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Use of active comparator tirals in dermatology: A repeated cross-sectional analysis

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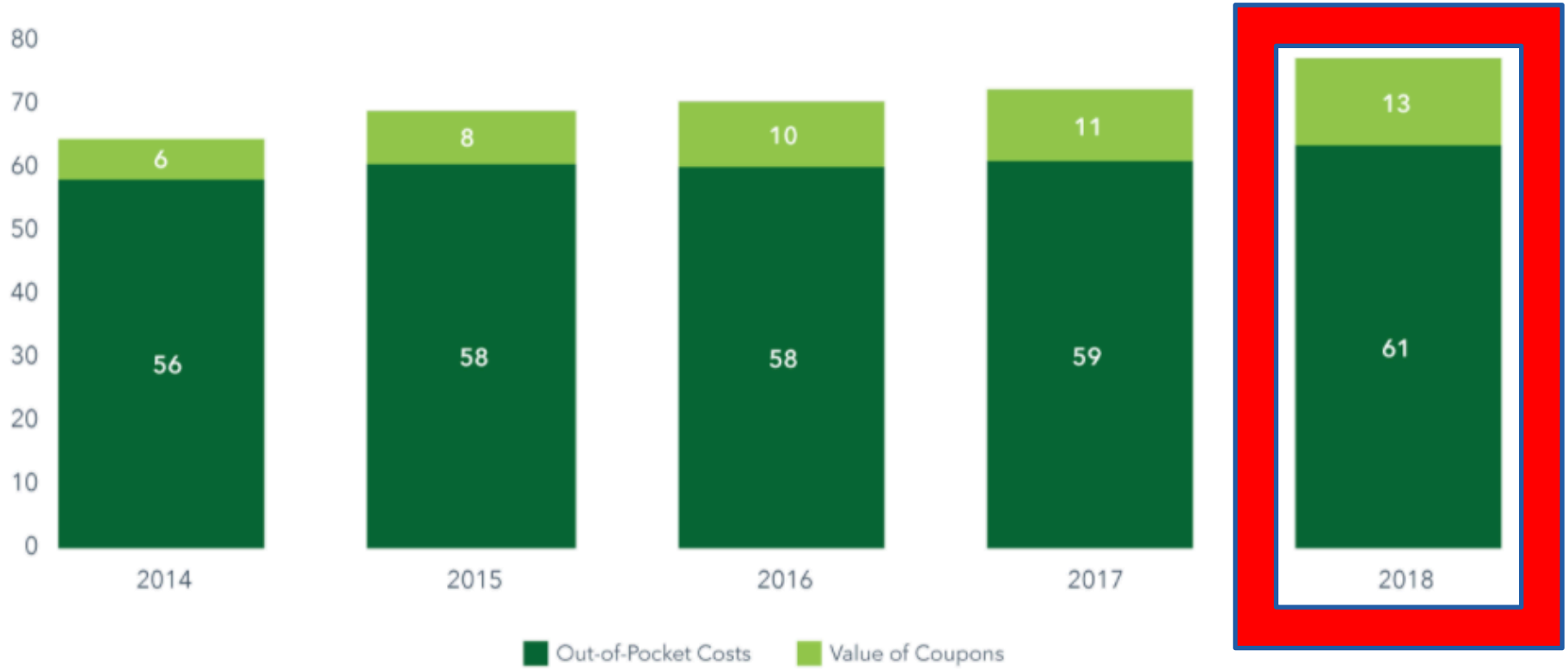
Introduction: Healthcare Spending Costs



Aitken M, Kleinrock M. *Medicine Use and Spending in the U.S.* IQVIA Insitute for Human Data Science; 2019. Accessed November 3, 2019.

- Overall out-of-pocket costs have risen to $61 billion in 2018

Healthcare spending impact on patients?

Spending on prescription medications is expected to rise to $420 billion by 2023.[2]

Nearly 30% of patients reported not taking prescription due to cost.

The Role of Active Comparator Clinical Trials

Placebo Controlled

vs.

Active Comparator

vs.

While placebo-controlled trials are valuable to understand efficacy, active comparator trial designs provide data that can guide clinical decision making by allowing direct comparisons between similar drugs

Active Comparators in Dermatology Topical Trials

In dermatology, subtle changes in concentration or combination of topical agents can be classified as a novel product.

0.1%

0.3%

While some new medications may improve patient outcomes, others may not offer meaningful benefit over existing less costly alternatives.

The Inquiry Question:

To evaluate trends in the use of active comparator trial designs for topical medications approved by the FDA between January 2002 and December 2020.

Methods

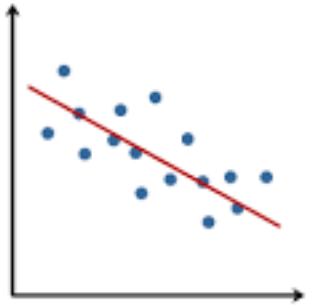
- **Population**
  - Food and Drug Administration
  - Physicians
  - Patients

- **Resources Used**
  - Clinical Trials Database
    - Clinical Trial Information
  - FDA Orange Book
    - Drug Approval Dates

Outcomes & Analysis

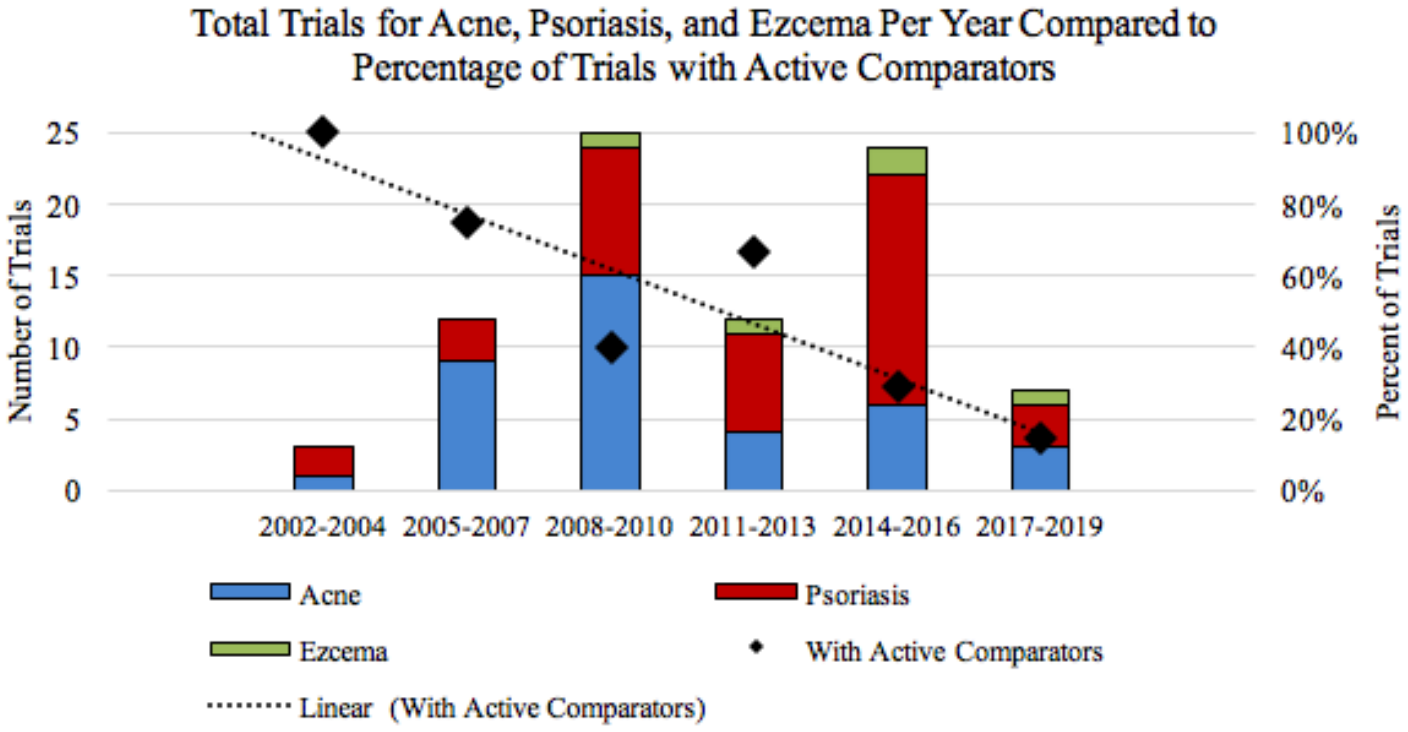
- **Outcomes**
  - Frequency of Active Comparator over Time
  - Frequency of Active Comparator by Trial Phase

- **Analysis**
  - Linear Regression



Outcomes

- Between 2002 and 2020, the proportion of clinical trials for acne, psoriasis, and eczema with an active comparator has decreased. (-5.2% per year, 95% CI -1.7% to -8.6%)



Outcomes

- Phase II studies were most likely to include and active comparator (71%), while phase III studies were least likely (32%).

% Trials with and Active Comparator by Clinical Indication				
	Phase II	*Phase III*	*Phase IV*	Total
Psoriasis	83% n=6	39% n=28	29% n=7	44% n=41
Acne	100% n=1	35% n=23	71% n=14	50% n=38
Actinic Keratosis	75% n=4	23% n=13	80% n=5	45% n=22
Antifungal	67% n=6	15% n=13	0% n=1	30% n=20
Rosacea	0% n=2	43% n=7	0% n=1	30% n=10
Eczema	50% n=2	0% n=2	0% n=1	20% n=5
Other	77% n=13	35% n=23	0% n=5	44% n=41
Total	71% n=34	32% n=109	47% n=34	42% n=117

Conclusions

- Although there is a greater need for comparative effectiveness data in the setting of a growing number of available treatments, our results highlight that the use of active comparator trials has decreased over time

Moving Forward (Impact):

- It will be important for clinicians, patients, payers, and

Role of Patient Reported Outcomes

Absolute Lesion Reduction vs. Quality of Life Index

- Cost-Benefits Analyses
- FDA Regulated Guidelines

Disclosures and Acknowledgements

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Citations

- Aitken M, Kleinrock M. *Medicine Use and Spending in the U.S.* IQVIA Insitute for Human Data Science; 2019. Accessed November 3, 2019.
- Kirzinger A. KFF Health Tracking Poll – February 2019: Prescription Drugs. *Medical Benefits*. 2019;36(6):4-5. Accessed January 19, 2021.
- Barbieri JS, Tan JKL, Adamson AS Active Comparator Trial Designs Used to Promote Development of Innovative New Medications. Cutis. 2020 Sep;106(3):E4-E6
- Olfson M, Marcus SC. Decline in placebo-controlled trial results suggests new directions for comparative effectiveness research. Health Aff Proj Hope. 2019;32 116-1122
- Drugs for Human Use Subchapter D, 21 C.F.R. § 300.50 (2020).


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