Community Pharmacists’ Attitudes Toward an Expanded Class of Nonprescription Drugs

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• Target Audience: [FOR APHA USE ONLY]

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• Activity Type: [FOR APHA USE ONLY]
Learning Objectives

• Describe circumstances which led to the proposal of the FDA’s new paradigm.

• Define an expanded nonprescription drug class under the new paradigm.

• Describe proposed dispensing requirements of nonprescription drugs under the new paradigm.

• List therapeutic classes that have been proposed for dispensing under the new paradigm.

• Identify the key factors which comprise community pharmacists’ attitudes toward an expanded definition of nonprescription drugs under the new paradigm.
Self-Assessment Question

Drugs that treat which of the following conditions are considered prospective candidates for the FDA’s proposed *new paradigm*?

a. Hypertension  
b. Allergies  
c. Asthma  
d. Obesity  
e. All of the above
The cost and time associated with a physician visit is one of the common barriers associated with access to medications for patients.

This has historically prompted the debate about creating a third class of drugs, “behind-the-counter”, or “BTC” class of drugs.

BTC drugs are those that do not require a prescription, but require a pharmacist’s consultation upon purchase.

Currently a de-facto BTC drug class exists in the United States to which drugs are added to this class on a case-by-case basis.
Background

• FDA March 2012 hearing entitled – “Using Innovative Technologies and Other Conditions of Safe Use to Expand Which Drug Products Can Be Considered Nonprescription.”

• The third class was re-positioned not as a BTC class “but rather as a new paradigm”.

• The FDA would approve certain prescription drugs for nonprescription use but only under certain conditions of safe use.
Background

• Pharmacists would recommend the appropriate drug based on the patient’s medical records and inform the patient about conditions for safe use of the drug.

• Alternatively, the FDA would recommend the use of innovative technologies such as computer algorithm-assisted kiosks and online questionnaires which would enable a patient to self-diagnose appropriately.
Background

- Drugs for ailments that are easily diagnosable and whose lab tests can easily be interpreted by pharmacists would be potential candidates for an expanded nonprescription drug class under the *new paradigm*.

- *New paradigm* drugs would have a manageable side effect profile (good benefit-to-risk ratio) and no risk of microbial resistance.

- Prospective candidates include medications for treating hypertension, hyperlipidemia, asthma, gastrointestinal reflux, allergies, pain, migraine, and obesity.
Study Significance

• Arguably, the community pharmacist is one of the most significant stakeholders in expanding the definition of nonprescription drugs.

• In response to the FDAs need for feedback on the new paradigm, this study measured community pharmacists’ attitudes toward the expansion of the definition of nonprescription drugs in the United States.
Study Objectives

1. Measure community pharmacists’ attitudes toward an expanded nonprescription drug class under the FDA’s proposed new paradigm.

2. Determine if community pharmacists’ attitudes toward the new paradigm differ by type of practice setting, location of community pharmacy, region where the practice is located, highest pharmacy degree earned, years of actively practicing pharmacy, position in the pharmacy, pharmacy association affiliation, and perceived workload.
Methods

• **Design**: A cross-sectional, non-experimental, descriptive design.

• **Target Population**: Community pharmacists in the United States.

• **Data Collection**: The study was conducted by means of a self-administered, web-based survey.

• **Sample**: A national convenience sample of community pharmacists in the United States.

• **Sample source**: A national panel of community pharmacists was provided gratis by Delta Marketing Dynamics (DMD).
Measures

Objective 1

• A 7-point linear, numeric agreement scale was used for measuring community pharmacists’ attitudes.

• The scale items were developed based on in-depth cognitive interviews, scales in the existing literature and transcripts from the FDA hearing.
Measures

Objective 2

Data were self-reported for eight demographic and practice characteristic variables:

1. Type of practice setting
2. Location of community pharmacy (rural or urban)
3. Region of the country where the practice is located
4. Highest pharmacy degree earned
5. Years of actively practicing pharmacy
6. Position in the pharmacy (staff, manager, owner)
7. Pharmacy association affiliation
8. Perceived workload
Data Collection

• The University of Mississippi’s Institutional Review Board (IRB) exempted this study from review.
• Qualtrics, a web-based survey design tool, was used for designing and distributing the survey.
• Survey was pre-tested among community pharmacists registered in Mississippi.
Analyses

• Sample description and descriptive statistics
  – Frequencies, means and percentages for the demographic variables and practice characteristics.

• Objective 1: Principal Component Analysis (PCA) with VARIMAX rotation
  – Scale reliabilities were assessed using Cronbach’s alpha.

• Objective 2: Multivariate Analysis of Variance (MANOVA)
  – The demographic/practice variables of interest were the independent variables and the components of attitudes identified using PCA were the dependent variables.
Sample Description

Demographics

• Average age: 49 years
• Gender: Males (61.4%), Females (38.6%)
• Race: Predominantly Caucasian (87.2%)
• Highest pharmacy degree: BSPharm (66%), PharmD (28%)
• Affiliation to a professional pharmacy organization: Members (65%), Non-members (35%)
Sample Description

Practice Characteristics

• Pharmacy type: Predominantly independent (38%)
• Position in the pharmacy: Staff pharmacists (29%), Managers (54.3%), Owners (15.8%)
• Location of pharmacy: Urban (58%), Rural (42%)
• Region of the country: Predominantly South (34%)
• Average hours of practice per week: 41 hours
• Average years of practice experience: 23.5 years
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<th>Overall Mean</th>
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<td>Component 6: Access</td>
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<td>0.472</td>
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Results for Objective 1

- Respondents generally agreed with attitudinal statements regarding the *new paradigm* (per-item mean: 5.45 ± 0.86).

- Respondents were generally positive about the provision of patient care under the proposed new paradigm and indicated there should be patient safety mechanisms in place.

- Respondents indicated significant workflow changes would have to be made to pharmacies, felt their own liability and workload would increase, and indicated they should be reimbursed for these services.

- Respondents were ambivalent about the effect of the *new paradigm* on patients’ access to medications and how the workload of other health providers would be affected.
Results for Objective 2

• Pharmacists working in independent pharmacies were more positive about the provision of patient care (means: 5.32 versus 5.05) and pharmacists working in chain pharmacies were more sensitive to workflow changes that would be required (means: 5.39 versus 4.96).

• Pharmacists affiliated with a professional organization were more positive about the provision of patient care (means: 5.32 versus 4.90) and pharmacists not affiliated with a professional organization were more sensitive to workflow changes that would be required (means: 5.35 versus 5.09).
Results for Objective 2

- Pharmacists from western states were more positive about the provision of patient care (means: 5.38 versus 4.90) than pharmacists from northeastern states.

- Pharmacy owners (mean: 5.48) and managers (mean: 5.23) were more positive about the provision of patient care as compared to staff pharmacists (mean: 4.91). Staff pharmacists (mean: 5.39) and pharmacy managers (mean: 5.22) were more sensitive than pharmacy owners to workflow changes that would be required (mean: 4.76).
Results for Objective 2

- Pharmacists with a PharmD were more positive about the provision of patient care (means: 5.41 versus 5.07) and more optimistic about the reduction in workload for non-pharmacist providers (means: 4.84 versus 4.32) as compared to those with a B.S. in Pharmacy.

- The greater the number of years that respondents practiced pharmacy, the more skeptical they were about the reduction in workload for non-pharmacist providers ($r = -0.139, p = 0.004$) and increasing patient access to medications ($r = -0.104, p = 0.029$).
Results for Objective 2

- The greater the respondents’ perceived workload, the more sensitive they were to workflow changes that would be required (r = 0.255, p < 0.0005).
Discussion

Type of Pharmacy

• Independent and chain pharmacies are inherently different with respect to structure, workflow, number of prescriptions filled, and staff size.
  – This may explain why independent pharmacists were more receptive to the patient care factor of the new paradigm.
  – Chain pharmacists, on the other hand, may be more sensitive to the significant structural changes that would have to take place because they are framing this in the context of the entire chain for which they work, not just their own store.
Discussion

Affiliation with a Professional Pharmacy Organization

• Pharmacists who belong to a professional organization may be more progressive and more prepared for changes that expand their professional role and focus on patient-centered care.
  – This may explain why pharmacists affiliated with a professional organization may be more receptive to the patient care factor identified in this study.
  – Those affiliated with a professional organization may be less sensitive to making changes in their current workflow settings if they already have a progressive mindset.
Discussion

Region of Practice

• Pharmacists from western states were more positive about the provision of patient care than pharmacists in northeastern states.

  – Comments from a respondent practicing in Washington State suggested that about 25 community pharmacists from Washington and California were interested in implementing and experimenting with a system similar to the new paradigm as part of a collaborative practice model.
Discussion

Position in the Pharmacy

• It might be expected that pharmacy owners and managers have more practice experience, or are more entrepreneurial in nature, and therefore they may be more positive about the provision of patient care under the new paradigm.

• Staff pharmacists and managers may have been more sensitive to workflow changes as a result of their experience largely being in the chain setting, whereas pharmacy owners most often came from the independent setting, therefore perceiving workflow changes as less daunting.
Discussion

Highest Pharmacy Degree

• Pharmacists with a PharmD (Doctor of Pharmacy) may view the provision of patient care under the new paradigm more positively than those without a PharmD, due to additional training on patient-centered care.

• Also, due to their training, PharmDs may be more familiar with the role of other healthcare professionals and therefore more acutely recognize the potential effect of the new paradigm on these other healthcare professionals.
  – This may explain why they were more optimistic about the reduction in workload for non-pharmacist providers.
Discussion

Years of Actively Practicing Pharmacy

• The greater the number of years that respondents practiced pharmacy, the more skeptical they were about the reduction in workload for non-pharmacist providers and increasing patient access to medications.
  – Those pharmacists who were educated more recently may be more optimistic about paradigm shifts in the community practice model.

Perceived Workload of the Pharmacist

• Respondents with greater perceived workload may understandably be more sensitive to taking on additional responsibilities that would further increase their workload.
Limitations

• There is potential for self-selection bias due to the use of a panel without offering an honorarium.
• Generalizability is limited due to the employment of a national convenience of community pharmacists.
• The cross-sectional nature of the study precludes implying any causal relationship among variables.
• The low scale reliability ($\alpha = 0.472$) obtained for the “access” factor should also be considered.
Key Points

• Community pharmacists’ attitudes toward the new paradigm are comprised of six factors including patient care, workflow, patient safety, impact on non-pharmacist providers, pharmacist burden, and access.

• Respondents were generally positive about the provision of patient care under the new paradigm but were skeptical about workflow change, professional liability, increased workload, and reimbursement issues.

• Respondent attitudes differed based on practice and demographic variables.
Self-Assessment Question

Drugs that treat which of the following conditions are considered prospective candidates for the FDA’s proposed *new paradigm*?

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b. Allergies
c. Asthma
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e. All of the above
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