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Development and testing of a module to promote generic oral contraceptive prescribing among nurse practitioners

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Abstract

Although generic oral contraceptives (OCPs) can improve adherence and reduce health care expenditures, use of generic OCPs remains low, and the factors that affect generic prescribing are not well understood. We aimed to understand the barriers and facilitators of generic OCP prescribing and potential solutions to increase generic OCP prescribing, as well as pilot an educational module to address clinician misconceptions about generic OCPs. We developed focus group scripts using the 4D model of appreciative inquiry. A total of four focus groups occurred, two at the American Association of Nurse Practitioners (AANP) national conference and two at the American College of Physicians (ACP) Internal Medicine meeting. Focus group transcripts were analyzed using a constant comparative method with no a priori hypothesis to generate emerging and reoccurring themes. Findings from these focus groups were used to develop an educational module promoting generic OCP prescribing. Participants were recruited from the

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AANP Network for Research and the ACP Research Panel. This study demonstrates that health system factors, workflow factors, clinician factors, and patient factors were the main barriers to and facilitators of generic OCP prescribing. Nurse practitioners were responsive to an educational module and reported increased willingness to discuss and prescribe generic OCPs after completing the module. Interventions to increase generic OCP prescribing must address clinician and patient factors within the context of workflow and larger health system factors.

Keywords

Contraceptives; oral; cost savings; drugs; generic; focus groups; generic substitution; nurse practitioners; workflow

Introduction

In the United States, oral contraceptives (OCPs) are the most frequently used contraceptive method by women of reproductive age (Jones, Mosher, & Daniels, 2012). Over 80% of sexually active women in the United States have used OCPs, making OCPs the most commonly prescribed drugs (Daniels, Mosher, & Jones, 2013). Although increased use of generic drugs has been shown to reduce costs and increase medication adherence, generic prescribing of OCPs has still room for improvement (Haas, Phillips, Gerstenberger, & Seger, 2005; Zhang & Sridhar, 2017). Previous work has shown a generic fill rate of 73% for OCPs in a nationally representative sample, despite the fact that almost all OCPs on the market are available as generic (Chee et al., 2018; Hall & Trussell, 2012).

Clinician misconceptions about generic drugs may be one reason for low rates of generic OCP prescribing. Recent studies of clinician knowledge and attitudes about generic drugs demonstrated that knowledge gaps and negative attitudes about generics are still common among clinicians. In one survey of practicing physicians, 32% did not agree with statements that generics are as safe as, as effective as, or do not cause more adverse effects than brand drugs (Kesselheim et al, 2016). However, no previous studies have looked specifically at generic OCP prescribing or examined perceptions of nurse practitioners (NPs) (Berg, Gross, Haskins, Zingaro, & Tomaszewski, 2008; Dunne, Shannon, Hannigan, Dunne, & Cullen, 2014; Kesselheim et al., 2016; Shrank et al., 2011).

In addition, OCPs face challenges to generic prescribing specific to this drug class. In response to patient and clinician concerns about medication adherence, an American College of Obstetricians and Gynecologists opinion released in 2007 and reaffirmed in 2018 supported patient or clinician requests for brand OCPs or the continuation of the same generic or brand OCP if the request is based on clinical experience or concerns regarding packaging or compliance or if the branded product is considered a better choice for that individual patient (American College of Obstetricians and Gynecologists Committee on Gynecologic Practice, 2007). This was despite U.S. Food and Drug Administration (FDA) approval requiring that generic versions of brand-name drugs are therapeutically equivalent and, therefore, interchangeable in clinical practice.

To provide high-value care and reduce costs through increased generic OCP prescribing, it is important to elicit the opinions of prescribers and develop educational messaging that targets issues of limited knowledge of and negative attitudes toward generic drugs. As the primary care workforce continues to diversify, exploring these issues across a variety of clinicians will be increasingly important (American Association of Nurse Practitioners (AANP), 2018). This study aimed to understand key factors that affect generic OCP prescribing and potential solutions to increase generic OCP prescribing, as well as pilot an educational intervention aimed at addressing misconceptions about generic drugs among primary care clinicians who prescribe OCPs, primarily NPs.

Methods

Focus group script development

To solicit primary care physician (PCP) and NP perceptions on generic prescribing, we developed focus group scripts using the 4D model of appreciative inquiry (Figure 1) (Michael & Roger, 2011). This technique is used to identify potential solutions and design interventions. It encompasses 1) Discovery, identifying the current best way to achieve a goal; 2) Dream, imagining new ways of achieving a goal; 3) Design, how to operationalize a change to reach a goal; and 4) Destiny, anticipating the best practice.

The first half of the script focused on Discovery. It aimed to assess clinician knowledge about generic drugs and identify current barriers to and facilitators of generic OCP prescribing. To probe for clinician knowledge about generic drugs, we asked about their understanding of the FDA standards that a generic drug is required to meet before it can get approved by the FDA and how they receive information about generic drugs. To probe for barriers to and facilitators of generic OCP prescribing, we asked about the factors that influenced their prescribing strategy for OCPs, how they select from the available OCP options, if they ever considered substituting a generic OCP but decided to prescribe the brand name instead, and what barriers existed to prescribing generic OCPs.

The second half focused on Dream, Design, and Destiny. It aimed to identify potential solutions to increase generic OCP prescribing and develop messages that would motivate clinicians to prescribe generic drugs. We asked about solutions that would make it easier for them to prescribe more generic OCPs, specifically asking about IT systems, payers, samples, and patient education. We also asked what messages would motivate their peers to increase the rate of OCP prescribing and who should deliver these messages.

The focus group script was reviewed by expert stakeholders and collaborators, including NPs, the FDA, and pharmacists, and it was read-through on subsequent conference calls to achieve consensus. These stakeholders encompassed diverse areas of expertise including health economics, value-based health care, adult learning theory, and qualitative research, as well as a variety of professions including pharmacy, hospital medicine, primary care practice, and obstetrics and gynecology. The script was piloted with a group of clinicians to ensure that focus groups would be completed in 1 hour. When the focus group script was complete, it was submitted to the University of Chicago Institutional Review Board (IRB),

the Office of Management and Budget (OMB), and the Research Involving Human Subjects Committee of the FDA. Approval was secured from all parties.

Focus group moderators, two physicians and two nurse investigators, were trained to conduct effective focus groups using the focus group scripts (O'Brien, Harris, Beckman, Reed, & Cook, 2014; Tong, Sainsbury, & Craig, 2007). This was to ensure no hierarchical communication between moderators and participants.

Educational module development

We used Kern's six-step approach to curriculum development (Thomas, Kern, Hughes, & Chen, 2016): 1) problem identification and needs assessment, 2) targeted needs assessment, 3) goals and objectives, 4) educational strategies, 5) implementation, and 6) evaluation and feedback. This study was approved by the University of Chicago Biological Sciences Division IRB (IRB15-1227-CR002), the OMB, and the Office for Human Research Protections.

Using focus group results and a prior survey of NPs and physicians identifying effective messaging to promote generic prescribing, we developed an educational module aimed at improving generic prescribing among NPs. The objectives of the module and the content were developed in collaboration with a diverse group of stakeholders with backgrounds in medicine, gynecology, advanced practice nursing, pharmacy, health economics, medical education, and at the FDA. Module objectives were to 1) reduce generic skepticism among clinicians, 2) improve knowledge of generic drugs and the approval process required for generics, and 3) increase clinician intent to discuss and prescribe generic OCPs.

The "Cost Savings and Generic Substitution of Oral Contraceptives (OCPs)" educational module included several components designed to mimic Kolb's learning cycle (Kolb & Kolb, 2005) of experience, reflection, conceptualization, and active experimentation. Participants watched a 10-minute video demonstrating the experience of a clinician discussing a generic OCP with a patient. This video 1) depicted barriers clinician may encounter when discussing generic drugs, such as patient preferences for brand drugs and the naming of OCPs and 2) demonstrated how these barriers could be addressed using knowledge gained from the rest of the module. The goal of the subsequent presentation was to encourage participants to reflect on the experience depicted in the video and focused on information about generic drugs that may be helpful in a similar scenario. A 14-slide PowerPoint presentation with voice-over recorded using TechSmith Camtasia software discussed barriers to generic OCP prescribing identified in our focus groups, information on the FDA generic approval process, and the importance of discussing and prescribing generics. After the presentation, participants completed an evaluation that included questions about their knowledge of generics and their future intent to discuss and prescribe generic OCPs. This survey allowed participants to conceptualize the information that had been presented in the module and actively experiment by thinking about whether they would prescribe generic in future clinical encounters. The module content was agreed on by the FDA and approved for the AANP Pharmacology CEU through The University of Chicago Pritzker School of Medicine, which is accredited with commendation by the Accreditation Council for Continuing Medical Education.

Evaluation of educational outcomes for the module was structured using three of the four levels of the Kirkpatrick model for training health professionals: 1) learner reaction, 2) knowledge, and 3) intention to change behavior. Knowledge was assessed using three questions assessing knowledge gaps identified in focus groups and literature review. Learner reaction and intention to change behavior were evaluated using a five-point Likert scale. The learner reaction questions asked participants about module usefulness and whether participants had less distrust of generic OCPs as a result of the module. The intention to change behavior asked participants whether they would increase discussing generics with patients or prescribing generic OCPs as a result of the module. In addition, an open-ended response item was included for respondents to include feedback on the module. Participants' baseline score on the generic skepticism index, demographic data (sex, ethnicity, race, age, and practice region), and clinician practice characteristics (frequency of prescribing OCPs, time spent in primary care, setting of patient care, and practice site) was also collected.

Study recruitment

A total of four focus groups occurred, two at the AANP national conference (June 23 and 24, 2016, in San Antonio, Texas) and two at the American College of Physicians (ACP) Internal Medicine meeting (May 6 and 7, 2016, in Washington, DC). The AANP is the largest full-service national professional membership organization for NPs of all specialties. The ACP is the largest medical specialty organization and the second largest physician group in the United States (ACP, n.d.). We screened AANP and ACP members to identify those who could comment on their experiences prescribing OCPs. Eligible members were between 35 and 65 years of age, clinically practiced in an office- or community-based setting, prescribed OCPs, based on an outpatient or primary care setting, and were unaffiliated with the FDA or pharmaceutical industry. Recruitment for this study was done through email from their respective professional societies. At the start of each focus group, participants reviewed a written consent form. Each focus group was digitally recorded on site by PSAV and transcribed verbatim by Voss Transcription (Voss Transcription, Valparaiso, IN).

Module testing with nurse practitioners

We piloted the module with volunteer NPs. The initial survey was distributed using the AANP Network for Research. The module was disseminated through the AANP via email.

Data analysis: focus groups

Focus group transcripts were analyzed using grounded theory, an inductive methodology that generates conceptual categories from qualitative data (Watling & Lingard, 2012). Transcripts were analyzed using a constant comparative method with no a priori hypothesis to generate emerging and reoccurring themes (Boeije, 2002; Fraenkel Jack & Wallen Norman, n.d.). The units of analysis were sentences and phrases. All coding was done in the qualitative software package ATLAS.ti 7 for Windows (Berlin, Germany). First, the transcript from one of the four focus groups was coded to identify preliminary codes. Disagreements in coded themes were resolved by discussion to consensus. The remainder of the transcripts were coded independently until interrater reliability was achieved (kappa statistic ≥ 0.6). Respondent validation and member check was performed with ACP and AANP participants (O'Brien et al., 2014). All reporting was performed within the Standards

for Reporting Qualitative Research and the Consolidated Criteria for Reporting Qualitative Research (O'Brien et al., 2014;Tong et al., 2007).

Data analysis: educational module

Descriptive statistics were generated to summarize NP postmodule survey data. Learner reaction and intention to change behavior responses were dichotomized between those who answered "agree" or "strongly agree" versus other responses. High knowledge was defined as individuals who correctly answered at least two of the three postmodule knowledge questions. Generic skeptics were categorized as those who responded "strongly disagree," "disagree," or "neutral" to at least one of the generic skepticism index questions (Kesselheim et al., 2016). We used Stata 14.0 (StataCorp LP, College Station, TX) to test the association of generic skepticism with learner reaction, intention to change behavior, and knowledge. We also compared NP responses to another ongoing study looking at PCPs who had taken the module.

Results

Demographics

A total of 12 NPs and 13 PCPs participated in our focus groups (Table 1). In the NP group, 92% (11/12) were women, and 17% (2/12) were African Americans. In the PCP focus group, 62% (8/13) were women, and 15% (2/13) were African Americans. There were no statistically significant differences in baseline characteristics between groups ($p < .05$). Both focus groups were geographically diverse and had participants from a variety of practice settings (private practice, Veterans Affairs, Indian Health Service, and Federally Qualified Health Centers).

Barriers and facilitators to generic prescribing

Nurse practitioners and PCPs identified 24 factors that affected their prescribing of generic OCPs. Of these 24 factors, 13 contained codes in both the barriers and facilitators category, whereas 11 contained codes in only one category. These factors were categorized into four themes: health system factors (Table 2), workflow factors (Table 2), clinician factors (Table 3), and patient factors (Table 3).

Overall, 41.9% (182/434) of codes reflected barriers to generic prescribing with the majority of these falling under the clinician factor theme ($n = 60$). The most common were 1) accessibility of information about generic drugs [3e] ($n = 13$) under the clinician factor theme: "Whenever I prescribe generic there's no supportive data" and 2) patient preference for brand under the patient factor theme: "my patients will sometimes come complaining that they're getting the generic." The second most common subtheme was attitude toward generics [3a] ($n = 12$) under the clinician factor theme: "generics are not going to be efficacious." Furthermore, clinicians also mentioned a lack of trusted sources [3b] ($n = 9$) to learn about generic drugs and a lack of knowledge about generic drugs [3d] ($n = 11$), which were categorized under the clinician factor theme. For health system factors, the availability of samples [1b] was the most frequently mentioned barrier: "And does the sample influence your prescribing strategy? Of course it does." There were also several barriers providers

identified that were specific to generic OCP prescribing. These barriers related to generic naming [2f] (*n* = 13) “you’re going to have to be savvy enough to be able to ask for that drug based on the generic drug equivalents” and multiple generic brands [2h] (*n* = 16) “when you have ten different brands of the same two ingredients of a birth control…it causes confusion.”

Clinicians also identified facilitators of generic prescribing 35.5% (154/434), with the majority falling under the workflow factor theme (*n* = 80). The most common subthemes were insurance [2d] (*n* = 17) under the workflow factor theme: “you prescribe the brand and then you get feedback saying try first generics.” Clinicians also mentioned default to generic [2b] (*n* = 15): “my EHR defaults to generic and if I want to do brand name there’s a separate button I need to click.” Cost [4a] (*n* = 26) under the patient factor theme was also frequently mentioned: “she readily went back to a generic when she realized how expensive it was.” Last, under health system factors, insurance company policies [1c] were the most frequently mentioned facilitator: “they have teams of people that are culling the environment for ways to make things cheaper.”

Although several barriers to and facilitators of generic prescribing were common among both NPs and physicians, there were significant differences between groups when looking at workflow factors. For disruptions of daily practice, NPs mentioned that prescribing generic drugs took more time and effort—disruption of daily practice that was a barrier to generic prescribing [2a] (*n* = 4). PCPs, on the other hand, mentioned that prescribing brand-name drugs took more time and effort than prescribing generic—disruption of daily practice that was a facilitator to generic prescribing [2a] (*n* = 10). In addition, NPs also specifically mentioned insurance companies and pharmacy as additional workflow barriers to prescribing generics, whereas PCPs did not.

Solutions to increase generic prescribing

Nurse practitioners and PCPs identified 13 solutions to increase generic prescribing (Table 4). These factors were categorized using the four themes used to categorize the barriers and facilitators: health system factors, workflow factors, clinician factors, and patient factors.

Of the codes related to solutions (*n* = 95/434), the most common subtheme was more information about generics [3j] (*n* = 32) under clinician factors: “if when you were going to write for generic drug you knew that they were going to be equivalent…there would be no thought process to doing it at all.” The second most common subtheme was advertising generics [4g] (*n* = 15) under patient factors: “Public service announcements within physician offices while they’re in the waiting room I think would be really effective.”

Nurse practitioners and PCPs also identified different solutions to increase generic OCP prescribing. PCPs mentioned simplifying generic OCP naming [2j] (*n* = 8) and mandatory generic substitution [1f] (*n* = 4), whereas NPs did not. Nurse practitioners more frequently mentioned point-of-care IT tools [2k] (*n* = 8) than PCPs (*n* = 1).

Module

The module was piloted with 52 NPs who participated in the initial survey. After completing the module, 92.3% found the module useful and 55.8% reported less distrust of generic OCPs. Furthermore, 84.6% were more likely to discuss generic OCPs with their patients, and 82.7% were more likely to prescribe generic OCPs. Looking at the clinician knowledge, 71.2% of respondents were categorized as high knowledge with 96.2% answering question 1 correctly (general facts about generic OCPs), 36.5% answering question 2 correctly (barriers to prescribing generic OCPs), and 48.1% answering question 3 correctly (definition of therapeutic equivalence).

Generic skepticism was associated with lower likelihood to find the module useful but was not associated with distrust of generics, likelihood of discussing or prescribing generic OCPs, or knowledge. Compared with physicians who had previously taken the module, NPs were more likely to find the module useful (92.3% vs. 78.4%, $p = .02$) and were more likely to discuss (84.6% vs. 68.8%, $p = .03$) and prescribe generic OCPs (82.7% vs. 66.8%, $p = .01$). Although knowledge scores for NPs were lower than physicians, they were still relatively high (71.2% vs. 88.0%, $p = .003$).

Discussion

To the best of our knowledge, this is the first study using qualitative methods to investigate clinician experiences with generic OCP prescribing and analyze generic OCP utilization and potential cost saving. In the discovery phase of the 4D model of appreciative inquiry, four factors that affected prescribing and potential solutions to increase generic prescribing were identified: health system factors, workflow factors, clinician factors, and patient factors. Clinicians noted that cost was a major driver of generic prescribing, and defaults to generic were important facilitators of generic prescribing. Concerns about generic efficacy and a lack of information about generics hindered generic OCP prescribing. For OCPs, generic naming was also an important barrier.

Our findings highlight the importance of clinician and workflow factors for generic OCP prescribing. Clinicians were still unaware of FDA standards for generic drugs. Furthermore, many expressed negative attitudes about generics, especially generic OCP efficacy. These knowledge gaps and misconceptions about generic drugs were compounded by a lack of trusted sources and difficult to access information about generic drugs.

Even so, the workflow in which clinicians are embedded does affect prescribing behavior. Clinicians were sensitive to systems and processes that affected the time and effort involved in prescribing certain drugs. Defaults to generic set through institutional policy and electronic medical record (EMR) options were frequently mentioned as facilitators of generic prescribing. Insurance company policies that required additional steps, such as prior authorization for brand-name OCPs, disincentivized clinicians from prescribing those drugs. Of interest, NPs mentioned experiences in which prescribing generic OCPs was actually more difficult than brand-name OCPs, whereas PCPs did not. The experiences they described all involved changes with insurance coverage or formulary lists that excluded the generic drug the patient was on, requiring additional effort to find covered alternatives.

Nurse practitioners also specifically mentioned insurance companies and pharmacy as additional workflow barriers to prescribing generics, whereas PCPs did not. Although these differences may be a result of different workflow patterns or clinical responsibilities, we are unable to compare these findings because no previous study has included NPs.

Moreover, clinicians mentioned the naming of generic drugs as a barrier specific to OCPs. The large number of generic OCPs further compounds the naming problem for clinicians who may not prescribe OCPs on a regular basis. Clinicians in our focus groups noted that they tended to prescribe the handful of OCPs they are comfortable with and often had to look up generic drugs they were less familiar with.

The solutions identified by clinicians in the Dream, Design, and Destiny phases of the 4D model aligned with the barriers to generic OCP prescribing. Both NPs and PCPs expressed a need for more information and more easily accessible information from a trusted source with no financial stake in generic prescribing. Similarly, they noted that patients should also be educated about generics. However, regarding the generic naming of OCPs, there were interesting differences between NPs and PCPs. Nurse practitioners expressed a need for better point-of-care IT tools that would allow them to look up generic versions of brand-name OCPs, whereas PCPs mentioned changing the existing naming structure to simplify generic OCP names.

The educational module we piloted with NPs showed that this group of clinicians is responsive to messaging promoting generic prescribing. Compared with a study looking at physicians, NPs were more likely to find the module useful and more likely to discuss generic OCPs and prescribe generic OCPs for future patients.

This study has implications for future design of interventions that aim to increase generic OCP prescribing. Our findings underscore the importance of addressing clinician and patient factors within the context of workflow and larger health system factors. An ideal solution might include a set of interventions that includes clinician education about generics coupled with point-of-care IT solutions that would make information about generic drugs, including generic OCP names, more accessible. Incorporating data from insurer formulary lists and patient insurance coverage into existing EMR platforms could also remove workflow barriers to generic OCP prescribing. Moreover, evidence-based messaging and education targeting clinician misconceptions about generic drugs may remove additional barriers to generic prescribing.

There were several limitations of this study. A small number of NPs and PCPs were sampled in our focus groups, and their responses may not be representative of clinician knowledge and attitudes. Practice setting data and prescribing data for focus group participants were lacking. For the module, a small number of NPs completed the module.

In conclusion, this study demonstrates that health system factors, workflow factors, clinician factors, and patient factors affect generic prescribing. For OCPs, generic naming compounded by the large number of OCPs available was a barrier to generic prescribing. Clinician concerns about generic OCP efficacy and a lack of information about generic OCPs were also important barriers, while cost and defaults to generic facilitated generic

prescribing. Almost all brand-name OCP prescriptions could be substituted with a generic, and substantial cost savings could be accrued as a result of switching patients from brand to generic OCPs. Messaging targeting clinicians that aims to promote generic prescribing should incorporate these findings.

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IMPROVE 4-D MODEL FOCUS GROUP SCRIPT - OCP

INTRODUCTION

Welcome and thank you for participating in this focus group. My name is X, co-investigator and this is Y, co-investigator. The objective of the focus group is to gather your opinions and perspectives on generic prescribing. I will be asking you several open-ended questions and you are encouraged to provide your opinions and perspectives in response to the questions. We expect that you will have different points of view and we are interested in hearing from each of you. To ensure we are able to accurately capture your responses for analysis, this session will be audio recorded. In addition, we may also take notes of your comments. Your opinions and comments are confidential and will be aggregated in the analysis. Your personal information will not be included in any reports. This focus group is expected to last about one hour. Are there any questions before we start?

DEFINITION & DISCOVERY:

Prompt: The purpose of this focus group is to understand when and why you prescribe certain drugs. ***(10 minutes)***

1. What is your understanding of FDA standards a generic drug is required to meet before it can get approved by the FDA? (probe for bioequivalence)
2. How do you receive information about generic drugs? For example, information about the differences between generic and non-generic drugs?
    i. Probe: journals, senior colleagues, pharmaceutical industry, marketing, FDA, institutions
    ii. Which of the ones you list have influenced you the most? Why?
3. What has your experience been with substituting generic for branded drugs? Be specific.
    i. In your practice, do you dispense as written? Do you review the formulary that you can check off or auto-populates with generic options?

Prompt: We are interested in discussing your prescribing practice for ***oral contraceptives. (20 minutes)***

4. What factors influence your prescribing strategy for **oral contraceptives**?
    a. Probe: IT workflows, institutions, insurance, mobile apps, social media, patient preferences, cost, efficacy profile, side effect profile, marketing, awareness & availability of generics, dispense as written, review the formulary
    b. *(Time permitting) How does this compare to how you prescribe* ***cholesterol-lowering agents****?*
5. How do you select from the number of **oral contraceptive** options available to you?
    a. *(Time permitting) How does this compare to how you prescribe* ***cholesterol-lowering agents****?*
6. Have you ever considered substituting a generic **oral contraceptive** for a patient but decided to prescribe the brand OCP instead? If so, what kinds of influenced you to prescribe the brand drug?
    a. Probe: Cost, patient's drug benefit design, therapeutic efficacy, side effects, dosing differences, patient preference, availability of samples, word of mouth/colleague perceptions,
    b. *(Time permitting) How does this compare to how you would prescribe* ***cholesterol-lowering agents****?*
7. What barriers exist for providers prescribing generic **oral contraceptives**?
    a. *(Time permitting) How do these barriers compare to barriers for* ***cholesterol-lowering agents****?*

DREAM & DESIGN (30 minutes):

Prompt: "Despite potential benefits to patients, payers and the healthcare system, providers have been slow to adopt the use of generic ***oral contraceptives****."*

1. How do you think the prescribing rates of generic **oral contraceptives** can be improved?
    a. Probe: On a(n)… IT, individual, patient, institutional, pharmacy, policy level, payer… level*
2. What solutions would make it easier for you to personally prescribe more generic **oral contraceptive** alternatives?
    a. Probe: IT systems, payer, samples, patient education
    b. *(Time permitting) Would your answers change if the aim was to improve generic prescribing of* ***cholesterol-lowering agents****?*
3. What messages do you think would help motivate your peers to increase the rate of generic **oral contraceptive** prescribing?
    a. What do you find compelling/influential about advertising/marketing for brand drugs that could be replicated for generic **oral contraceptives**?
    b. Who should deliver messages to promote generic prescribing?
        i. Prompt: FDA, colleagues, professional societies, institutions, pharmaceutical companies
    c. What method of communication is the best way to get this information to you?
    b. Probe: journals, professional societies, FDA, social media, phone alerts, decision-support
4. What information could FDA specifically provide to improve your perception of generic **oral contraceptives**?
    i. (Time permitting) Would your answers change if the aim was to improve generic prescribing of ***cholesterol-lowering agents****?*
5. Thinking back to our discussion, is there anything else that you would like to comment on now?

Thank you again for your participation. Your input is invaluable.

Figure 1.

Focus group script used by moderators to assess clinician knowledge about generic drugs, identify barriers to prescribing generic OCPs, and develop solutions to increase generic prescribing.

Table 1.

Characteristics of focus group participants

Physicians	
Participants, n	13
Age, mean ± SD	50.0 ± 7.6
Sex, n (%)	
Female	8 (62)
Male	5 (38)
Race, n (%)	
African American	2 (15)
White	8 (62)
Hispanic	1 (8)
Other	2 (15)
Geographic region, n	
Northeast	1
Midwest	3
South	7
West	1
Unknown	1
NPs	
Participants, n	12
Sex, n (%)	
Female	11 (92)
Male	1 (8)
Race, n (%)	
African American	2 (17)
White	10 (83)
Geographic region, n	
Northeast	4
South	5
West	1
Other	1
Unknown	1

Note: NP = nurse practitioner.

Table 2.

Health and workflow factors that affect generic prescribing

Health System Factors (Theme 1)		
Subthemes	**Examples of Barrier Code (*n* = PCP, NP)**	**Examples of Facilitator Code (*n* = PCP, NP)**
State generic substitution law (1a)		"Texas Law has it printed on the prescriptions, it's generic unless you specify otherwise" "I write a lot of birth control and I know it's going to be substituted" (5, 4)
Availability of samples (1b)	"And does the sample influence your prescribing strategy? Of course it does" (7,3)	"Our office doesn't allow samples" (0, 2)
Insurance companies (1c)		"they have teams of people that are culling the environment for ways to make things cheaper" (6, 4)
Availability of generics (1d)	"it was a generic medication that became branded and it's not available as a generic" "there's many times where…there's only brand names" (3, 4)	
Workflow Factors (Theme 2)		
Subthemes	**Examples of Barrier Code (*n* = PCP, NP)**	**Examples of Facilitator Code (*n* = PCP, NP)**
Disruption of daily practice (2a)	"We have to go on knowledge base and no generics because it's coming back as rejected" (0, 4)	"That's a disruption to my daily practice so it makes it easier to default to the generic" "I'm not going to tie up my staff's time just to get…a brand name for you" (9, 0)
Default to generic (2b)		"My EHR defaults to generic and if I want to do brand name there's a separate button I need to click" "I just assume they get generic unless there is some reason" (10, 5)
Pharmacy (2c)	"if you write the brand name many of the pharmacies don't take the opportunity to do that [substitute generic]" "I'll still get calls from pharmacy about can we substitute this" (1, 2)	"I often write brand names and the pharmacist would change it [at] her discretion to generics" "I just click generic can be substituted and I make the pharmacy figure out what's correct" (7, 9)
Insurance (2d)	"in recent times the insurance is not covering a lot of medications now, especially the generic drugs" (2, 7)	"What insurance will cover" "Many times…you prescribe the brand and then you get feedback saying…try generics" (8, 9)
Formulary (2e)	"When they get to their third refill, they're [patients] getting something different…Oh no, the box changed. Who's the manufacturer?" (1, 2)	"we had such a limited formulary…I only had maybe one or two medications to pick from so it was pretty easy" (4, 5)
Generic naming (2f)	"you're going to have to be savvy enough to be able to ask for that drug based on the generic drug equivalents" "they keep changing, have different names" "I use brand names because it's easier to write or remember to spell" (9, 4)	
Point-of-care IT tools (2g)	"And when you order EHR, when you click on a birth control pill, it probably drops down a hundred different names. You're like, whoa" (0, 1)	"My EHR…if you type in a brand name it gives you a drop down so you can tell if there's a generic" "When you prescribe a brand name it [EHR] will come up with the preferred generic alternatives" (7, 7)

Health System Factors (Theme 1)		
Subthemes	**Examples of Barrier Code (*n* = PCP, NP)**	**Examples of Facilitator Code (*n* = PCP, NP)**
Multiple generic brands (2h)	“when you have ten different brands of the same two ingredients of a birth control…it causes confusion” (6, 10)	

Note: EHR = electronic health record; NP = nurse practitioner; PCP = primary care physician.

Table 3.

Clinician and patient factors that affect generic prescribing

Clinician Factors (Theme 3)		
Subthemes	**Examples of Barrier Code (*n* = PCP, NP)**	**Examples of Facilitator Code (*n* = PCP, NP)**
Attitude toward generics (3a)	"So, there's some concern probably on their part that it's not as equivalent to the brand" "it's not going to be equivalent but it'll be similar" (9, 3)	"it is fairly rare that most physicians…do a brand name drug…when there's an equivalent way to do it generically" "It [generics] work as well as the brand" (5, 2)
Lack of trusted sources (3b)	"The perception when you get information from insurance company, it's not acceptable" "I don't think the pharmaceutical companies would be considered a trusted source" (6, 3)	
Reluctance to switch patient medication (3c)	"unless we can have a good argument about why a generic alternative is equivalent they want to continue drug X" "[once] somebody gets started on a brand name med…they're taking a leap of faith to switch it" (6, 3)	
Level of knowledge about generics (3d)	"my understanding is that there's no additional testing that's needed before a generic can be put out" "I thought there was no specific done for these drugs [generics]" (6, 5)	"Isn't it something like 78 percent effective—there's a percent that it has to be pure" "I was educated about the generic when I learned about Crestor" (8, 4)
Accessibility of information about generics (3e)	"If we knew our [generic] options then it's easy to do the prescribing" "But, whenever I prescribe generic there's no supportive data." (6, 7)	"it's like I've never heard of this, let me go look it up. So I look them up before I even go see the patient" (1,1)
Specialists (3g)	"I think to depend on the gynecologist opinion what they had before if I refill it for them to any shade it—I hear it is more toward whoever involve in women care more" (5,1)	"I learn sometimes from the specialist that I refer to." (2, 0)
Prior experience (3h)	"One of the major factors for me is what's been tried before" (3, 5)	
Patient Factors (Theme 4)		
Subthemes	**Examples of Barrier Code (*n* = PCP, NP)**	**Examples of Facilitator Code (*n* = PCP, NP)**
Cost (4a)	"don't rely on them [generics] as such a lower cost alternative" "Celebrex went generic…patients are still coming in saying it's going to cost me $200" (3, 4)	"I think it's patient complaints about cost" "she readily went back to a generic when she realized how expensive it was" (12,14)
Preference (4b)	"I would only go with brand if the patient requested" "Patient they still wanted the brand because their conception [is] that brand is better" (12, 5)	"my patients who want the generic drugs" (1, 2)
Side effects (4c)	"if the patient is allergic to the color…that may be a valid point" "if that patient comes back in with muscle aches or any intolerance then I go to Crestor" (6, 7)	"Now, they come in because they've seen the ads that it's higher risk of blood clot if they were on Yaz so, they want to switch to something else." (1, 0)
DTC advertising (4d)	"they want the drug because they've seen the commercial" "I think that this direct to consumer marketing is detrimental" (3, 5)	
Pill and package (4e)	"all of a sudden today it's blue, she's not comfortable taking that" "you write Ortho novum 777, they get a bottle that comes back that says Tri-Nessa…it confuses the patient" (2, 1)	

Note: NP = nurse practitioner; DTC = direct to consumer.

Table 4.

Potential solutions to increase generic prescribing

Themes	Subthemes	Examples of Solution Codes (*n* = PCP, NP)
Health system factors (theme 1)	Mandatory generic substitution (4, 0) (1f)	"Make it be—I'm going to use the word mandate but, the fact of the matter is, I think a lot of times from the physician standpoint, when you're thinking about a lot of drugs, the brand name that you've known the drug by is so easier"
	Limit samples (2, 2) (1g)	"There's so much data that patients who gets samples end up spending more money for their meds which is why I don't have any samples in my office"
	Limit formulary (1, 2) (1h)	"So I think if we limited the formulary and there was some kind of way of figuring out what things were, it wouldn't be such a barrier"
	Consistent use of guidelines (0,1) (1j)	"Make it a lot easier if they'd follow guidelines"
	Educate specialists (1, 0) (1k)	"targeting the specialists, I don't know that this is so relevant for contraception but, for other drugs for sure, the specialists are frequently the ones starting brand"
Workflow factors (theme 2)	Simplify generic naming (8, 0) (2j)	"Find a way to simplify the nomenclature so it's real clear what's in it." "Parallel naming so that you can tell this is second generation, this is third generation"
	Point-of-care IT tools (2, 10) (2k)	"One of the things I think would be helpful to insure more generic prescriptions is, when a patient is loaded in to my EMR, automatically a certain formulary is loaded"
	Reduce disruption of daily practice (1, 2) (2m)	"Don't let me type it in and then send it back to me two hours later saying this needs a prior authorization or this isn't covered under the plan…by two hours the patient's gone and I've moved on to the next crisis of the morning"
Clinician factors (theme 3)	More info about generics (19, 13) (3j)	"It would probably help to have the prescribing information available" "if the FDA would assure me that the generic is equivalent then yes, that would prompt me to prescribe more generics"
	Practice review (2, 1) (3k)	"they'll come with lists of our patients who are on name brands and they will have reviewed the patient's chart and they will have said…why aren't you using this or this?" "insurance companies are sending you little reminders for you to decide on which medication is better for your patient"
Patient factors (theme 4)	Advertise generics (14, 4) (4g)	"I think patients are becoming so savvy about health costs that more like a public service announcement type thing" "Public service announcements within physician offices while they're in the waiting room I think would be really effective"
	Limit DTC (3, 1) (4h)	"Banning direct advertising" "direct to consumer marketing is problematic. I think it's unethical actually."
	Reduce cost (3, 1) (4j)	"Cheaper than the brand names"

Note: DTC = direct to consumer; EMR = electronic medical record; NP = nurse practitioner; PCP = primary care physician.