

Identifying Message to PROmote Value & Education (IMPROVE) of Generic Oral Contraceptive Prescribing

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Introduction

- Generic drug prescribing is an underutilized method to improve the value of care and increase patient access to medicines .
- In national surveys,1 in 3 providers report skepticisms towards generic drugs.¹
- In the U.S., Oral Contraceptives (OCs) are the most frequently used contraceptives methods in women of reproductive age.
- Despite FDA approval requiring that generics are therapeutically equivalent to their brand name counterpart, patients and providers have expressed concerns about the effectiveness of generic OCs.
- In 2013, 22% of OCs prescribed were brand-name; 98% had an available generic
- Eliciting perspectives from key OCs prescribers Primary Care Physicians (PCPs) and Nurse Practitioner (NPs) could improve interventions promoting generic drug prescribing.

Objectives

- Identify barriers to prescribing of generic OCs
- Understand facilitators of generic OCs prescribing
- Propose potential solutions to increasing prescribing of generic OCs among key prescribers (PCP's and NP's)

Methods

 Focus group scripts developed, pilot-tested, and revised using a 4-D model of appreciative inquiry (Fig. 1).

Discovery & Dream

- What is your understanding of FDA standards for approving generic drug?
- What has your experience been substituting generic for branded drugs?
- What factors influence you prescribing OCs?

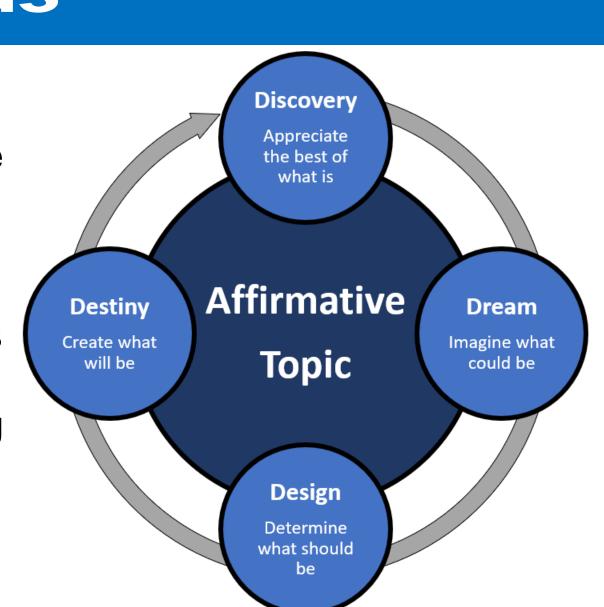


Fig. 1: 4-D Model of Appreciative Inquiry

<u>Design</u>

- How do you think the prescribing rates of generic OCs can be improved?
- What messages would help motivate your peers to increase the rate of generic OCs prescribing? Who should deliver these messages?
- What information can FDA provide to improve your perception?
- Conducted two 60-minute focus group sessions, one each at the American College of Physicians (ACP) Internal Medicine, and American Association of Nurse Practitioners (AANP) Annual Meetings.

Focus Group (FG) Screening Criteria

- Age between 35-65 years old
- Prescribed OCs
- Clinically practice (>50% time) in an outpatient-based setting
- Unaffiliated with the FDA or pharmaceutical industry

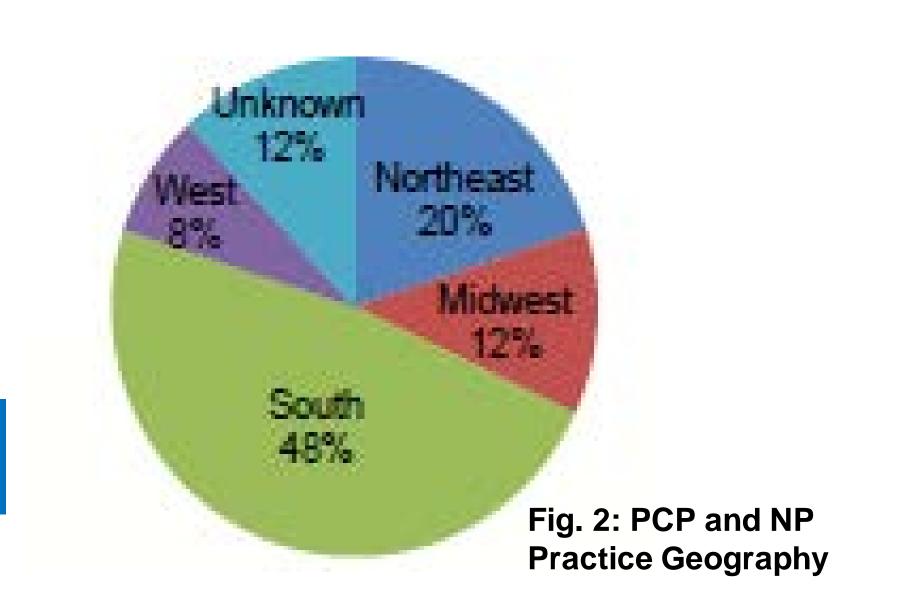
Transcripts were analyzed qualitatively via Atlas.ti software.

Results

Table 2: Barriers and Facilitators of Generic OCs Prescribing

Focus Groups Non-Black/ **Hispanic African American** PCP (n=12) 9 (75%) 2 (17%) NP (n=12) 11 (92%) 10 (83%) 2 (17 %)

Table 1: Demographics of Participants in OCs



Theme

Health

System

Workflow

Provider

Patient

Theme

Health

system

Workflow

Provider

Patient

Subtheme (PCP, NP)

Availability of samples (6,3)

Multiple generic brands (3,8)

Lack of trusted sources (5,8)

Confusion about

Preference (13,3)

DTC advertising (2,4)

Pill and package (2,1)

Subtheme (PCP, NP)

Availability of samples (5,6)

Insurance companies (7,9)

Default to generic (13,9)

Point of care IT tools (4,6)

Cost (10,12)

Lack of trusted sources (5,8)

generic naming (8,3)

Health Systems Workflow Factors Factors

- State Generic Substitution Laws Availability of
- Insurance Companies Availability of Generics

Table 3: Example Barriers (Representative quotes on select barriers to generic OCs prescribing amongst PCP's and NP's)

Samples

 Performance Metrics

equivalents that are in it.

they're getting the generic.

Table 4: Example Facilitators (Representative quotes on select barriers to generic OCs prescribing amongst PCP's and NP's)

formulary is loaded

doesn't make sense and its causes confusion.

Knowledge about generics (6,2) My understanding is that there's no additional testing...before a generic can be put out...

My Electronic Health Records (EHR) defaults to generic.

Insurance companies are not trusted by the public, or by us.

I think it's patient complaints about cost

Insurance companies are not trusted by the public, or by us.

Provider Factors

- Practice Disruption Default to
 - Generic Pharmacy Insurance
 - Formulary Generic Nomenclature

Examples

If you're going to generically prescribing an oral contraceptive ... you're going to have to go

When you have ten different brands of the same two ingredients of a birth control, it kind of

I actually have a different problem in that my patients will sometimes come complaining that

Examples

Insurance companies will sometimes—If I order a brand...fill a 30-day (courtesy) supply and

then send a letter to the patient...and they'll give them a list of what's covered generically.

One of the things I think would be helpful to insure more generic prescriptions is when a

patient is loaded in to my Electronic Medical Records (EMR), automatically a certain

She readily went back to a generic when she realized how expensive it was

Texas law has it printed on the prescriptions, it's generic unless you specify otherwise

..[S]o, I think some of it [patient preference] is the direct result of marketing.

..[A] II of a sudden today it [the OCs] is blue, she's not comfortable taking that.

in there and be savvy enough to be able to ask for that drug based on the generic drug

We used to use lots of samples of all the different pills. We don't have that anymore.

 Multiple Generic Brands

Point of Care IT

Patient Factors

- Attitude Towards Cost
- Preference Lack of Trusted Prior Experience Sources Side Effects
- Reluctance to Direct-to-Consumer Switch Patient Advertising Medication Pill and
- Level of Packaging Knowledge **About Generics**
- Generics Specialists

Info About

Accessibility to

Generics

Conclusions

Limitations

- Small sample size of PCPs and NPs.
- Inter-rater reliability data have not yet been completed.
- Practice and prescribing setting data for FG participants was lacking.

Conclusions

- Providers' knowledge of FDA bioequivalence standards was low.
- Negative attitudes and accessibility of information about generic options were frequency cited as barriers.
- For OCs specifically, complicated generic nomenclature was a barrier.
- Participants identified 13 solutions to increase generic OCs prescribing that aligned with the four identified themes.

Fig. 3: Example Solutions to Increase Prescribing Identified by Providers

Health System: Simplify generic nomenclature

Workflow: Point of care IT tools integrated with EMR

Provider: Evidence based messaging for providers from trusted sources (i.e. Professional Societies)

Patient: Public service style advertising of generic OC's to patients

Next Steps

- Develop evidence-based messaging for providers about generic OCs is an opportunity to increase generic OCs prescribing.
- Survey to test messaging was recently completed through ACP and AANP: -Surveyed approximately 500 NPs and 400 PCPs
- -Knowledge and vignette-style questions focused on OCs and antidepressant prescribing strategies.

References

1.Kesselheim, A.S., et al., physicians: Results of a national survey. JAMA Intern Med. 2016;176(6):845-847.

2. The Amundsen Group. Measuring Generic Efficiency in Medicare Part D.

http://www.phrma.org/sites/default/files/pdf/Amundsen_PhRMA_LIS_Generic_Efficiency_Summary.p df. Accessed May 19, 2015.

3.Rosenberg MJ, Waugh MS. Oral contraceptive discontinuation: A prospective evaluation of frequency and reasons. American Journal of Obstetrics and Gynecology. 1998;179(3):577-582. 4. Ansbacher R. Low-dose oral contraceptives: health consequences of discontinuation. Contraception. 2000;62(6):285-288.

Acknowledgements

- Funding for this work was made possible, in part, by the U.S. Food and Drug Administration through Grant U01FD005485.
- Views expressed in this poster do not necessarily reflect the official policies of the Department of Health and Human Services, nor does any mention of trade names, commercial practices, or organization imply endorsement by the United States Government.









