



# IMPACT OF PATIENT DIARY FORMAT ON QUALITY OF LIFE OUTCOMES IN PEOPLE WITH PARKINSON'S DISEASE

**I. Budhiarso<sup>1</sup>, D. Bushnell<sup>1</sup>, M. Martin<sup>1</sup>, and T. Hogan<sup>2</sup>**

<sup>1</sup>Health Research Associates, Inc, Seattle, WA, USA, <sup>2</sup>Novartis Pharma, AG, Basel, Switzerland

---

Presented at the:  
5th Annual Conference of The International  
Society for Quality of Life (ISOQOL)  
November 15-17, 1998 • Baltimore, Maryland, U.S.A.

Project Sponsored by:  
Novartis Pharma, AG  
Basel, Switzerland

# Introduction



**Patient diary data is a primary source of information about changes in patient health states**



**Issue: feasibility, compliance and format**



**Expected differences in the resulting data:  
- Issue of “false positive” and “false negative”**



**Formats: dichotomous response format (“On”/”Off”) and trichotomous response format (“On”/“Off”/“Neither On or Off”)**

# Definition



**State “On” is good motor function/able to move well**



**State “Off” is poor motor function/able to move slowly or not at all**



**State “Neither On or Off” is for patient’s inability to classify their state as either “On” or “Off”**

# Objective



**Identify the diary format which would provide the highest quality data**



**Assess the impact of diary format on quality of life outcomes in people with Parkinson's Disease**

# Methods



**Patients were screened by two clinic neurologists at the Kansas University Medical Center**



**Study coordinators administered the**

- **UPDRS (Unified Parkinson's Disease Rating Scale): for function**
- **PIMS (Parkinson's Impact Scale): for quality of life**
- **PSI (Parkinson's Symptoms Inventory): for symptom and distress**



**Eligible patients were given a 3-day diary:**

- **to be self-administered at home**
- **completed on the following three full consecutive days**
- **then returned by mail to the Kansas University MC**



**Two weeks after the first diary was completed, a second 3-day diary was mailed**

## Study Design:

- patients who received one diary format at baseline then received the other diary format at follow-up.

	<b>Group A</b>	<b>Group B</b>
	<b>N=25</b>	<b>N=27</b>
<b>Time 1</b>	<b>Dichotomous Diary</b>	<b>Trichotomous Diary</b>
<b>Time 2</b>	<b>Trichotomous Diary</b>	<b>Dichotomous Diary</b>

# Sample of Patient Diary - Dichotomous

## PATIENT DIARY

Patient Name \_\_\_\_\_ ID # \_\_\_\_\_

Last
First
Middle

Day 1: \_\_\_\_\_ Day 2: \_\_\_\_\_ Day 3: \_\_\_\_\_

**Instructions:** Use one diary page for each day, for the entire 24 hour period. For each 30-minute period as indicated below, please put an "X" in the one column that best describes your physical state: On, Off, Asleep. Also with an "X", indicate when periods of disabling dyskinesia occur. Your spouse or constant companion may help to complete this form if necessary.

**Definitions:**

- On:** Good motor function; able to move well
- Off:** Poor motor function; able to move slowly or not at all
- Disabling Dyskinesia:** Abnormal involuntary movements that interfere with activities or cause distress

<i>Circle Time Study Medication Taken</i>	ON	OFF	ASLEEP	Presence of Disabling Dyskinesia	<i>Circle Time Study Medication Taken</i>	ON	OFF	ASLEEP	Presence of Disabling Dyskinesia
MIDNIGHT-----	-----	-----	-----	-----	NOON-----	-----	-----	-----	-----
12:30 a.m.-----	-----	-----	-----	-----	12:30 p.m.-----	-----	-----	-----	-----
1:00 a.m.-----	-----	-----	-----	-----	1:00 p.m.-----	-----	-----	-----	-----
1:30 a.m.-----	-----	-----	-----	-----	1:30 p.m.-----	-----	-----	-----	-----
2:00 a.m.-----	-----	-----	-----	-----	2:00 p.m.-----	-----	-----	-----	-----
2:30 a.m.-----	-----	-----	-----	-----	2:30 p.m.-----	-----	-----	-----	-----
3:00 a.m.-----	-----	-----	-----	-----	3:00 p.m.-----	-----	-----	-----	-----
3:30 a.m.-----	-----	-----	-----	-----	3:30 p.m.-----	-----	-----	-----	-----
4:00 a.m.-----	-----	-----	-----	-----	4:00 p.m.-----	-----	-----	-----	-----
4:30 a.m.-----	-----	-----	-----	-----	4:30 p.m.-----	-----	-----	-----	-----
5:00 a.m.-----	-----	-----	-----	-----	5:00 p.m.-----	-----	-----	-----	-----
5:30 a.m.-----	-----	-----	-----	-----	5:30 p.m.-----	-----	-----	-----	-----
6:00 a.m.-----	-----	-----	-----	-----	6:00 p.m.-----	-----	-----	-----	-----
6:30 a.m.-----	-----	-----	-----	-----	6:30 p.m.-----	-----	-----	-----	-----
7:00 a.m.-----	-----	-----	-----	-----	7:00 p.m.-----	-----	-----	-----	-----
7:30 a.m.-----	-----	-----	-----	-----	7:30 p.m.-----	-----	-----	-----	-----
8:00 a.m.-----	-----	-----	-----	-----	8:00 p.m.-----	-----	-----	-----	-----
8:30 a.m.-----	-----	-----	-----	-----	8:30 p.m.-----	-----	-----	-----	-----
9:00 a.m.-----	-----	-----	-----	-----	9:00 p.m.-----	-----	-----	-----	-----
9:30 a.m.-----	-----	-----	-----	-----	9:30 p.m.-----	-----	-----	-----	-----
10:00 a.m.-----	-----	-----	-----	-----	10:00 p.m.-----	-----	-----	-----	-----
10:30 a.m.-----	-----	-----	-----	-----	10:30 p.m.-----	-----	-----	-----	-----
11:00 a.m.-----	-----	-----	-----	-----	11:00 p.m.-----	-----	-----	-----	-----
11:30 a.m.-----	-----	-----	-----	-----	11:30 p.m.-----	-----	-----	-----	-----

# Sample of Patient Diary - Trichotomous

## PATIENT DIARY

Patient Name \_\_\_\_\_ ID # \_\_\_\_\_

Last
First
Middle

Day 1: \_\_\_\_\_ Day 2: \_\_\_\_\_ Day 3: \_\_\_\_\_

**Instructions:** Use one diary page for each day, for the entire 24 hour period. For each 30-minute period as indicated below, please put an "X" in the one column that best describes your physical state: On, Off, Asleep. Also with an "X", indicate when periods of disabling dyskinesia occur. Your spouse or constant companion may help to complete this form if necessary.

- Definitions:**
- On:** Good motor function; able to move well
  - Off:** Poor motor function; able to move slowly or not at all
  - Disabling Dyskinesia:** Abnormal involuntary movements that interfere with activities or cause distress

<i>Circle Time Study Medication Taken</i>	ON	Neither ON or OFF	OFF	ASLEEP	Presence of Disabling Dvskinesia	<i>Circle Time Study Medication Taken</i>	ON	Neither ON or OFF	OFF	ASLEEP	Presence of Disabling Dvskinesia
MIDNIGHT-----	----	----	----	----	----	NOON-----	----	----	----	----	----
12:30 a.m.-----	----	----	----	----	----	12:30 p.m.-----	----	----	----	----	----
1:00 a.m.-----	----	----	----	----	----	1:00 p.m.-----	----	----	----	----	----
1:30 a.m.-----	----	----	----	----	----	1:30 p.m.-----	----	----	----	----	----
2:00 a.m.-----	----	----	----	----	----	2:00 p.m.-----	----	----	----	----	----
2:30 a.m.-----	----	----	----	----	----	2:30 p.m.-----	----	----	----	----	----
3:00 a.m.-----	----	----	----	----	----	3:00 p.m.-----	----	----	----	----	----
3:30 a.m.-----	----	----	----	----	----	3:30 p.m.-----	----	----	----	----	----
4:00 a.m.-----	----	----	----	----	----	4:00 p.m.-----	----	----	----	----	----
4:30 a.m.-----	----	----	----	----	----	4:30 p.m.-----	----	----	----	----	----
5:00 a.m.-----	----	----	----	----	----	5:00 p.m.-----	----	----	----	----	----
5:30 a.m.-----	----	----	----	----	----	5:30 p.m.-----	----	----	----	----	----
6:00 a.m.-----	----	----	----	----	----	6:00 p.m.-----	----	----	----	----	----
6:30 a.m.-----	----	----	----	----	----	6:30 p.m.-----	----	----	----	----	----
7:00 a.m.-----	----	----	----	----	----	7:00 p.m.-----	----	----	----	----	----
7:30 a.m.-----	----	----	----	----	----	7:30 p.m.-----	----	----	----	----	----
8:00 a.m.-----	----	----	----	----	----	8:00 p.m.-----	----	----	----	----	----
8:30 a.m.-----	----	----	----	----	----	8:30 p.m.-----	----	----	----	----	----
9:00 a.m.-----	----	----	----	----	----	9:00 p.m.-----	----	----	----	----	----
9:30 a.m.-----	----	----	----	----	----	9:30 p.m.-----	----	----	----	----	----
10:00 a.m.-----	----	----	----	----	----	10:00 p.m.-----	----	----	----	----	----
10:30 a.m.-----	----	----	----	----	----	10:30 p.m.-----	----	----	----	----	----
11:00 a.m.-----	----	----	----	----	----	11:00 p.m.-----	----	----	----	----	----
11:30 a.m.-----	----	----	----	----	----	11:30 p.m.-----	----	----	----	----	----





# Sample

## Inclusion Criteria



- **Diagnosed with Parkinson's Disease:**
  - presence 2 out of 3 symptoms: tremor, bradykinesia and rigidity, and a sustained responsiveness to l-dopa therapy
- **Moderate to severe "On/Off" states for at least 6 months prior to enrollment**
- **State "Off" more than 25% of an average day**
- **On stable anti-Parkinsonian therapy for at least one month prior to enrollment**

## Inclusion Criteria



- **Abnormal forms of Parkinsonism including drug induced Parkinsonism and dementia**

## Sample Size



- **52 participants from Kansas City area**

# Results



**Demographic Characteristics**



**Physical States**



**Correlations to other instruments**

# Population Demographic Characteristics (n=52)



DEMOGRAPHIC	n	PERCENT
<b>Diagnosed with PD (Years)</b> <ul style="list-style-type: none"> <li>• Mean (StdDev) = 10.5 (6.3)</li> <li>• Range= 1 - 28</li> </ul>		
<b>Age (Years)</b> <ul style="list-style-type: none"> <li>• Mean (StdDev) = 67 (12.4)</li> <li>• Range= 26 - 88</li> </ul>		
<b>Ethnicity</b> <ul style="list-style-type: none"> <li>• White (non-Hispanic)</li> </ul>	52	100
<b>Marital Status</b> <ul style="list-style-type: none"> <li>• Married or living as married</li> <li>• Widowed</li> <li>• Divorced</li> </ul>	43 6 3	83 12 5
<b>Education</b> <ul style="list-style-type: none"> <li>• High school and under</li> <li>• College</li> <li>• Graduate/Professional</li> </ul>	32 13 7	61.5 25 13.5
<b>Income</b> <ul style="list-style-type: none"> <li>• Under \$25000</li> <li>• \$25000 - 49999</li> <li>• \$50000 and over</li> <li>• Missing</li> </ul>	15 7 14 16	29 13 27 31

## Mostly

- **Elderly**
- **White**
- **Married**
- **≤ High School**
- **< \$50 000 per year**

# Physical States

Physical State	Dichotomous	Trichotomous	Tri-Di Differences
	Hours Spent Over 3 days	Hours Spent Over 3 days	Hours Spent Over 3 days
	Mean% (Std.Dev)	Mean% (Std.Dev)	Mean%(Std.Dev)
Asleep	33.7 (7.4)	31.4 (8.2)	-2.3 (5.8)
<b>On</b>	39.7 (14.3)	30.1 (15.4)	-9.6 (13.8)
<b>Off</b>	24.0 (13.1)	17.9 (8.8)	-6.12 (13.7)
<b>Neither</b>	-----	17.6 (12.9)	17.6 (12.9)
Other*/**	2.1 (6.5)	2.8 (8.9)	0.7 (7.0)
Dyskinesia**	13.8 (21.3)	8.4 (12.5)	-5.4 (21.0)
Medication**	16.0 (10.6)	16.2 (4.5)	0.1 (4.5)

} -15.7

\* Other is any record for “Presence of Disabling Dyskinesia” only, “Medication” only, and “Presence of Disabling Dyskinesia” plus “Medication”, when state “On”, “Off” or “Asleep” is not checked.

\*\* Number of times in 72 hours

- **The Presence of a third response column (“Neither On or Off”) lowered the percent time recorded in “On” and “Off”**
- **The decrease in “On” and “Off” (from Dichotomous to Trichotomous) was explained by the presence of a third column “Neither On or Off” (t-stat=0.24 / p=0.82)**

# Correlations with other instruments

	State ON		State OFF		Disabling Dyskinesia		Medication Taken	
	Dicho	Tricho	Dicho	Tricho	Dicho	Tricho	Dicho	Tricho
<b>UPDRS :</b>								
- Mentation	-0.09	-0.29*	0.13	0.21	0.19	0.27	-0.01	-0.02
- ADL	-0.29*	-0.35**	0.31*	0.21	0.22	0.23	0.16	0.17
- Motor	-0.39**	-0.32*	0.24	-0.22	0.10	0.10	-0.11	-0.12
- Total	-0.28*	-0.33*	0.24	-0.02	0.21	0.23	0.02	0.03
<b>PSI :</b>								
- Frequency	-0.29*	-0.46**	0.27	0.30*	0.24	0.39**	0.15	0.10
- Distress	-0.32*	-0.35*	0.29*	0.25	0.34*	0.46**	0.12	0.12
<b>PIMS :</b>								
- Best	<b>-0.27*</b>	<b>-0.31*</b>	0.19	0.31*	0.22	0.39**	0.15	0.12
- Worst	-0.37**	-0.28*	<b>0.35*</b>	<b>0.41**</b>	0.26	0.35*	0.21	0.20
Disabling Dyskinesia	-0.28*	-0.17	0.46**	0.26			0.20	0.31*
Medication Taken	-0.09	-0.19	0.29*	0.32*	0.20	0.31*		

\*\* Significant at the 0.01 level

\* Significant at the 0.05 level

**Correlations between “On” and quality of life (PIMS) :**  
 ⇒ Increased from -0.27 (Dichotomous) to -0.31 (Trichotomous)

**Correlations between “Off” and quality of life (PIMS):**  
 ⇒ Increased from 0.35 (Dichotomous) to 0.41 (Trichotomous)

# Conclusion

- **A lower percent time was recorded in “On” and “Off” states using the trichotomous diary format**
- **The presence of a third column (“Neither On or Off”) explains the decrease in “On” and “Off”**
- **A trichotomous diary format increases correlations between On/Off states and quality of life**



---

**Therefore the use of trichotomous response options appear to improve data quality by decreasing the “noise” caused by false negative and false positive responses. This prevents incorrect shifts in the relationship between diary data and quality of life**