**Characterization of Oral** **Antibiotics for Acne Treatment**

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**Disclosures:** None.

**1. Objectives:**

We aim to characterize 1) the use of oral antibiotics for the treatment of acne in children and adolescents and 2) guideline compliance of current clinical practice around the world.

**2. Rationale:**

Acne is a common and disabling medical problem, especially among adolescents.[1] Guidelines established by the American Academy of Dermatology (AAD) recommend to minimize the duration of systemic antibiotics for the management of acne ideally to 3-4 months and no longer than 6 months in order to decrease risk of resistance.[1] A recent systematic review demonstrated that over 50% of P acnes strains are reported as resistant in all major regions of the world.[2] In addition to promoting resistance, long-term oral antibiotic use has been associated with a number of adverse events including microbiome disruption and pharyngitis, and possible associations with inflammatory bowel disease and obesity.[3] Despite these adverse effects, oral antibiotics are often prescribed for acne for longer durations than acne guidelines recommend.[3] A large retrospective cohort study of teenagers in the UK revealed that 29% of antibiotic courses prescribed by general practitioners exceeded 6 months in duration.[3] OHDSI network evidence will identify areas of the globe most in need of improving guideline concordance.

**3. Research questions:**

We hypothesize that the type and duration of oral antibiotic therapy will vary and course duration will exceed guideline recommendations.

**4. Research Methods:**

***Study Design:***

This study will be a retrospective, observational, cohort study. Outcomes of interest are the 1) type of antibiotic prescribed and 2) duration of oral antibiotic therapy among patients with acne.

A course of oral antibiotics for acne will be defined by a prescription for at least 30 days in patients with a prior diagnosis of acne. Start date of therapy will be defined as the date of first prescription. End date of therapy will be defined as the date of last prescription in series plus the number of days the medication was supplied.

***Data Sources: TBD***

* Electronic Health Record (EHR) –TBD if valid source
* Claims-
	+ CPRD (UK),
	+ JMDC (Japan),
	+ Optum (US),
	+ Truven Commercial Claims and Encounters (CCAE) (US)
	+ Truven Medicaid (US),
	+ France?
	+ Germany?

TBD

***Outcomes***

* Treatment with oral antibiotics among patients with acne
* Type of antibiotic
* Number and duration of therapeutic courses

***Study Population:***

* Inclusion Criteria:
	+ Patients between the ages 12-22 years at the start of the study (as of 1/1/2003)
	+ With a diagnosis of acne as defined by OHDSI concept\_IDs - TBD
	+ ICD-9 and ICD-10 codes (ICD9: 706.1 (other acne); ICD10: L70.0 (acne vulgaris), L70.8 (other acne))
	+ and an antibiotic start date between 1/1/2003 and the present date.
* Exclusion Criteria:
	+ Oral antibiotic courses > 5 years (TBD: Need more information from Drs. Barbieri and Margolis on how often this data was inaccurate in ref [2])
* Oral Antibiotic Criteria:
* Definition of a course of oral antibiotics ≥ 30 days
* Start date= date of first prescription (on or after 1/1/2003)
* End date= date of last prescription in series + number of days of medication supplied
* Prescriptions with <180 day gap between start of prescription will be considered as part of one course of therapy

***Potential misclassifications***

* Prescription for oral antibiotics for another medical condition TBD-
	+ - Cystic fibrosis?
		- Inflammatory airway diseases?
		- MRSA- methicillin-resistant staphylococcus aureus
		- VRE - vancomycin-resistant enterococcus

***Analytic Plan***

* Outcomes are the type, number of courses, and duration of course of antibiotic therapy for acne
* Comparison of outcomes across different countries, as presented by the different data sources
* Sensitivity analysis of all persons with an acne diagnosis vs. those with acne diagnosis without concomitant other diagnoses (CF, IAD, MRSA, VRE) that may require chronic oral antibiotic therapy

**6. Protection of human subjects:**

This study will use de-identified data.

IRB approval - Each participating data site confirmed Institutional Review Board approval for the study or confirmed that their analysis did not require approval because it was exempt or was deemed nonhuman subjects research (e.g., because the database had previously been de-identified).

**7. Plans for disseminating and communicating study results:**

The study results will be posted on the OHDSI website after completion of the study and published in a peer-reviewed scientific journal.

**Initial Proposal Date:** August 25, 2016

**Launch Date:** TBD

**Study Closure Date:** TBD

**Results Submission:** Email

**References:**

1. Zaenglein  AL, Pathy AL, Schlosser BJ, et. al. Guidelines of care for the management of acne vulgaris. J Am Acad Deramtol 2016;74(5):945-73.
2. Walsh TR, Efthimiou J, Dreno B. Systematic review of antibiotic resistance in acne: an increasing topical and oral threat. Lancet Infect Dis 2016;16(3):e23-33.
3. Barbieri JS, Hoffstad O, Margolis DJ. Duration of oral tetracycline-class antibiotic therapy and use of topical retinoids for the treatment of acne among general practitioners (GP): A retrospective cohort study. J Am Acad Dermatol 2016. doi: 10.1016/j.jaad.2016.06.057. [Epub ahead of print]