

Patient Receipt and Understanding of Written Information Provided with Isotretinoin Prescriptions

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Background

- **Research study conducted in 2004-2005 to assess receipt and understanding of the isotretinoin Medication Guide and estrogen Mandatory Patient Package Insert**
 - Focus on the Medication Guide (MG) for today's presentation
- **Study funded by AHRQ* and FDA**
- **Partial results published**
 - *J Gen Intern Med* 2007;22:98-101

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Study Purpose

- **Assess the receipt of MG by patients receiving prescriptions isotretinoin**
 - all marketed products, at time of study
- **Assess how thoroughly patients read the material**
- **Conduct preliminary evaluation of patient understanding of key risks associated with isotretinoin (as described in the MG)**



Methods

- **Patient survey study**
 - Sample size of 200 isotretinoin patients was sought
 - Attempt to balance number of participants with different marketed brands
 - To attain this sample size, study was conducted from February 2004 through January 2005



Methods (continued)

- **Adult patients with isotretinoin prescriptions were identified using claims data from a pharmacy benefits manager**
 - Claims were reviewed every 2 weeks
 - Patients were only eligible once during the study period
 - Patients were contacted by telephone within 24 days of prescription fill/refill for participation

Patients gave informed consent for participation



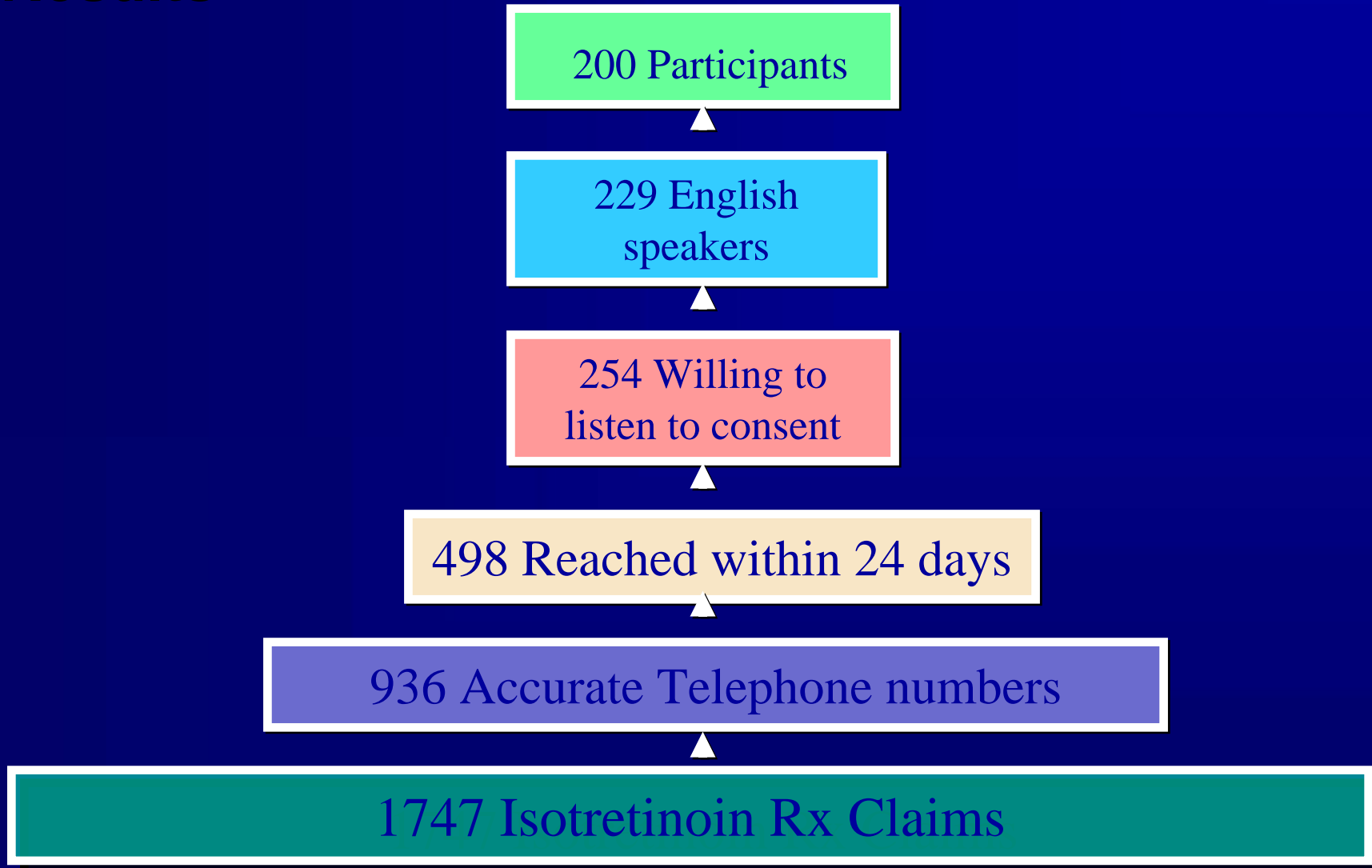
Methods (continued)

■ Survey

- Designed to assess receipt of MG with most recent prescription as well as with past prescriptions
- Tried to differentiate MG from all other written medication information through use of a detailed description of the MG
- Maximum of 11 questions for any patient
- Administered by trained interviewers



Results



Results: Participant Characteristics

	Participant (N=200)	Non-participant (N=1547)	P-value
Median Age (25 th , 75 th percentile)	30 (22, 40)	28 (23, 36)	0.09
Female, N (%)	138 (69)	1046 (68)	0.70
US Region			
NE	167 (84)	1386 (90)	0.01
SE	33 (17)	146 (9)	
Midwest	0	3 (<1)	
West	0	12 (<1)	
Time			
Q1 2004	43 (22)	385 (25)	<0.01
Q2 2004	60 (30)	363 (23)	
Q3 2004	22 (11)	335 (22)	
Q4 2004	66 (33)	346 (22)	
Q1 2005	9 (5)	118 (8)	



Results: Confidence and Receipt

- 172 (86%) were 'very confident' or 'confident' in their drug knowledge
- 186 (93%) stated that they received the MG with most recent Rx
 - MG is enclosed in drug packaging
 - Rx fill/refill is only one mechanism of receiving MG
- Difference in level of confidence among those who received vs. not received MG
 - 88% vs. 64% were 'very confident' or 'confident'



Results: Extent of Reading the MG with Recent Rx

	N (%)
Read completely	77 (41.4)
Read more than one section	30 (16.1)
Read one section	1 (0.5)
Skimmed	28 (15.1)
Didn't read at all	49 (26.3)
Don't remember	1 (0.5)



Results: Extent of Reading the MG (continued)

- **Of the 109 who didn't completely read the MG with the most recent Rx:**
 - 27 (25%) said they completely read it in the past
 - 33 (30%) said they didn't read it completely at any point in the past.
 - 49 (45%) had either never received the MG before or never received isotretinoin before.
- **Of the 49 who didn't read the MG at all with the most recent Rx, 10 (20%) didn't read it at all before and 19 (39%) either didn't receive the MG or isotretinoin before.**



Results: Patient Understanding of Key Risks

- “I am now going to read to you five different statements. Without looking at any of the medication information that you may have received with your ‘Accutane’ please tell me which of the following statements, if any, (is/are) true for ‘Accutane’...
 - Accutane may cause bleeding
 - Accutane may cause birth defects
 - Accutane may cause heart attacks
 - Accutane may cause mental problems or suicide
 - Accutane may cause abnormal heart rhythms”



What is the most important information I should know about Accutane?

- Accutane is used to treat a type of severe acne (nodular acne) that has not been helped by other treatments, including antibiotics.
- Because Accutane can cause birth defects, Accutane is only for patients who can understand and agree to carry out all of the instructions in the iPLEDGE program.
- Accutane may cause serious mental health problems.

1. **Birth defects** (deformed babies), loss of a baby before birth (miscarriage), death of the baby, and early (premature) births. Female patients who are pregnant or who plan to become pregnant must not take Accutane. Female patients must not get pregnant:

- for 1 month before starting Accutane
- while taking Accutane
- for 1 month after stopping Accutane.

If you get pregnant while taking Accutane, stop taking it right away and call your doctor. Doctors and patients should report all cases of pregnancy to:

- FDA MedWatch at 1-800-FDA-1088, and
- the iPLEDGE pregnancy registry at 1-800-495-0654

2. **Serious mental health problems.** Accutane may cause:

- depression
- psychosis (seeing or hearing things that are not real)
- **suicide.** Some patients taking Accutane have had thoughts about hurting themselves or putting an end to their own lives (suicidal thoughts). Some people tried to end their own lives. And some people have ended their own lives.



Results: Patient Understanding (continued)

	Response N (%)		
	Yes	No	Don't Know
Bleeding	81 (43.6)	75 (40.3)	30 (16.1)
Birth Defects	179 (96.2)	1 (0.5)	6 (3.2)
Heart Attack	38 (20.4)	102 (54.8)	46 (24.7)
Mental Problems	157 (84.4)	23 (12.4)	6 (3.2)
Abnormal Heart Rhythm	65 (35.0)	67 (36.0)	54 (29.0)

Of 115 women aged 18-45, 4 (3.5%) reported “no” or “don’t know” to the birth defects question



Results: Patient Understanding (continued)

- **Mean number of correct responses was 3.1 \pm 1.1 (out of 5)**
 - Only slightly better than the expected score from guessing ($p < 0.01$)
- **Propensity-weighted score model predicted:**
 - Increased score (by 0.6) in patients with high confidence level
 - Increased score (by 0.6) in patients who recently completely read the MG



Summary

	Excellent	Good	Fair	Poor
Receipt		✓		
Reading				✓
Understanding			✓	

We must find better ways to communicate risk to patients

