

**“Diabetes & asthma medications for  
uninsured Latinos through  
pharmaceutical patient assistance  
programs: Is it worth the effort?”**

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## Presentation Learning Objectives

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- Apply the process of acquiring medications through patient assistance programs (PAPs) to individual patient situations
- Articulate common eligibility criteria and required documentation for PAPs
- Identify potential barriers to effective utilization of PAPs



# What is the problem?

## The Uninsured and Healthcare Coverage

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- Estimated 47.0 million (15.9%) uninsured in the U.S. (U.S. Census, 2006)
  - Nation's highest: Hispanics/Latinos = 32.7%
    - Asthma 80% higher in Puerto Ricans than other racial/ethnic minorities (NCHS, 2002)
    - Type II diabetes higher among Mexican- Americans & Puerto Ricans than non-Hispanic whites (NIDDK, 2005).
- Many uninsured patients cannot afford prescribed medications
  - Medication costs increasing since 1990, accounting for 11% of annual health care spending (KFF, 2004)



# Potential Short-term Solution?

## Pharmaceutical-sponsored Patient Assistance Programs (PAPs)

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- Voluntary, manufacturer-sponsored programs provide medications at reduced or no charge
- More than 75 manufacturers offer more than 800 medications (Montemayor, 2002)
- Individual application and eligibility requirements



# What do we know about PAPs?

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- Good programs (Kelley, 2002) versus too complex and labor intensive (Duke, Raube & Lipton, 2005)
- Cost-savings for individual patients (Havrda et al., 2005) and organizations (Coleman et al, 2003; Weiner, Dischler & Horvitz, 2001)
- Scant data on patient medication adherence and other health outcomes



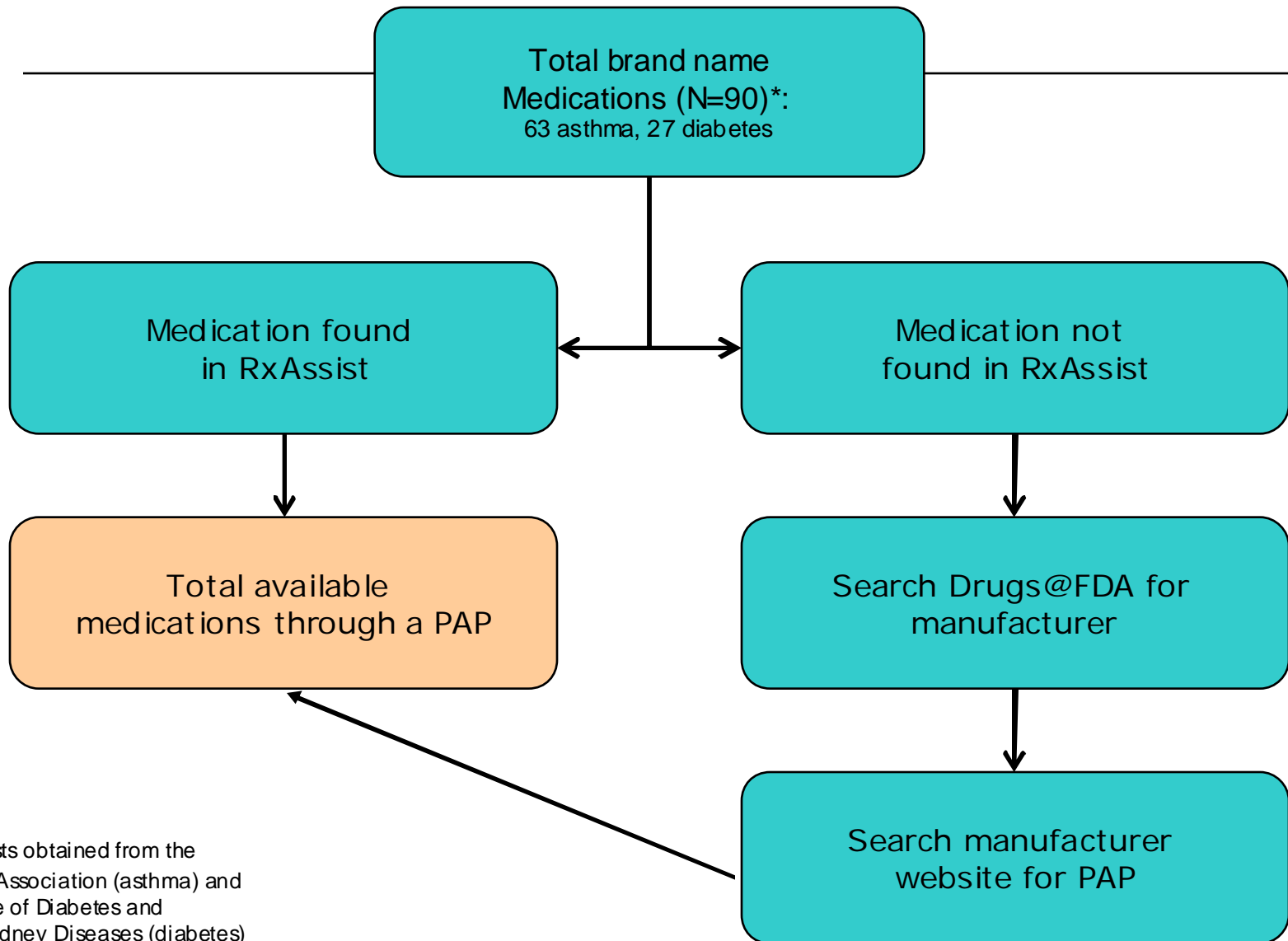
# Research Questions:

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- Availability: What medications prescribed for Type II diabetes and asthma are available through PAPs?
- Accessibility: Among the medications available through PAPs, which medications are accessible to an uninsured Latino patient, given a specific set of characteristics?
- Applicability: Among the medications accessible through PAPs, do any of them meet first-line pharmacologic treatment guidelines?

# Methods: Availability

Conducted March 2007



\* Brand name lists obtained from the American Lung Association (asthma) and National Institute of Diabetes and Digestive and Kidney Diseases (diabetes)



# Methods: Accessibility

## Hypothetical Latino Patient Profiles

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### **Profile 1: Mary**

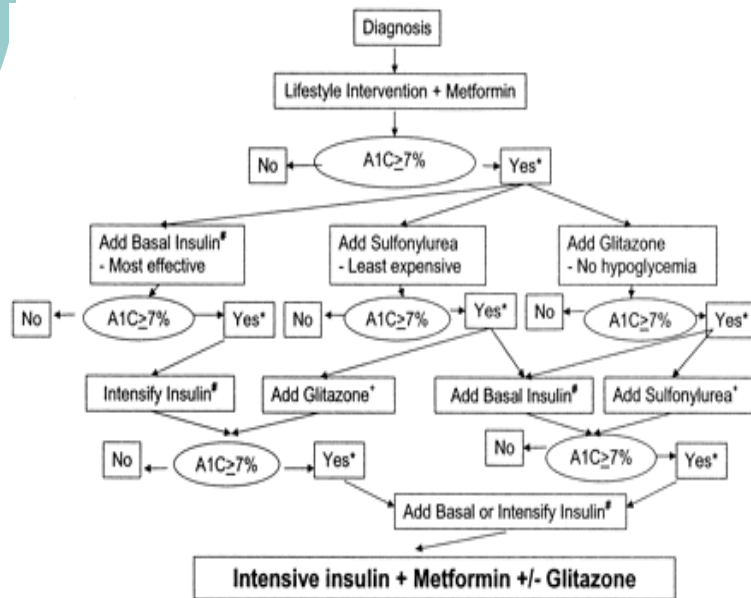
- No health insurance
- Annual income: \$40,000 (Family of 4)
- U.S. citizen
- Limited English language proficiency/Spanish preferred
- Recently diagnosed with Type II Diabetes during an Emergency Room visit

### **Profile 2: Daniel**

- No health insurance
- Annual income: \$25,000 (Single + 1 child)
- Proficient in English
- Not yet U.S. citizen
- Severe asthma most of adult life



# Methods: Applicability to Clinical Guidelines



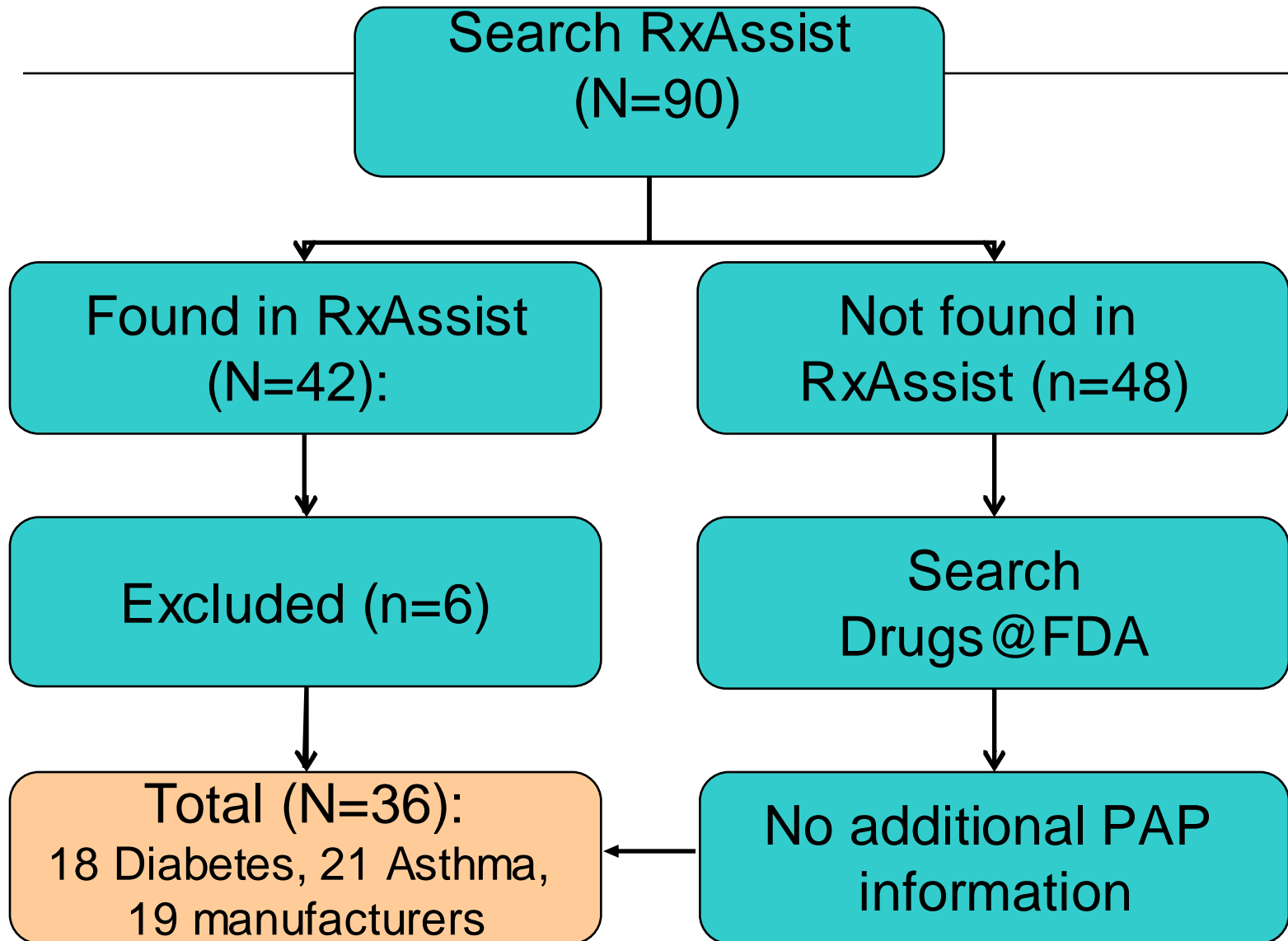
APPENDIX A-1. STEPWISE APPROACH FOR MANAGING ASTHMA (continued)  
 Figure 2. Stepwise Approach for Managing Asthma in Adults and Children Older Than 5 Years of Age: Treatment (Updates EPR-2 Figures 3-4a and 3-4b)

Classify Severity, Clinical Features Before Treatment or Asthma Control	PEF or FEV <sub>1</sub> Variability	Medications Required to Maintain Long-Term Control
Symptoms/Daily Symptoms/Night	PEF or FEV <sub>1</sub> Variability	Daily Medications
<b>Step 4</b> Severe Persistent	Controlled: $\leq 10\%$ Frequent: $>30\%$	<ul style="list-style-type: none"> <li>Preferred treatment:                             <ul style="list-style-type: none"> <li>High-dose inhaled corticosteroids AND</li> <li>Long-acting inhaled beta<sub>2</sub>-agonists</li> </ul> </li> <li>Alternative treatment (based on clinical judgment):                             <ul style="list-style-type: none"> <li>Combination of inhaled corticosteroids and long-acting beta<sub>2</sub>-agonists generally do not exceed 600 mcg per day. (Make repeat attempts to reduce systemic corticosteroids and maintain control with high-dose inhaled corticosteroids.)</li> </ul> </li> </ul>
<b>Step 3</b> Moderate Persistent	Daily: $\leq 1$ episode/week Night: $>30\%$	<ul style="list-style-type: none"> <li>Preferred treatment:                             <ul style="list-style-type: none"> <li>Low-to-medium-dose inhaled corticosteroids and long-acting inhaled beta<sub>2</sub>-agonists.</li> </ul> </li> <li>Alternative treatment (based on clinical judgment):                             <ul style="list-style-type: none"> <li>Increase inhaled corticosteroids within medium-dose range OR</li> <li>Low-to-medium-dose inhaled corticosteroids and either leukotriene modifier or theophylline.</li> </ul> </li> <li>It is critical to monitor patients with recurring severe exacerbations.                             <ul style="list-style-type: none"> <li>Preferred treatment:                                     <ul style="list-style-type: none"> <li>Increase inhaled corticosteroids within medium-dose range and add long-acting inhaled beta<sub>2</sub>-agonists.</li> </ul> </li> <li>Alternative treatment:                                     <ul style="list-style-type: none"> <li>Increase inhaled corticosteroids within medium-dose range and add either leukotriene modifier or theophylline.</li> </ul> </li> </ul> </li> </ul>
<b>Step 2</b> Mild Persistent	$>2$ weeks but $< 1$ a day $> 2$ nights/month	<ul style="list-style-type: none"> <li>Preferred treatment:                             <ul style="list-style-type: none"> <li>Low-dose inhaled corticosteroids.</li> </ul> </li> <li>Alternative treatment (based on clinical judgment):                             <ul style="list-style-type: none"> <li>Leukotriene modifier, montelukast, CR or extended-release theophylline to attain concentration of 5-15 mcg/mL.</li> </ul> </li> </ul>
<b>Step 1</b> Mild Intermittent	$\leq 2$ days/week $\leq 2$ nights/month	<ul style="list-style-type: none"> <li>No daily medications needed.</li> <li>Severe exacerbations may occur, separated by long periods of normal lung function and no symptoms. A course of systemic corticosteroids is recommended.</li> </ul>
<b>Quick Relief</b>		<ul style="list-style-type: none"> <li>Short-acting bronchodilator: 2-4 puffs short-acting inhaled beta<sub>2</sub>-agonists as needed for symptoms.</li> <li>Intensity of treatment will depend on severity of exacerbation, up to 3 treatments at 20-minute intervals.</li> </ul>

American Diabetes Association

National Asthma Education & Prevention Program (2002)/NHLBI

# Results: Which medications are available through PAPs?





# Results: PAP application & Eligibility

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<b>Application requirement</b>	<b>Most common (Frequency)</b>	<b>Of note:</b>
<b>Medications available (n=36)</b>		1)Pfizer (n=6) 2)GSK (n=4)
<b>Insurance status</b>	Minimum: No medication coverage (n=16)	Bristol-Meyers Squibb: uninsured only
<b>Income eligibility</b>	At or below 200% FPL (n=8)	Did not specify (n=8)
<b>U.S. citizenship</b>	Required (n=12)	Did not specify (n=5)

# Results: PAP application & Eligibility (cont)

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<b>Application requirement</b>	<b>Most common (Frequency)</b>	<b>Of note:</b>
<b>Required attachments</b>	IRS Tax form and/or prescription (n=12)	Required none (n=3)
<b>Required signatures</b>	Provider & Patient (n=16)	GSK: Include "Advocate"
<b>Application Languages</b>	English only (n=14)	English & Spanish (n=4)
<b>Delivery Location</b>	Provider (n=11)	GSK: Pharmacy + \$10 co-pay

## Results: PAP application & Eligibility (cont)

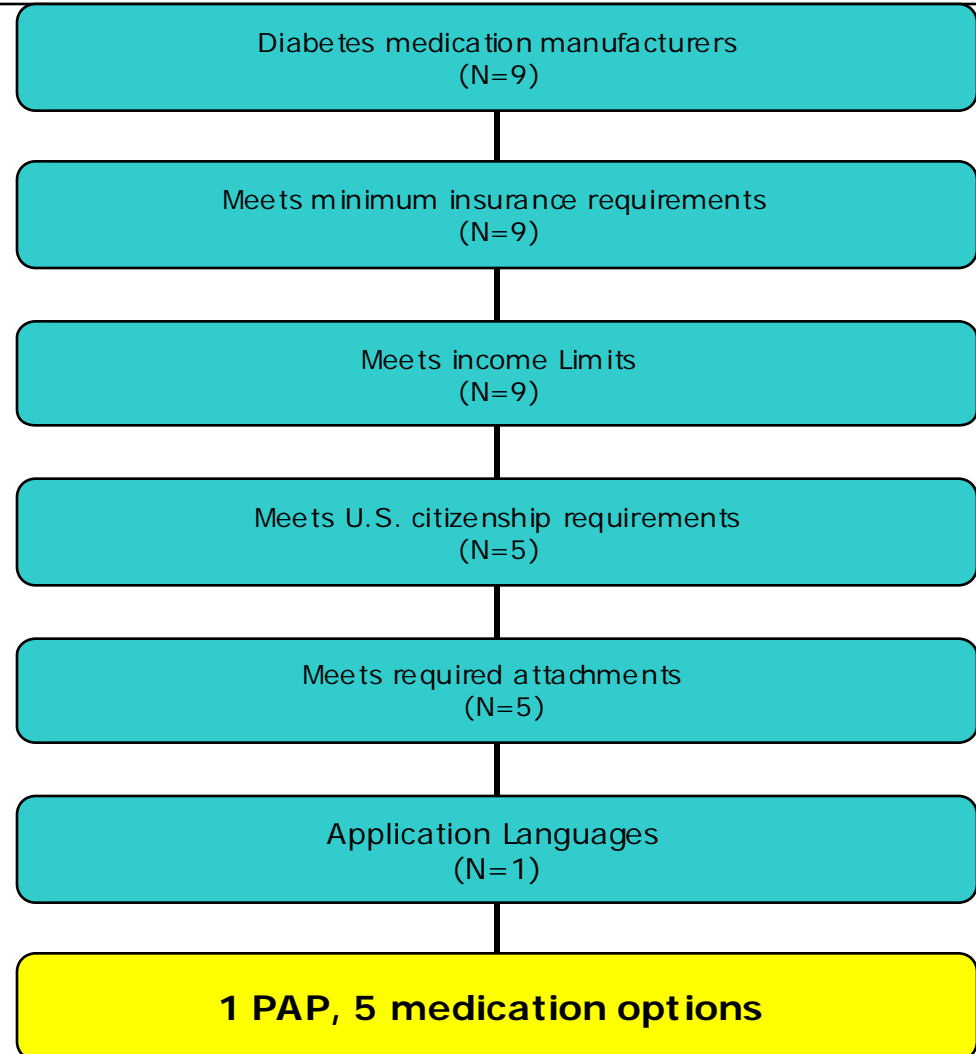
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<b>Application requirement</b>	<b>Most common (Frequency)</b>	<b>Of note:</b>
<b>Delivery Time</b>	0-2 weeks (n=9)	Ranged from 0-8 weeks
<b>Medication Supply</b>	90-day supply (n=14)	Ranged from 30-120 day supply
<b>Re-application</b>	Every 12 months (n=10)	Every time a refill is needed (n=5)

# Results: Which medications are accessible to Mary?

## **Profile:**

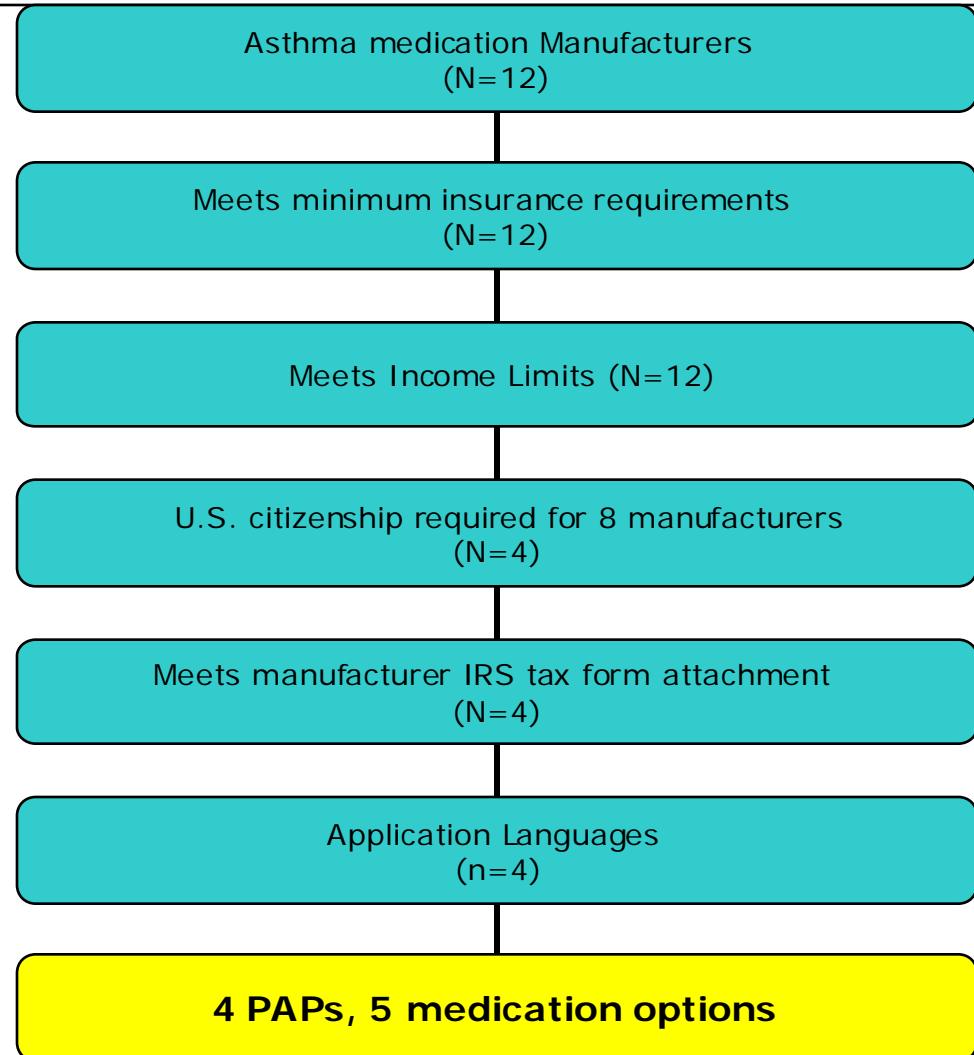
- No health insurance
- Annual income: \$40,000 (Family of 4)
- U.S. citizen
- Limited English language proficiency/Spanish preferred
- Recently diagnosed with Type II Diabetes



# Results: Which medications are accessible to Dan?

## ***Profile:***

- No health insurance
- Annual income: \$25,000 (Single + 1 child)
- Proficient in English
- Not yet U.S. citizen
- Severe asthma most of adult life





# Results: Application of Clinical Guidelines

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## ADA (Diabetes)

- 1<sup>st</sup> Line treatment: Lifestyle changes + metformin

## NAEEP (Asthma)

- 1<sup>st</sup> Line treatment for severe, adult asthma: high-dose inhaled corticosteroid + long-acting inhaled beta2-agonist 24

### Mary's options:

- Diabinese®
- Glucotrol®
- Glucotrol XL®
- Glyset®
- Micronase®

### Dan's options:

- Azmacort®
  - Aerobid®
  - Aerobid-M®
  - Xolair®
  - Medrol®
- } Inhaled corticosteroids

Accessible medications did not meet full clinical guidelines for either profile





# Study Conclusions

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- **Availability**: Found 40% of studied asthma and diabetes medications provided by PAPs
- **Accessibility**: Medication options were limited by general characteristics of uninsured
  - Barriers:
    - Language
    - Citizenship
    - Income
- **Applicability**: None met the clinical practice guidelines for first-line treatment
  - New Asthma Guidelines released September 2007



# Limitations

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- Small sample of medications
  - Listings from reputable organizations
- Hypothetical patients
  - Based on general characteristics of uninsured
- Guidelines versus practice
- Focused only on 2 disease states
- Focused only on brand-name medications
  - Social justice perspective
  - Generics available: RxOutreach, Xubex
  - Likely to change availability but not necessarily accessibility or applicability



# So, are PAPs worth the effort?

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- PAPs are viable, short-term option to meet medication needs in the absence of universal health care coverage in the U.S.
- Keep in mind:
  - PAPs are not a substitute for comprehensive health care
  - Many patients need assistance to apply to PAPs
- Start a voluntary program for to assist with PAP applications within your institution:
  - Register at <http://www.rxassist.org> to get information on how to set up a program!



# For more information:

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