Slide 1

Session 8: How to Effectively Present Scientific Data

Joseph Saseen, PharmD
Professor and Vice Chair, Department of Clinical Pharmacy
University of Colorado Anschutz Medical Campus

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Slide 2

Disclosure

- Joseph Saseen reports no conflicts of interest

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Slide 3

Session Objectives

- Demonstrate how to describe the **background** of a topic that has led to a research question
- Identify components of a **research study** that should be included in a professional presentation
- Employ PowerPoint, tables, and figures to succinctly and **effectively present research findings**
- Prepare Answer **questions** about a research study in a professional manner

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Slide 4

Slide 5

Delilah
Brashman

https://youtu.be/lpyctY38I50

Slide 6

The effect of medical marijuana
on migraine headache
frequency in an adult population

Presented by: Delilah Brashman, PharmD, BCPS, PGY2
Ambulatory Care Resident
University of Colorado Anschutz Medical Campus
Aurora, CO
Abstract #35

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and Pharmaceutical Sciences   100+ years of education, patient care & scientific discovery.

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University of Colorado Skaggs School of
Pharmacy and Pharmaceutical Sciences

- Established in 1911
- Anschutz Medical Campus
- School:
  » 55 faculty members
  » 600 students
  » 8 PGY2 residents

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Slide 8

Disclosure Statement

- IRB Status: Approved, Exempt
- Co-investigators:
  » Sarah Anderson, PharmD, BCPS
  » Laura Borgelt, PharmD, BCPS
- Conflicts of interest: none
- Project Sponsorship: none

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Slide 9

Background: Cannabis

- Two common species:
  » *Cannabis indica* and *Cannabis sativa*
- Cannabis contains over 400 compounds, >60 are cannabinoids
  » Delta-9- tetrahydrocannabinol (THC)
    ▪ Most common psychoactive cannabinoid
  » Cannabidiol (CBD) common cannabinoid, accounting for 40% of the plant's extract
    ▪ The primary constituent of medical marijuana (MMJ)

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Slide 10

Background: Migraines

- Migraine headache (HA) affects 8% of children, 6% of men, and 18% of women
- Serotonergic pathways play an integral role in the pathogenesis and treatment
- Current pharmacotherapy options:
  » Triptans
  » NSAIDs
  » Acetaminophen
  » Antiepileptics

J Headache Pain. 2008;9:267-276
Neurology. 2012;78:1337-134510

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Slide 11

Background

- There is evidence THC has the following effects on serotonin and dopamine:
  » Inhibits serotonin release from platelets
  » Stimulates 5-HT synthesis
  » Modulates dopaminergic imbalances
- Is MMJ effective for migraines?
- Is MMJ safe?

Neuroendocrinol Lett. 2008;29(2):192-200

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Slide 12

Study Objectives

1. Describe the effect of MMJ on the frequency of migraine headaches.
2. Describe the types and doses of MMJ being used.
3. Describe the patient reported effects of MMJ.

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Methods

- Design:
  - » Retrospective observational chart review of patients from January 1, 2010 through September 30, 2014
- Setting:
  - » Specialty clinics in Colorado Springs and Buena Vista

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Methods

Inclusion Criteria	Exclusion Criteria
• Adults with primary diagnosis of migraine headache and 1 follow-up visit • Ages 18 to 89 years	• Wards of the state • Prisoners or those on probation • Decisionally challenged

Slide 15

Outcomes

Primary Outcome	•Frequency of migraine HA
Secondary Outcomes	• Types and doses of MMJ used • Patient reported side effects

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Statistical Analysis

- Descriptive statistics
  - » Demographics & clinical data
    - Mean & standard deviation
      - » Normally distributed data
    - Median & interquartile range
      - » Non-parametric data
    - Proportions
      - » Nominal data

Slide 17

Results: Baseline Characteristics
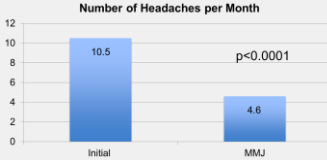
N=121	
Female (%)	63 (52)
History of migraine headache, mean years	14
Previous drug treatment, no. of patients (%)	58 (48.7)
Current drug treatment, no. of patient (%)	53 (43.8)
Frequency of MMJ use, days per month [range]	29.5 [1-30]
1 type of MMJ, no. of patients (%)	59 (48.7)
2 types of MMJ, no. of patients (%)	51 (42.1)
3+ types of MMJ, no. of patients (%)	11 (9)

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Results: Migraine Frequency

Number of Headaches per Month

Initial: 10.5
MMJ: 4.6
$p < 0.0001$

Slide 19

Results: Patient-Reported Migraine HA Frequency

15
3
103

■ Decreased
■ Increased
■ Same

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Results: Average Dose of MMJ

- Vaporize (n=42)*
  » 2.64 oz/month
- Edible (n=66)*
  » 2.59 oz/month
- Topical (n=15)*
  » 2.73 oz/month
- Smoke (n=65)*
  » 1.59 oz/month   *Some patients used >1 type of MMJ

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Results: Patient-Reported Positive Effects (n=48)

Patients, n	Effect	Vaporize	Edible	Topical	Smoke
24	Decreased frequency & prevents HA	X	X	X	X
14	Aborts HA	5	1	1	7
4	Relieves pain		3	1	
1	Reduced nausea				1
5	Other		4	1	

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Results: Patient-Reported Negative Effects (n=14)

Patients, n	Effect	Vaporize	Edible	Topical	Smoke
2	Somnolence		X		
2	Hard to control		X		
1	Increased HA, seizure	X	X		
1	Bad dreams				X
1	Jittery & nauseous				X
1	Memory loss			X	
6	Other negative reports		X	X	X

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Discussion

- Patients self reported side effects
- No standard MMJ concentration or dose has been confirmed for migraine HA treatment or prevention
- Unknown if there is a preferred MMJ dose or route of administration for migraine HA

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Conclusions

- MMJ ↓ the number of migraine HA per month; 10.5 to 4.6 (p<0.0001)
- Most common form of MMJ = smoking; 53.7% of patients
- Almost all subjects used MMJ daily for migraine HA prevention
- Negative side effects were reported by 10.7% of patients

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Next Steps

- Randomized controlled trials are warranted to substantiate the correlation of MMJ with frequency of migraine HA
- Long-term effects of MMJ remain to be determined
- Further data on preferred modality for migraine HA treatment and prevention are needed

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Questions

- Contact information
  - Delilah.Brashman@ucdenver.edu

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Slide 27

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Slide 28

Hillary P. Smithsonian

https://youtu.be/RbqBYZzZIP8

Slide 29

Changes in Pharmacy Students' Perceptions of Underserved Populations After a 6-week Clinical Rotation in a FQHC Clinic

Hillary P. Smithsonian, PharmD
PGY2 Ambulatory Care Pharmacy Resident
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Abstract #1007

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Disclosures

- IRB approved, exempt
- Co-investigators:
  » Benjamin Chavez, Emily Kosirog, Jennifer Petrie, Joseph Saseen, Rhianna Tuchscherer*
- Conflicts of interest: None
- Project sponsorship: None

Slide 31

University of Colorado School of Pharmacy

- 4 year PharmD program
  - Approximately 160 students/class
- Experiential education
  - One 3rd year advanced-Introductory Pharmacy Practice Experiences (aIPPE)
  - Seven 4th year Advanced Pharmacy Practice Experiences (APPE)

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Background

- Pharmacists can play a key role in providing quality care to underserved patient populations
- Stigma towards the underserved exists in the general population, and potentially among pharmacists too

Educators **+** Curriculum **+** Experiential **=** Diminished health disparities

Social Psychology Quarterly. 1997; 60(4):323-337.

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Background

Accreditation Council for Pharmacy Education (ACPE) 2016 Standards

- Standard 3: Approach to Practice and Care
  - "Recognize social determinants of health to diminish disparities and inequities in access to quality care"
- Standard 13: APPE Curriculum
  - "Expose students to diverse patient populations as related to age, gender, race/ethnicity, socioeconomic factors (e.g., rural/urban, poverty/affluence), and disease states"

Accreditation Council for Pharmacy Education. 2016.

Slide 34

Background

- Survey of dental students showed certain attitudes towards the underserved declined over 4 years

- Medical students are more likely to pursue a practice in primary care and with the underserved after exposure

J Dent Educ. 2016 May;80(5):517-25.
Med Educ Online. 2015, 20: 27535.

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Slide 35

Primary Objective

Assess changes in student attitudes and perceptions towards providing care to the underserved population after a 6-week clinical experience within a federally qualified health center (FQHC) clinic

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Slide 36

Methods

- Pre-post survey design

Pre-rotation survey

6-week clinical rotation
- Exposure to direct patient care

Post-rotation survey

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Slide 37

Methods

- Original survey
  - » Incorporates new questions as well as questions adapted from previous studies
  - » Categorical and 5 point Likert Scale

| 1 = Strongly Disagree | 2 = Disagree | 3 = Neutral | 4 = Agree | 5 = Strongly Agree |

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Methods

Inclusion Criteria

- Pharmacy student at University of Colorado
- Completion of an APPE or aIPPE rotation at an FQHC clinic between 11/16/16 – 6/30/17

Exclusion Criteria

- 2nd rotation experience at FQHC
- Survey not completed within time frame

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Data Collection

- Data collection in process
- 28 surveys from 3 rotation blocks have been collected

Demographics (n=28)	
Characteristic	**% of Respondents**
Gender (female)	67.9%
Language (multilingual)	57.1%
↳ *Spanish*	*32.1%*
Age (25 – 29 years)	57.1%
Race (White/Caucasian)	66.7%

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Data Analysis

- Descriptive statistics completed for primary objective
- Change in pre- to post- score for each question and sum of domain score
  - → Wilcoxon signed-rank test
- Negatively worded questions reverse-scored for domain scores
- Significance set at p-value 0.01

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Primary Objective

Statement (n= 28)	Avg. Pre-Rotation	Avg. Post-Rotation	P-value
Access to Care/Resources	12.3	12.8	0.23
1. Access to medical care is a right.	4.3	4.5	0.62
2. Access to medical care is a privilege.	2.7	2.8	0.71
3. Underserved patients have just as much access to healthcare as other patient populations.	2.3	2.5	0.59
4. Underserved patients use more resources and get sick more often because they don't take care of themselves.	2.5	2.6	0.81

1 = Strongly Disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, 5 = Strongly Agree

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Primary Objective

Statement (n=28)	Avg. Pre-Rotation	Avg. Post-Rotation	P-value
Student/Professional Responsibility	8.9	9.3	0.74
5. Pharmacy students should be concerned about the problems of the underserved.	4.5	4.6	0.60
6. As a future pharmacist, I feel that it is my responsibility to provide quality care to the underserved.	4.4	4.6	0.36

1 = Strongly Disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, 5 = Strongly Agree

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Slide 43

Primary Objective

Statement (n=28)	Avg. Pre-Rotation	Avg. Post-Rotation	P-value
Personal Impact	18.2	20.4	<0.0001*
7. Working with underserved patients is very satisfying.	4.2	4.5	0.0042*
8. Working with underserved populations offers more intellectual stimulation than other opportunities.	3.3	3.5	0.42
9. I feel that I can significantly impact the health care of the underserved through pharmacy services.	4.2	4.6	0.0032*
10. Underserved patients are more likely to accept my recommendations than other patient populations.	3.1	3.7	0.003*
11. I would like to work with underserved populations in my pharmacy career.	3.8	4.1	0.0059*

1 = Strongly Disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, 5 = Strongly Agree

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Primary Objective

Statement (n=28)	Avg. Pre-Rotation	Avg. Post-Rotation	P-value
Perceptions and/or Barriers	9.2	9.8	0.3
12. Pharmacists working with underserved patients are more altruistic than others.	2.68	3.11	0.16
13. Pharmacists working with underserved populations earn a lower salary than other pharmacists.	3.11	3.12	1.00
14. Pharmacists would be interested in working with the underserved if they knew these populations better.	3.50	3.79	0.20

1 = Strongly Disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, 5 = Strongly Agree

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Primary Objective

Statement (n= 28)	Avg. Pre-Rotation	Avg. Post-Rotation	P-value
Educational	14.6	16.7	<0.0001*
15. Pharmacy education should include exposure to underserved patient care.	4.14	4.50	0.048*
16. I feel that I have enough exposure to underserved populations in my pharmacy training.	3.07	3.82	0.018*
17. I feel that my pharmacy education adequately prepared me to provide care to underserved patients.	3.43	4.11	0.003*
18. All pharmacy students should be required to have a 6-week rotation with an underserved population.	3.79	4.11	0.26

1 = Strongly Disagree, 2 = Disagree, 3 = Neutral, 4 = Agree, 5 = Strongly Agree

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Limitations

- Survey not validated yet, but will be

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Conclusions

- Clinical rotations within an FQHC clinic can positively impact pharmacy student attitudes towards underserved populations
- The more students exposed to underserved populations → more graduating student pharmacists that explore job opportunities within underserved areas

Looking forward:
Identify areas in the PharmD curriculum that can be improved upon to promote care to the underserved

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Changes in Pharmacy Students' Perceptions of Underserved Populations After a 6-week Clinical Rotation in a FQHC Clinic

Hillary P. Smithsonian, PharmD
Hillary.Smtihsonian@ucdenver.edu

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100+ years of education, patient care & scientific discovery.

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Dolly
Bleacher

https://www.youtube.com/watch?v=GzhMt481-js

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Slide 50

Comparison of new-onset gout incidence in adults prescribed chlorthalidone versus hydrochlorothiazide

Dolly Bleacher, PharmD
PGY-2 Ambulatory Care Resident
University of Colorado Skaggs School of Pharmacy
and Pharmaceutical Sciences

IRB Status: Received

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Disclosure Statement

- Dolly Bleacher, PharmD
- Potential conflicts of interest: none
  - Sponsorship: none
  - Proprietary information may be subject to different interpretations
  - Presentation of this slide indicates my agreement to abide by the non-commercialism guidelines provided on the CE Requirements page

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Research Background

Slide 53

Gout

- One of the most common rheumatic diseases
- Painful and bothersome condition
- Associated costs burdensome to the healthcare system
- Prevalence rising in the United States

Khanna D. Arthritis Care Res. 2012 Oct;64(10):1447–1461.
Image: http://www.webmd.com/arthritis/ss/slideshow-gout

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Comorbidities and Risk Factors

- Hypertension
- Obesity
- Metabolic Syndrome
- Type II Diabetes
- Chronic Kidney Disease
- Dietary factors
- Medications
    – Thiazide diuretics

Khanna D. Arthritis Care Res. 2012 Oct;64(10):1447–1461.

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Thiazides and Hyperuricemia

Lumen of Proximal Tubule | Proximal Tubular Cells | Interstitial Space (Basolateral Side)

HCTZ, CTD

Na+ — SLC5A8 → Uric Acid — OAT1 → ↑Uric Acid
Anion ← Uric Acid
Anion ← URAT1 — Anion
Uric Acid ←
Uric Acid ← MRP4 — Uric Acid — UAT → ↑Uric Acid
Uric Acid ← UAT

Renal Filtrate | Proximal Tubular Cells

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Thiazide Diuretics

- First-line treatment option for hypertension
- No particular thiazide diuretic recommended over another
- Hydrochlorothiazide (HCTZ) most widely prescribed
- Chlorthalidone (CTD) most widely studied in medical literature

Weber MA. J Hypertens. 2014 Jan;32(1):3-15.
Roush GC. Hypertension. 2012; 59: 1110-1117

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HCTZ vs. CTD

- CTD 1.5 – 2 x more potent than HCTZ
- CTD longer duration of action
- Limited Head-to-head CTD vs. HCTZ comparisons

Ernst ME. Hypertension. 2006; 47: 352-358

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Research Methodology

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Research Objectives

To assess the percentage of patients that develop new-onset gout diagnoses associated with hydrochlorothiazide vs. chlorthalidone

Evaluate the treatment duration prior to gout diagnosis

Assess the dose of diuretics used
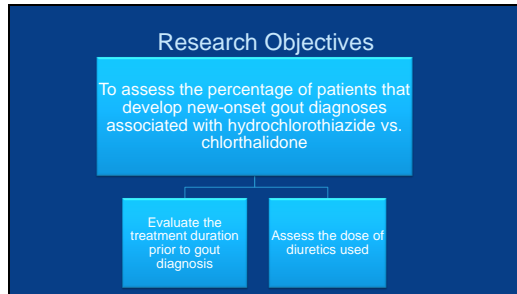
Slide 60

Study Design

- IRB approval
- Retrospective cohort study
- Database analysis
  - Pharmetrics Integrated Database
    - 2000 - 2012
    - De-identified medical and pharmacy claims
    - Demographic information
    - Approximately 70 million lives from more than 100 U.S. health plans

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Inclusion Criteria

- Adults age 18-89 years old
- Prescription claim for either HCTZ or CTD (index date)
- Diagnosis of hypertension prior to the index date
- Continuous medical and prescription benefit eligibility throughout the 36 month study period

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Exclusion Criteria

- History of gout prior to index date
- Hyperuricemia of malignancy/tumor lysis syndrome
- Diagnosis of lymphoma, leukemia, myeloma
- Stage IV or V CKD
- Heart failure
- Any patient who switched between HCTZ to CTD after the index date

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Exclusion Criteria

Medications that increase uric acid	Medications that decrease uric acid
- Loop diuretics - Niacin - Calcineurin inhibitors - Levadopa - Teriperatide - Ethambutol - Pyrazinamide	- Losartan - Fenofibrates

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Outcome Analysis

- CTD matched 1:2 with HCTZ
  - Age
  - Sex
  - Risk Factors
    - Alcohol abuse, CKD, DM, HLD, obesity, urolithiasis
  - Chronic Condition Index
- Gout occurrence within 12 mo after index date
  - ICD-9 code or NDC code for gout specific drug
  - Bivariate descriptive statistics

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Outcome Analysis

- Length of diuretic treatment exposure from index date to gout event
  - Time-to-event analysis
- HCTZ and CTD dose characteristics
  - Average daily dose
  - Starting dose of CTD or HCTZ
  - Dose of CTD or HCTZ at last fill prior to gout event
  - Bivariate descriptive statistics

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Research Results

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Baseline Demographics

	CTD	HCTZ
	n(%)	n(%)
Total subjects	1,011	2,022
Gender		
Female	528(52.23)	1,056(52.23)
Geographical Region		
East	194(19.19)	369(18.25)
Midwest	480(47.48)	802(39.66)
South	288(28.49)	721(35.66)
West	49(4.85)	130(6.43)
Age		
18-40	12(12.66)	256(12.66)
41-50	20(20.08)	406(20.08)
51-60	350(34.62)	700(34.62)
61-70	236(23.34)	472(23.34)
>=71	94(9.30)	188(9.30)

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Baseline Comorbidities

	CTD	HCTZ
	n(%)	n(%)
Chronic Condition Index		
0	46(4.55)	92(4.55)
1	100(9.89)	200(9.89)
2	205(20.28)	410(20.28)
3	193(19.09)	386(19.09)
4	184(18.20)	368(18.20)
5	128(12.66)	256(12.66)
6	92(9.10)	184(9.10)
7	40(3.96)	80(3.96)
>=8	23(2.27)	46(2.27)

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Results

	CTD	HCTZ	p
	n	n	
Total subjects	1,011	2,022	
New – Onset Gout	17 (1.7%)	26 (1.3%)	0.27
Days to first occurrence of gout (mean)	183.6	152.7	0.39
Dose Analysis			
Average daily dose (mg)	22.7	24.3	0.78
Average dose prescribed at index date (mg)	22.1	23.6	0.45
Average last prescribed dose (mg)	22.8	25	0.37

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Results

- Age at gout onset
  - CTD = 58
  - HCTZ = 56
  > 57
- CCI of those with gout
  - CTD = 3.8
  - HCTZ = 4.2
  > 4

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Limitations

- Many variables unavailable
  - Racial/ethnic background
  - Laboratory values
  - Lifestyle factors (ie diet, alcohol)
  - BMI
- Undercoded Conditions
  - Obesity
  - CKD
- Results representative of insured population
- Assumption of gout medication indication

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Conclusion

- Patients prescribed typical doses of CTD for hypertension have a similar risk of developing new-onset gout compared to patients prescribed similar doses of HCTZ.

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Acknowledgements

- Joseph Saseen, Pharm.D., BCPS
- Kavita Nair Ph.D.
- Vahram Ghushchyan Ph.D.
- Richard R. Allen M.S.

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