

## The PTRQoL System

Pharmaceutical Therapy Related Quality of Life: A  
system providing effective, efficient screening for  
side effects (ADEs/ADRs) in the community  
pharmacy population

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## Ongoing Growth in Rx Drug Use, Side Effects, & Non-Compliance

- Spending on prescription drugs has markedly increased from \$51 billion in 1993 to a projected \$453.7 billion by 2018
- Nearly 81 %percent of adults aged 57 to 85 use at least one prescription medication; 33% use 5 or more
- The increased use of drugs also means a rising number of adverse drug events (ADEs) and adverse drug reactions (ADRs)- what the public thinks of as “side effects”.
- as ADE/ADRs increase in severity, compliance to prescribed therapy suffers-
- and Non-compliance to medications costs the United States health care system an estimated **160 billion dollars a year**

## The “Side Effect Iceberg”

- Together, ADEs and ADRs are estimated to result in more than 100,000 deaths each year
- They are between the fourth and sixth leading cause of death in the United States
- They are estimated to account for nearly 10 percent of all hospital admissions.
- Serious and fatal ADEs reported to the Food and Drug Administration (FDA) more than doubled from 1998 to 2005
- And yet, ADE/ADRs are estimated to be underreported by as much as 94 percent.
- **Side effects are a big, mostly hidden problem.**

## Who Can Best Address “Side Effects”?

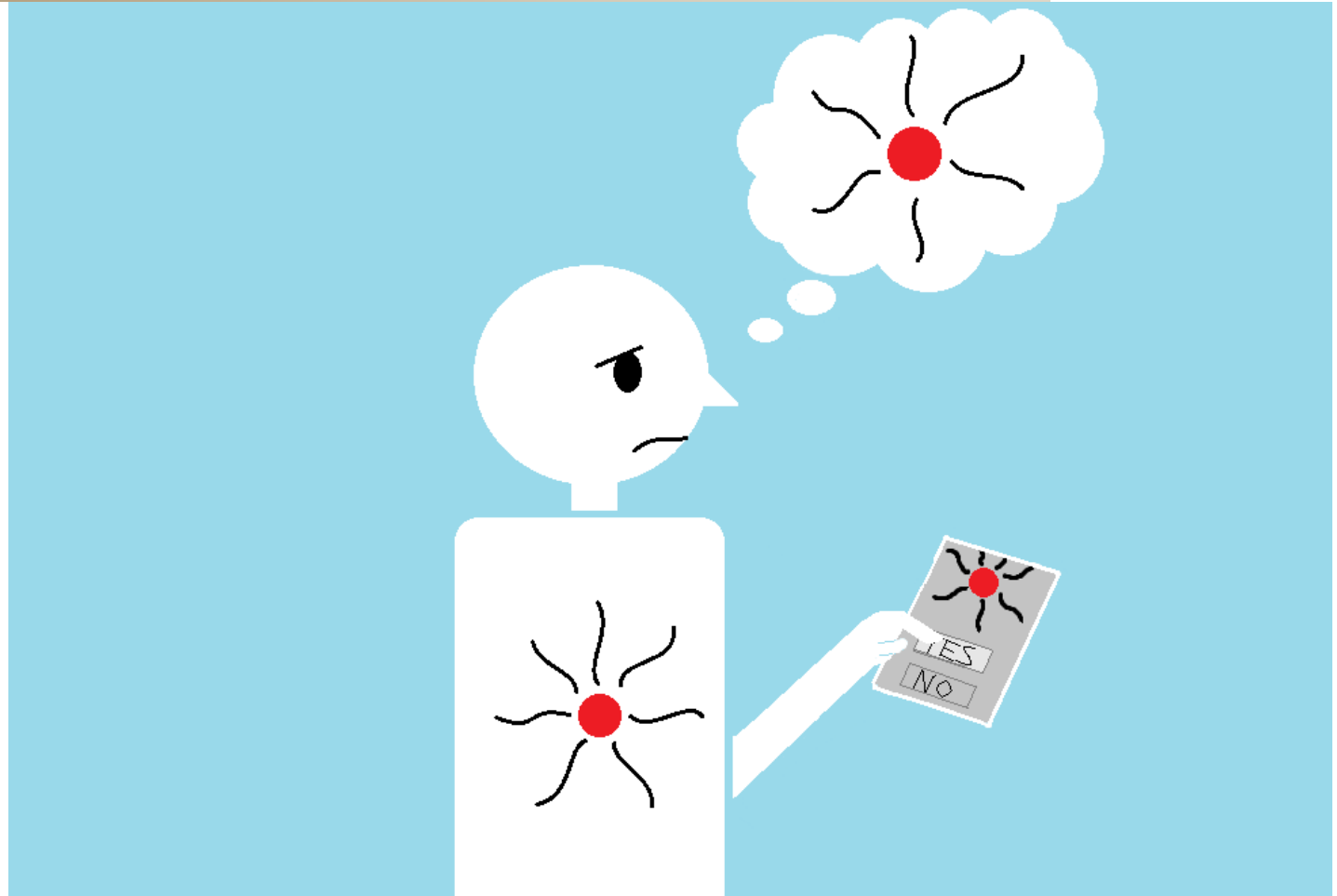
- Which health care players are positioned to impact ADE/ADRs? My MD asks “Any problems with your meds?”
- Ultimately, community pharmacists are best positioned & trained to assess the consequences of prescription drug therapy
- Previous research has demonstrated pharmacists’ ability to reduce ADE/ADRs
- A big issue is, “How do we discover which patients in community practice need assistance at a reasonable cost?”
- **PTRQoL** is a completely new discovery/approach, much more efficient than the current standard of practice (random pharmacist inquiry).

## PTRQoL's Purpose

- The PTRQoL system is designed to address the “Don’t Knows”
  - What the patients, pharmacist, administrators and third party payers don’t know, but need to
- Resolve the knowledge gap and patients feel better, pharmacists can do more, and costs can go down

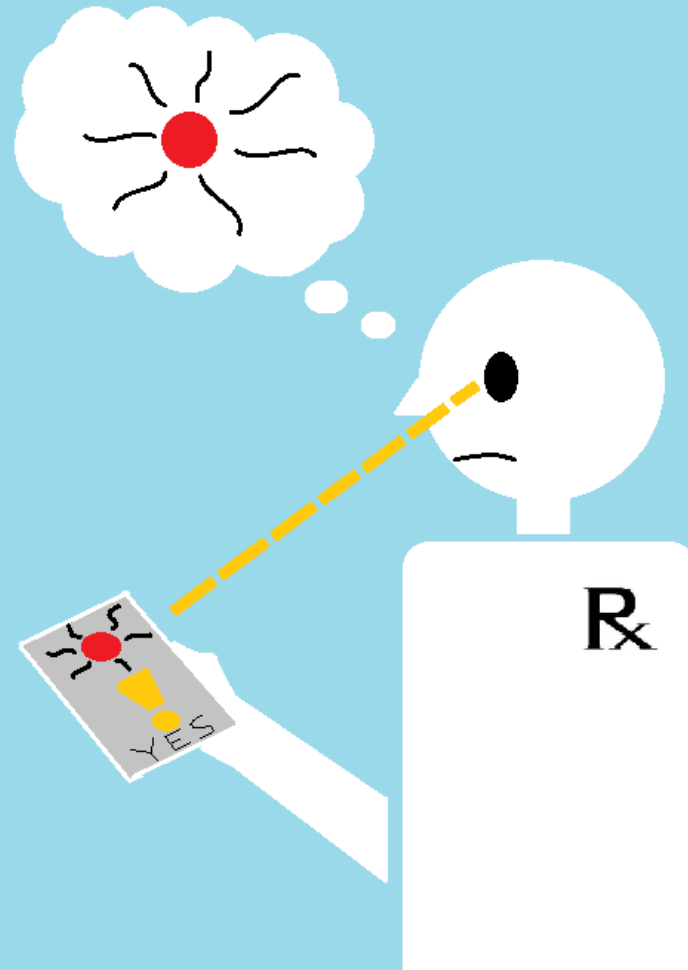
## “Don’t Knows” - Patient

I feel a little odd, but how do I know if this is a effect caused by my medication?  
Here’s a question that sounds a lot like what I feel.....



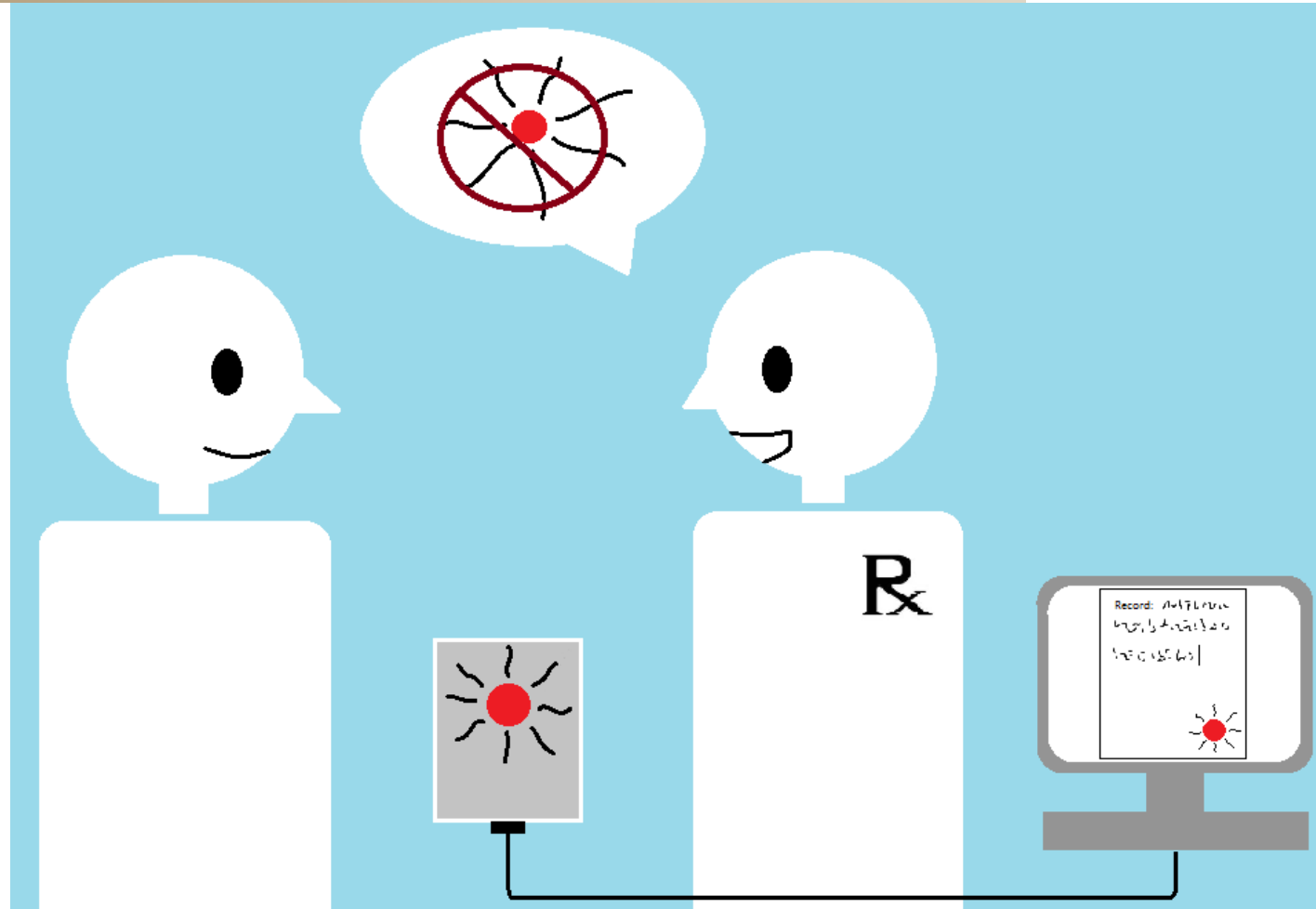
## “Don’t Knows” - Pharmacist

I know my patients experience side effects, but I have no idea which ones. This patient is showing signs of dyspepsia we see a lot with the drug they are on.



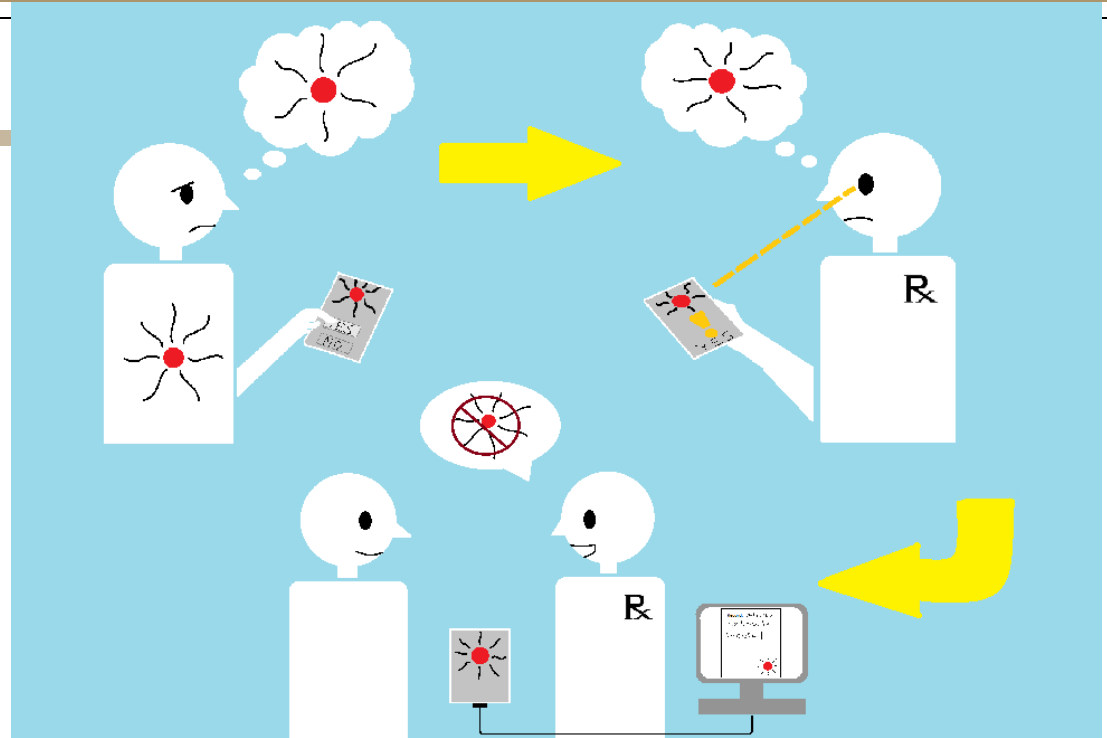
## “Don’t Knows” - Solution

Sound like this comes on after your single dose in the AM. Let me call your physician and suggest a lower dose more often....





## Overall Impact



- PTRQoL quickly, cheaply, and efficiently identifies those patients who are having problems with their medication consumption experience – so pharmacists can act to solve those problems- and documents the interaction.

# A Brief Demonstration

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# frequency

## select drug

Select the first letter of the prescribed drug:

A B C D E F G H I J K L M  
N O P Q R S T U V W X Y Z

Show all drugs

Tap the text to the right to select the drug ->

Tap to select drugs that begin with L

Levoxylin  
Lexapro  
lidocaine  
Lidoderm  
Lipitor  
Lisinopril  
Lisinopril and Hydrochlorothiazide  
Lopressor  
Lorazepam  
Lorcet

Settings

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Patent Pending

Patient Survey  
Lisinopril

Instructions: Tap yes or no to answer the questions below.

1. In the past 4 weeks, have you experienced a cough?

Yes ☒ No ☐

How often did you have this problem in the last 4 weeks? Tap to answer

When you have the issue, on average, how bad is it? Tap to answer

Only once or twice  
Almost every week  
Weekly  
More than once a week  
Daily

2. In the past 4 weeks, have you had a headache?

Yes ☐ No ☐

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## Pharmacist sees “Impact” via color-coded bars

iPad Home 2:00 PM 56%

Lisinopril - ACE-I

The patient answered yes to each of the questions listed below. Please indicate whether, in your professional judgement, the adverse reaction/adverse drug experience is associated with the patient's medication therapy.

1. In the past 4 weeks, have you experienced a cough?  
Frequency of the issue: Daily  
Severity of the issue: Almost intolerable

Do you feel the adverse reaction was due to this medication? Tap to answer

2. In the past 4 weeks, have you had a headache?  
Frequency of the issue: Only Once or Twice  
Severity of the issue: Not a real problem

Do you feel the adverse reaction was due to this medication? Tap to answer

3. In the past 4 weeks, have you had a feeling of being dizzy, disoriented, or “swimmy”?  
Frequency of the issue: More than once a week  
Severity of the issue: Rather bothersome

Do you feel the adverse reaction was due to this medication? Tap to answer

Save Results

## intensity

Patient Survey  
Lisinopril

Instructions: Tap yes or no to answer the questions below.

1. In the past 4 weeks, have you experienced a cough?

Yes ☒ No ☐

How often did you have this problem in the last 4 weeks? Daily

When you have the issue, on average, how bad is it? Tap to answer

Not a real problem  
Barely noticeable  
Mildly troublesome  
Rather bothersome  
Very bothersome  
Almost intolerable

2. In the past 4 weeks, have you had a headache?

Yes ☐ No ☐

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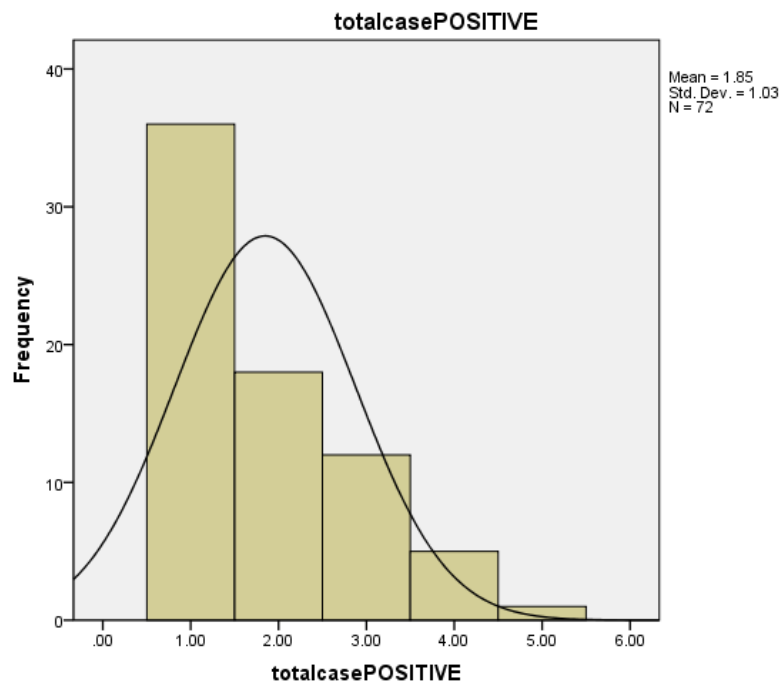
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## Preliminary Data-Paper & Pencil

- Proof of concept was explored using paper and pencil checklists
- Data from more than 2000 patient interactions:
  - 49% of patients have at least 1 ADR/ADE
  - Pharmacists report:
    - Learning more about patients
    - Solving real problems, in real time
    - Positive patient response to experience
- But process was slow and cumbersome, serious work flow issues
- So we automated the process

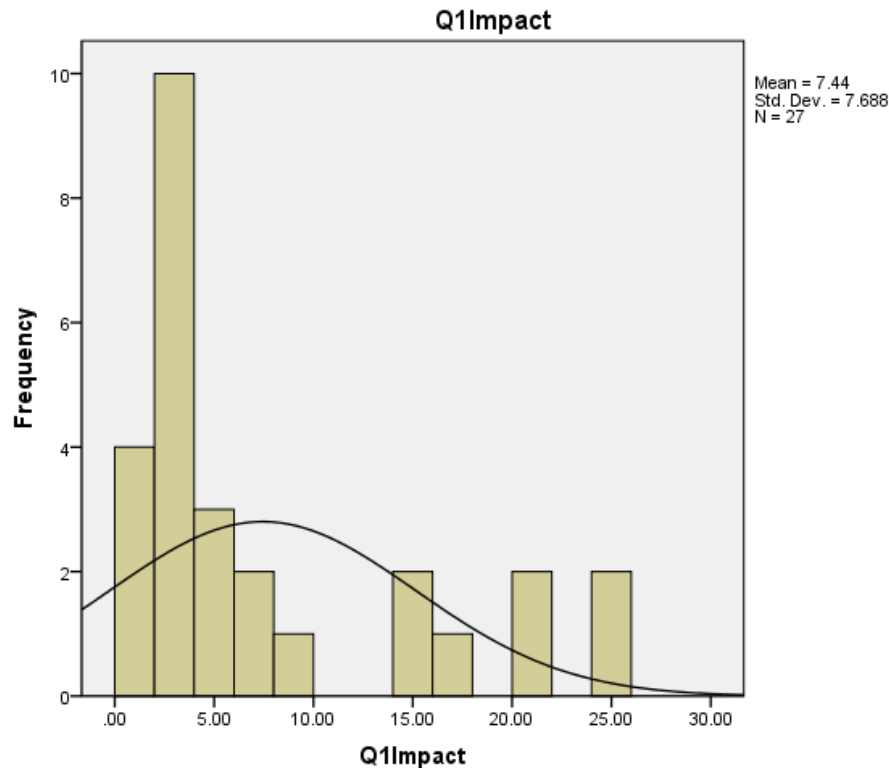
## Preliminary Data – I-Pad based System

- 9 sites online, 101 patients to date.
- 72% indicate at least ONE ADE/ADR-(36%=1, 18%=2, 12%=3, 5%=4, and 1%=5)



## Question One Impact

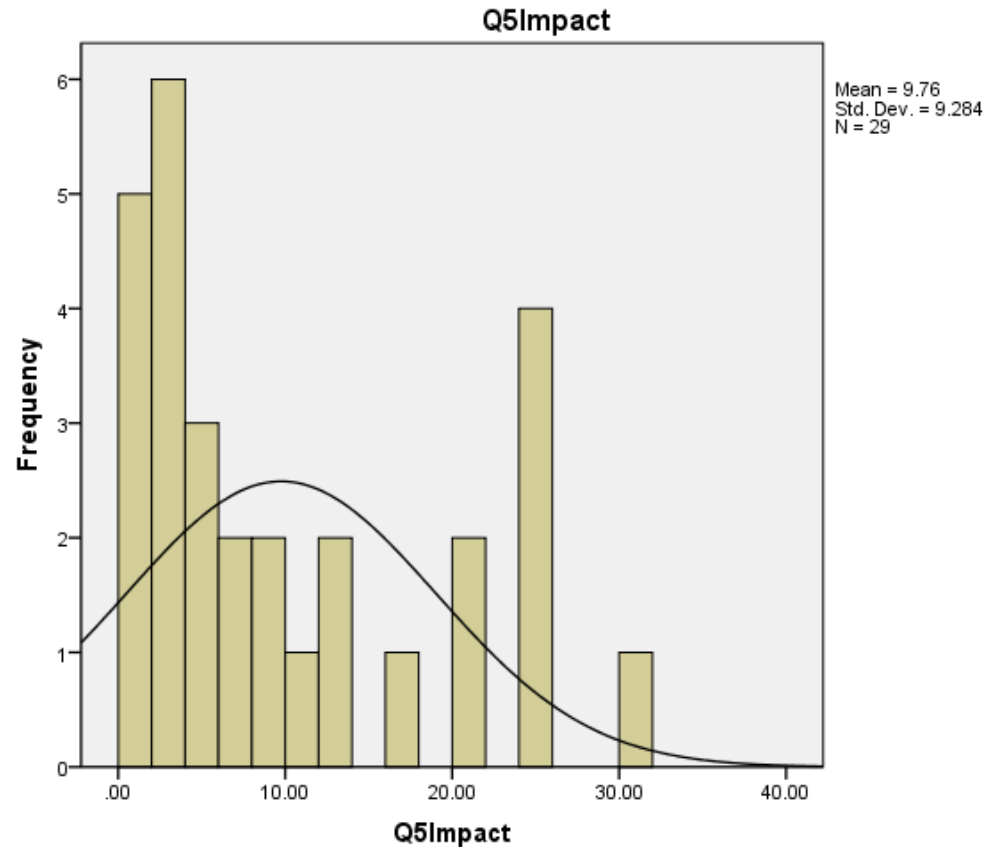
- Impact is product of frequency & intensity



Q1 is the single most common ADE/ADR for any drug. Note the mean impact across all drugs=7.44

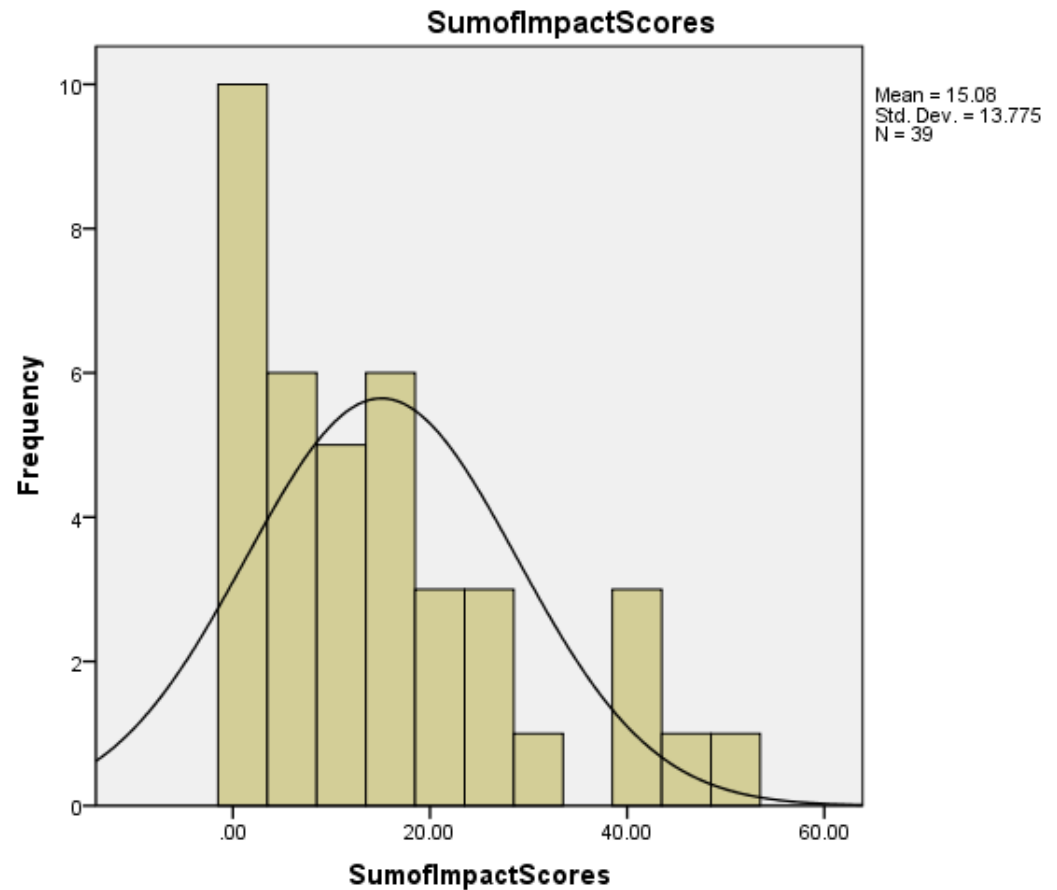
## Question Five Impact

But for Q5 across all drugs, while the incidence is less (as we would expect) the mean impact at 9.76 is actually larger. Less common ADE/ADRs may be more severe.



# TOTAL Case Impact Score

And, as we can see here, the sum of total impact scores across patients (all reported ADE/ADRS for each) is sometimes a considerable burden



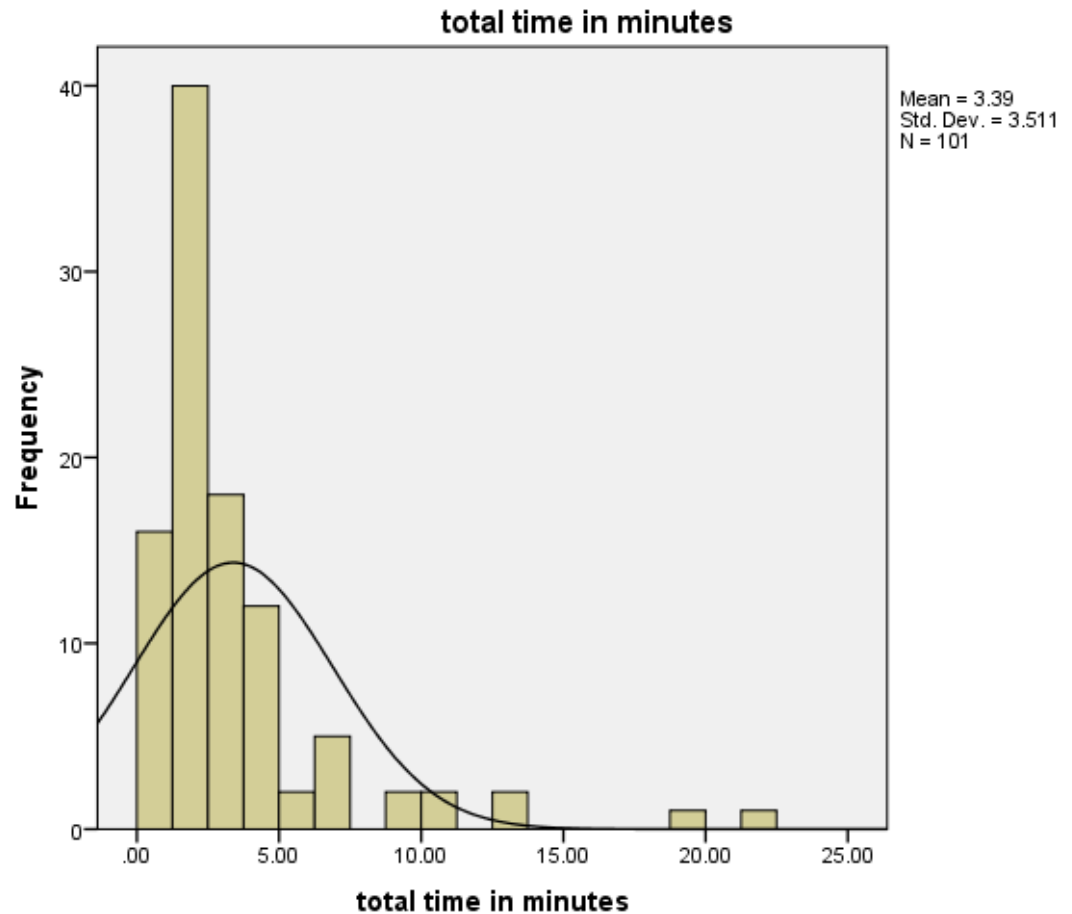


## Early Results – I-Pad Data

- The early results are tentative; as our sample size grows we will have quite a bit more confidence
- But the data to date suggests that a major fraction of patients are experiencing on-going ADE/ADRs
- Also, a large fraction of patients have more than one issue
- And finally, for many so afflicted, the impact, the sheer intrusiveness of their ADE/ADRs is substantial and clearly actionable.

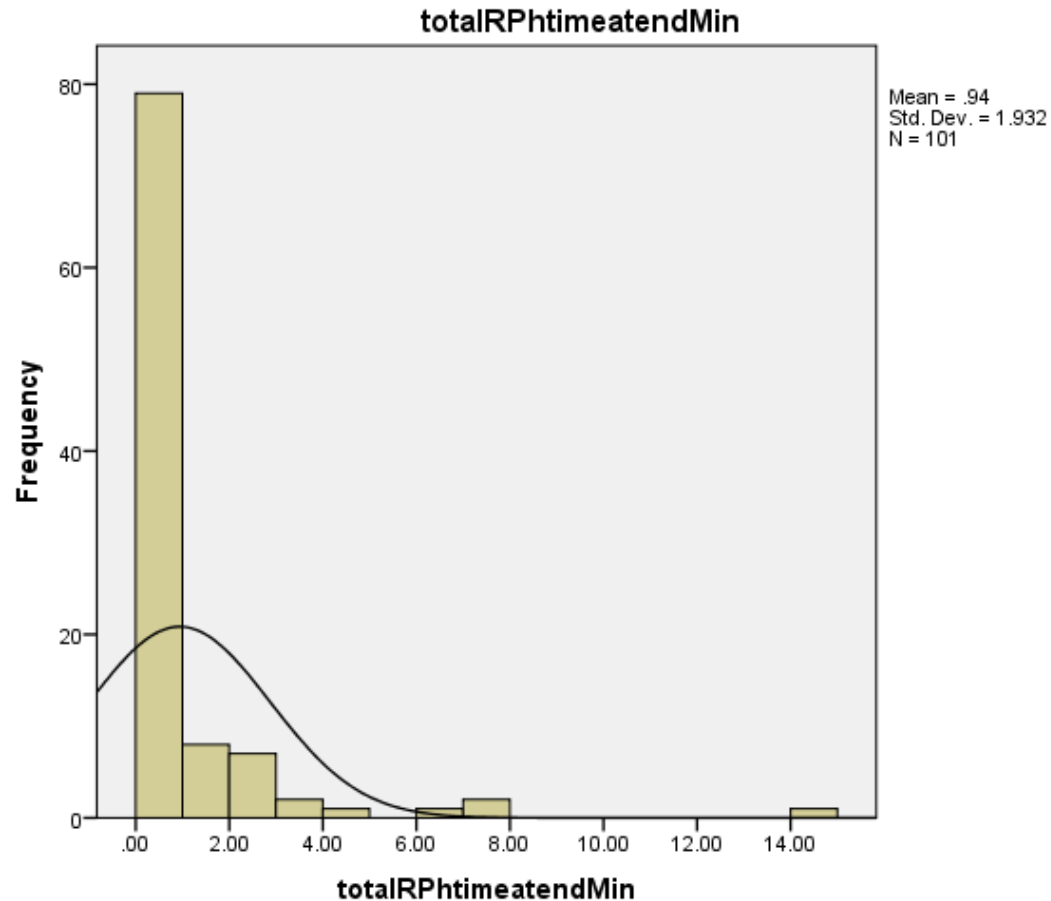
## TIME REQUIRED

- Average time required for total process=3.39 minutes



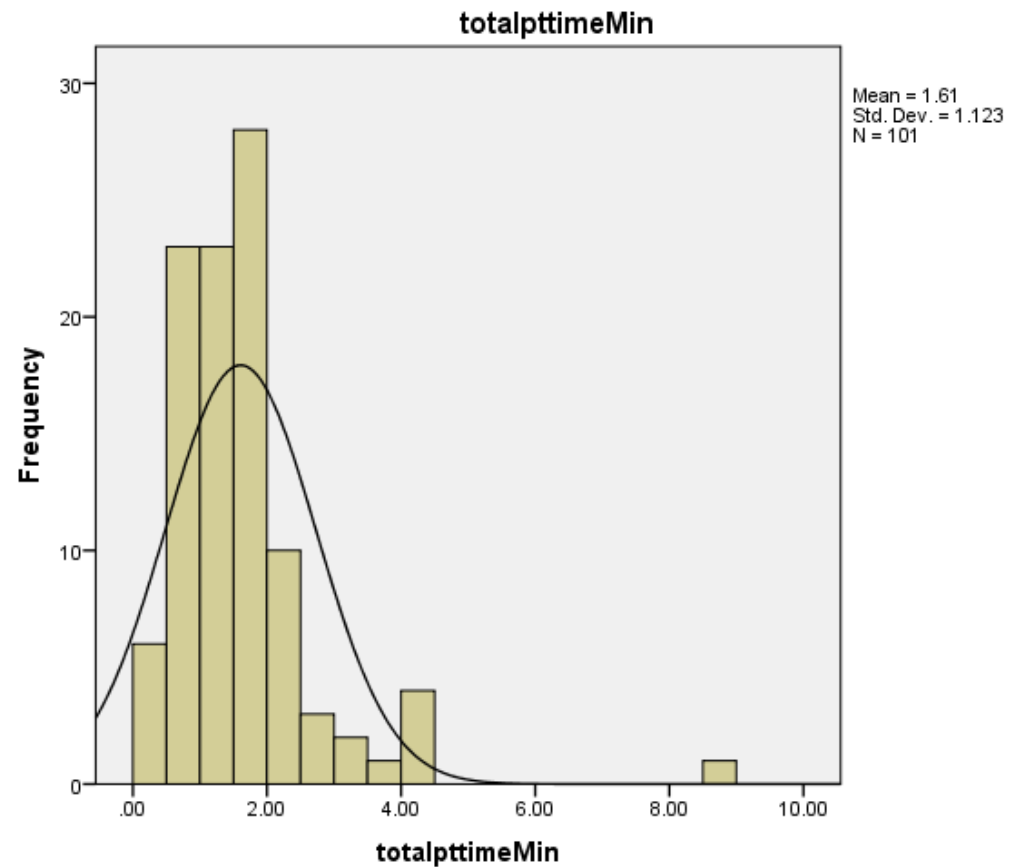
# PHARMACIST TIME

- Average RPh. Time= 0.94 minutes
- Less than 60 seconds



# PATIENT TIME

- Average Pt. Time=1.61 minutes



## Value Added

- For a few seconds of RPh time, and a few minutes of the Pts time, we could begin to directly address the “Side effects Iceberg”
- I-Pad is only a demo platform
- Full implementation would involve permanently installed touch screens integrated into the dispensing software, or on a webpage
- Rph. will only need to interpret results and counsel

## Potential Impact

- Better therapy compliance as ADE/ADR issues resolved, better health and quality of life, increased level of engagement in own care
- Higher value placed on interactions with a pharmacist, who may gain higher sense of professional satisfaction, potential for reaching out to prescribers by providing feedback about ADE/ADRs, possible role in suggesting alternatives
- Provides a defined and unique role for pharmacy that no other group currently attempts to address

## Further Impact

- Enhanced net cost effectiveness of drugs as pts with ADE/ADR issues are identified & moved to better drug matches.
- Opportunity for true comparative effectiveness evaluation of therapies
- Will provide data necessary to show the value of incremental improvements in drugs
- And all at a very low cost

# QUESTIONS?