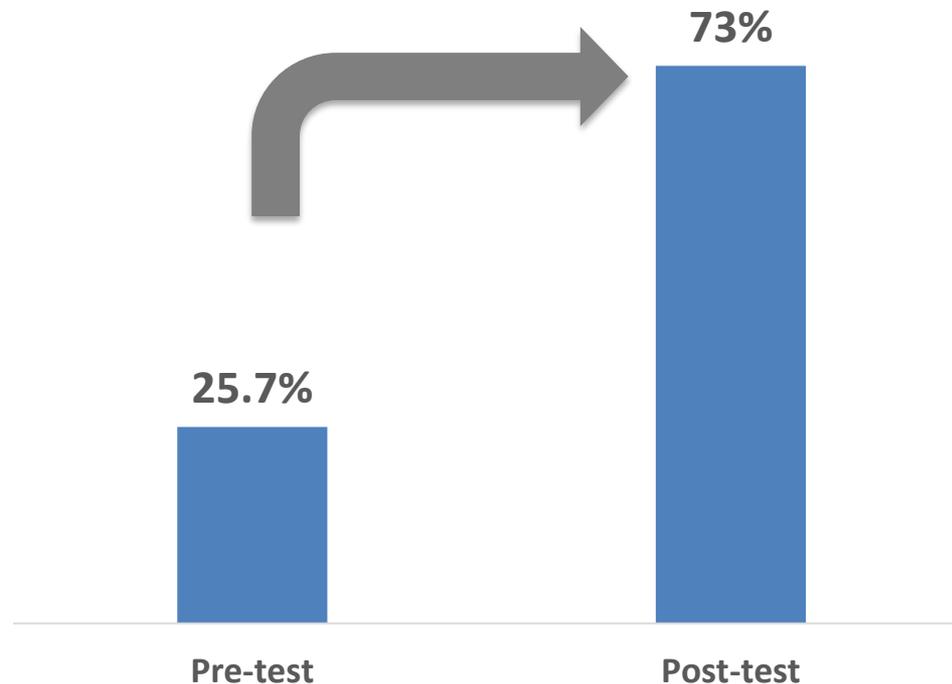
Pre/Post Test Comparison: Question Example

Question: According to the U.S. CDC, in approximately what percentage of adults with asthma is uncontrolled?

Answer Choices:

- A. 20%
- B. 30%
- C. 40%
- D. **50%***
- E. 60%

***Best Answer: 50% (D)**



Increase in knowledge:
184% from baseline to post-test.

Pre/Post Test Comparison:

Question Example (Addresses Learning Objective 2)

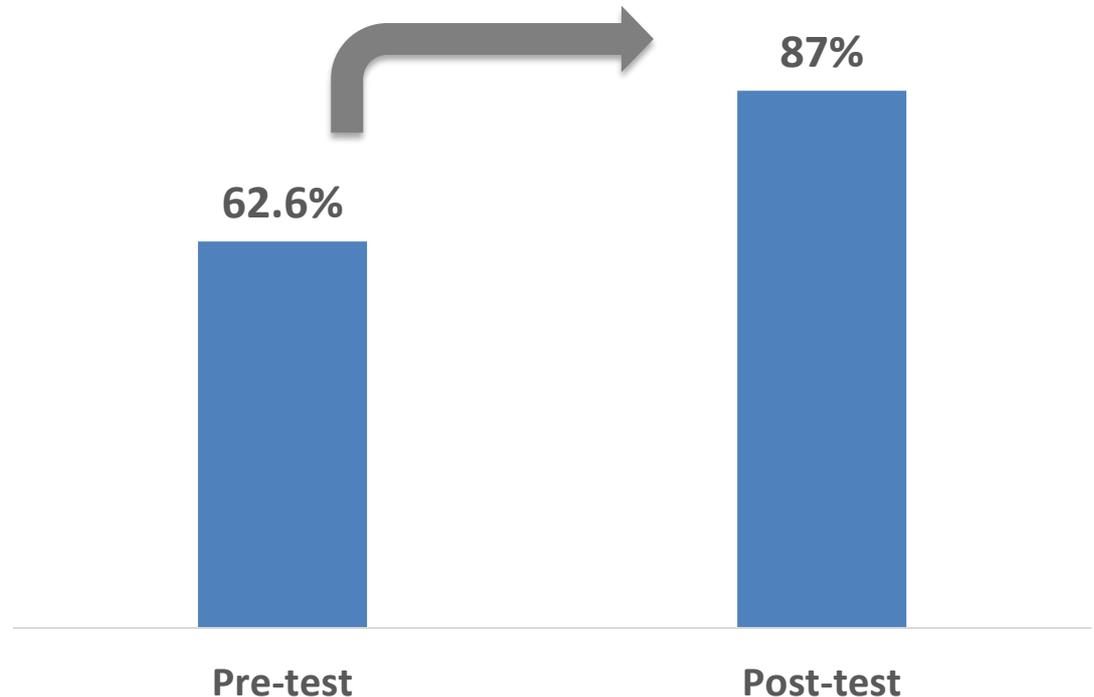
Question: Which of the following is NOT one of the inhaled glucocorticoid therapy mechanisms of action?

Answer Choices:

- A. Inhibition of cytokine production
- B. Inhibition of inflammatory cell recruitment
- C. Increase in lymphocytes in circulation***
- D. Reduced microvascular leak and edema formation

***Best Answer: Increase in lymphocytes in circulation (C)**

Increase in knowledge: **39%** from baseline to post-test.



Pre/Post Test Comparison:

Question Example (Addresses Learning Objective 3)

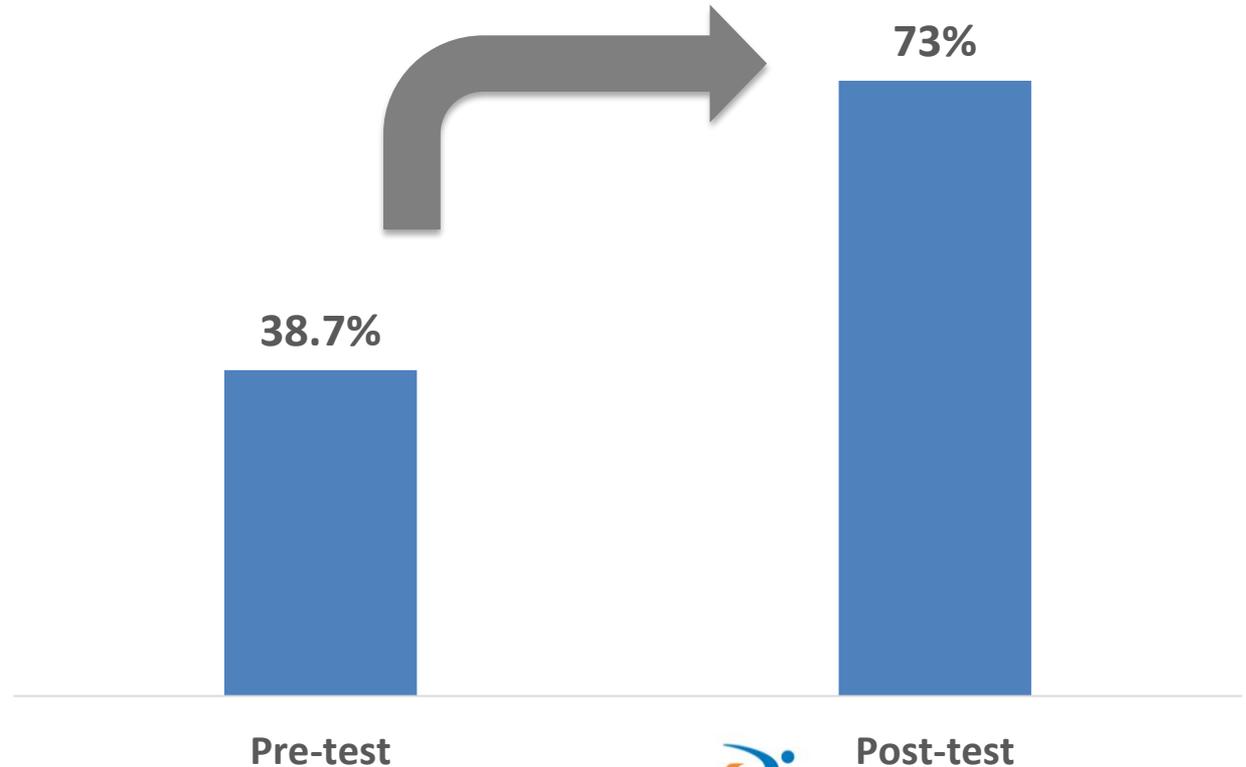
Question: The slowing of the rate of growth observed in children on ICS is not reflected in differences in adult height:

Answer Choices:

- A. True
- B. False*

***Best Answer: False (B)**

Increase in knowledge: **89%** from baseline to post-test.



Pre/Post Test Comparison: Question Example (Addresses Learning Objective 3)

Question: The most orally available ICS is:

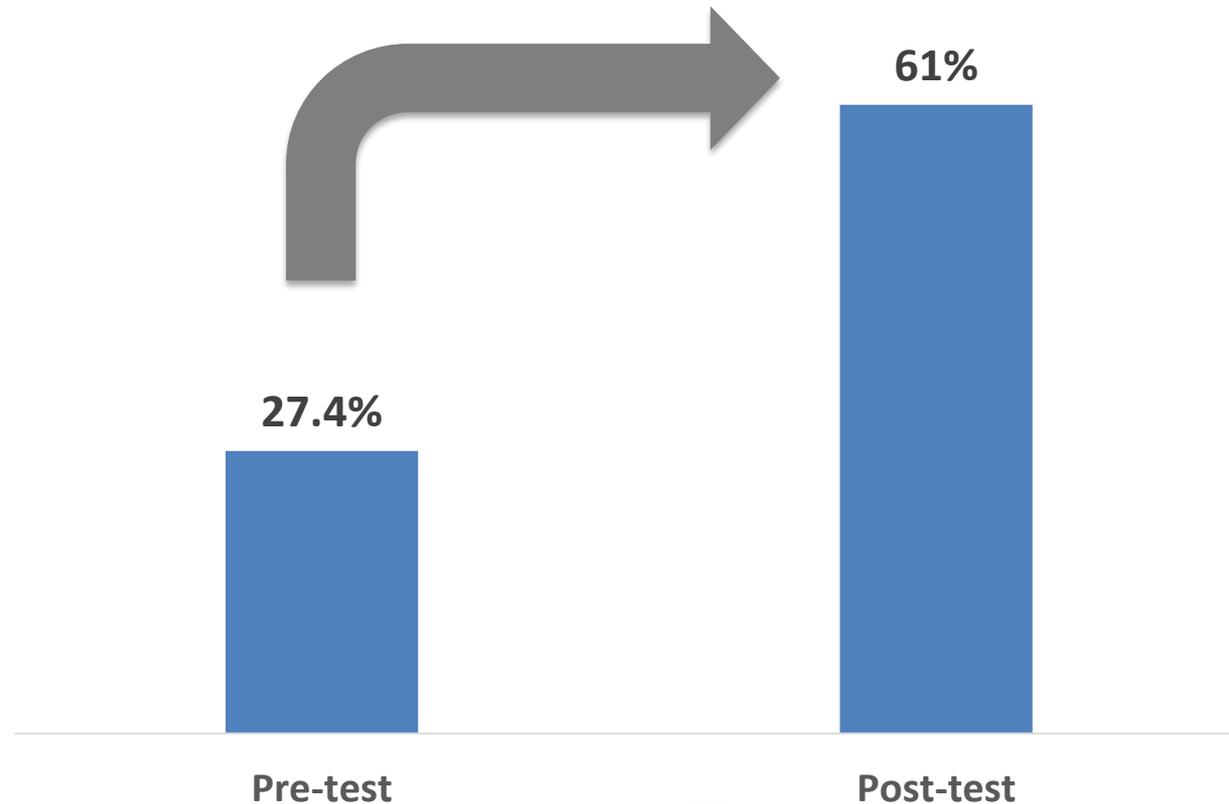
Answer Choices:

- A. 17-Beclomethasone MP*
- B. Fluticasone Propionate
- C. Des-CIC
- D. Budesonide
- E. Mometasone Furoate

***Best Answer:**

17-Beclomethasone MP

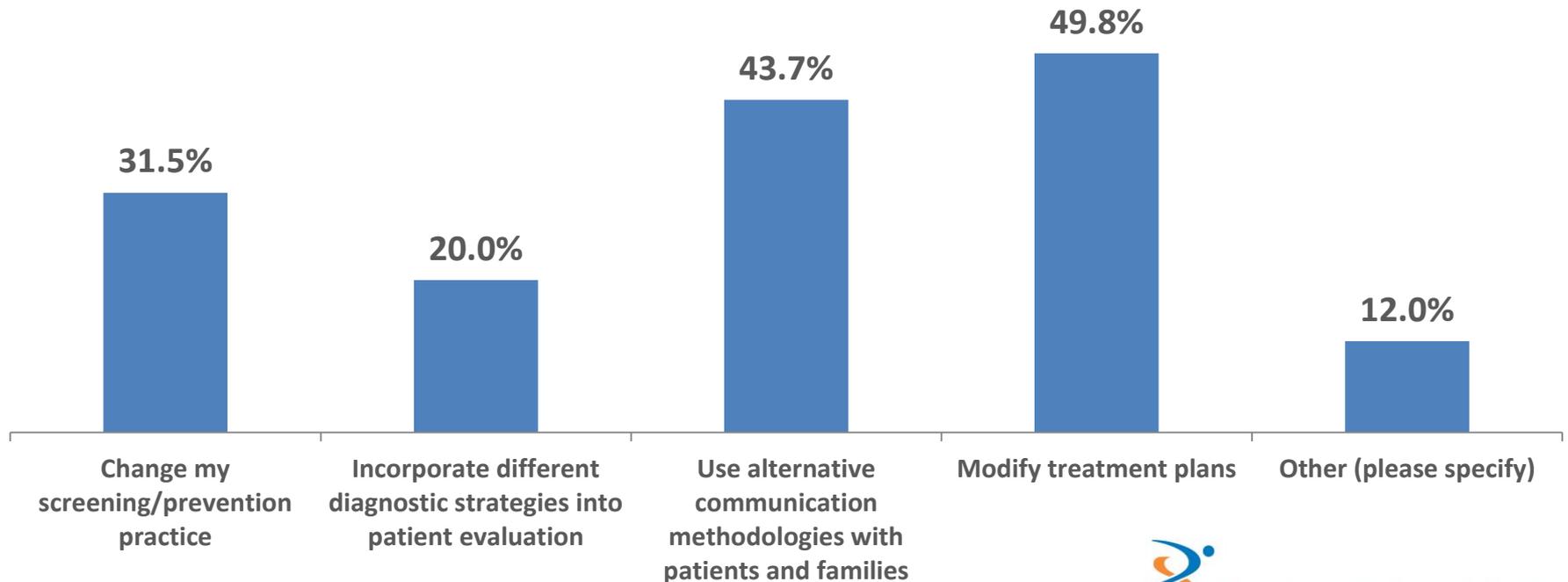
**Increase in knowledge:
123% from baseline to
post-test.**



Level 4 Outcomes: Competence (Intent to Change)

91% of participants that completed the evaluation stated that they are somewhat to extremely likely to make a **change to their practice based on the content presented.**

The changes **I intend** to make in my practice include (check all that apply):



Evaluation Results

The attendees' responses to evaluation questions demonstrated the following, averaged across the eleven locations:

- **91%** of participants stated that they are extremely or somewhat likely to **make a change to their practice** based on the information presented.
- **99%** of participants indicated that the materials were presented objectively and **free of commercial bias**.
- **94%** of participants reported that the educational content of the activity **met the learning objectives**.
- **99%** indicated that the content was **evidence-based and clinically relevant**.

Evaluation Results Linked to Learning Objectives

What is the most important take-away for you from this activity?

[Learner responses including linkage to learning objectives (LO)]

- Patients with asthma need to be educated about their disease with a well designed treatment plan which they can follow and are well instructed on use of inhalers and nebulizers if needed for control. **LO 2 & LO 4**
- Realizing how long term use of ICS affects growth on children. **LO 2**
- Inhaled corticosteroids are an effective asthma therapy, but monitoring for side effects and using the lowest effective dose is important. **LO 4**
- Communication with patients and families. **LO 4**
- Considering potency, technique in delivery don't assume patients know how to use their devices and finally, allow them to reflect on their needs. **LO 4**
- Educate the patient on benefits and side effects of medication and allow them to make informed decisions about their treatment. **LO 3 & LO 4**
- Learning the new statistics on long term effects using vs. not using ICS and outcomes. **LO 1**
- The association between ICS potency and side effects. **LO 5**
- That use of inhaled corticosteroids does not greatly affect the growth rate of a child. Shocked that only about 30% of patients with asthma have an action plan. **LO 2 & LO 4**

*See slide 8 for the list of learning objectives

Level 5 Outcomes: Performance (Self-reported) - 45-Day Survey Results

- **92%** of respondents (n=146) indicated that this CME activity provided new ideas or information they have used in practice. The majority of respondents report seeing 5-10 patients with asthma per week.
- **73%** of respondents indicated that their patients have benefited from the information learned during this CME activity.
- The top three changes respondents have made or intend to make (for those that had not seen any asthma patients within the 45-day time period) are:
 1. Change my screening/prevention practice
 2. Incorporate different diagnostic strategies into patient evaluation
 3. Use alternative communication methodologies with patients and families

Additional Educational Needs

Learner responses to follow-up survey questions presented at each activity location indicated further education would be beneficial in the following areas:

- Clinical relevance of steroid properties in relation to safety and efficacy.
- Approaches to shared decision making between patients and providers to balance safety and efficacy.
- Safety of the combination of intranasal and inhaled corticosteroids.

Attendee Comments

- “Very good material and knowledgeable presenter.”
- “Thank you. I expected a presentation favoring a particular drug and this was free of bias.”
- “Professional presentation of the information. The incorporation of research data, meds, audience responses & discussion of incorporating into practice was excellent.”
- “I highly appreciate your effort and time spent to help refresh us on comprehensive treatment regimen for Asthma.”
- “Thank you for offering this lecture programs. I learned a lot of important information about the asthma medication.”
- “Excellent team work! It is greatly appreciated that National Jewish is making this extra effort to provide more education to caregivers nationwide about asthma and ICS.”