

How do Psychiatric Patients Perceive the Side Effects of Their Medications?

Oleg Lapshin, Craig J. Skinner, Joseph Finkelstein

Department of Epidemiology and Preventive Medicine, University of Maryland

Corresponding author: Oleg Lapshin, MD, MPH, Department of Epidemiology and Preventive Medicine, University of Maryland, 100 N. Greene St, Room 525, Baltimore, MD, 21201, USA, olapshin@gmail.com

Abstract

***Aims:** Available instruments for the assessment of medication side effects give limited information about the overall impact of medication side effects on patient well-being. We have developed a scale to assess adverse drug events that can potentially be used in any field of medicine.*

***Methods:** A convenience sample of 61 consecutive psychiatric patients was enrolled from a rehabilitation clinic. The Side Effect Survey (SidES), designed for this study, was used to assess adverse drug effects. The Udvalg for Kliniske Undersogelser (UKU) Side Effect Rating Scale was used independently as another tool to assess medication side effects.*

***Results:** Overall reliability of the scale was good with Cronbach-alpha 0.81-0.96. Criterion-related validity of SidES was analyzed through a comparison of corresponding items in SidES with the UKU Side Effect Rating Scale. For 41 of 48 symptoms, there was a correlation between similar items in UKU and SidES at $p < 0.01$. The total scores of SidES and the number of medications taken by the patients correlated at $r = 0.49$, and $r = 0.43$, $p < 0.0001$.*

***Conclusion:** In this study SidES demonstrated good psychometric properties. Assessment of the overall impact of medication side effect could be useful for the development of safer medications and treatment regimens (German J Psychiatry 2006;9:74-93).*

Keywords: medication side effects, rating scales, psychotropic medications

Received: 13.4.2006

Revised version: 27.6.2006

Published: 1.7.2006

Introduction

The adverse drug reaction is “an appreciably harmful or unpleasant reaction, resulting from an intervention related to the use of a medicinal product, which predicts hazard from future administration and warrants prevention or specific treatment, or alteration of the dosage regimen or withdrawal of the product” (Edwards & Aronson, 2000). The problem of adverse drug reactions from prescribed medication, commonly referred to as side effects, is a very important issue despite the evident successes of pharmaceutical science in the development of safer medicines. Twenty-five percent of ambulatory patients re-

ported adverse drug events. 37% of ameliorable adverse drug events (those in which the severity could possibly have been reduced by treatment or medication adjustments) have been attributed to the patient’s failure to inform the physician of the symptoms (Gandhi et al., 2003).

There are many tools available to assist clinicians in evaluating adverse drug reactions. Most of all available scales for assessing adverse drug reactions have been developed and investigated for the evaluation of unintended results from antipsychotic medications (Table 1). These instruments give information about the impact of medication side effects with respect to symptoms experienced by the patient, and as expected are mostly used in psychiatric healthcare delivery. Currently the most comprehensive instrument for assessing

drug reactions is the Udvalg for Kliniske Undersogelser (UKU) Side Effect Rating Scale (Jordan et al., 2004). This scale has come to be accepted as a standard for quantifying the adverse effects of antipsychotic drugs. The UKU scale was designed to be administered by a trained investigator and relies in part on physical exam. Although effective for evaluating safety of antipsychotic medications, it is not intended for safety monitoring of other classes of drugs. There

is a need for adverse medication effect assessment scales for the wide variety of drugs prescribed for psychiatric patients and used in other fields of healthcare delivery (Andersson, 1979; Carelle et al., 2002). Additionally, there is a need for the development of time considerate instruments that are less intrusive on the limited time often allowed for provider/patient encounters as well as those that may allow the patient to self-assess their own drug reactions.

Table 1. Examples of the Scales Used for Assessment of Medication Side Effects

Scales	Medications Scale Designed for	Symptoms Rated	What is Rated	Assessment
Udvalg for Kliniske Undersogelser (UKU) Side Effect Rating Scale (Lingjaerde et al., 1987)	Psychotropic	48 symptoms in 4 categories; psychic, autonomic, neurologic, and other	Clinician assessed magnitude of symptoms, perceived causality, degree of disability	Interview and physical exam
Approaches to Schizophrenia Communication (Dott et al., 2001)	Psychotropic	18 items	Patient distress	Interview
UKU-SERS-Pat (Lindstrom et al., 2001)	Psychotropic	All groups, 42 items	Degree, patient-rated	Interview
The Liverpool University Neuroleptic Side Effect Rating Scale (LUNSERS) (Day et al., 1995)	Psychotropic	All groups, 41 symptom and 10 'red herring' items	Degree, patient-rated	Interview
ADR Detection Questionnaire (Corso et al., 1992)	Any medications	All groups, 24 items	Presence	Interview
Abnormal involuntary movement scale (AIMS) (Munetz & Benjamin, 1988)	Psychotropic	Involuntary movements, 12-item	Degree, clinician-rated	Interview and physical exam
Scale of Extrapyramidal Symptoms (Simpson & Angus, 1970)	Psychotropic	Extrapyramidal Symptoms	Degree, duration, distress,	Interview and physical exam
Systematic Assessment for Treatment Emergent Events—General Inquiry (SAFTEE—GI) (Clyde, 1986)	Psychotropic	General inquiry about medication side effects	Degree, causality, duration, distress	Interview, physical exam, laboratory assessment
Systematic Assessment for Treatment Emergent Events— Specific Inquiry (SAFTEE—SI)(Clyde, 1986)	Psychotropic	All groups, 77 items	Degree, disability, causality, distress	Interview, physical exam, laboratory assessment
Monitoring of Medication side effects Scale (MOSES) (Kalachnik, 1988)	Psychotropic and Antiepileptic	All groups, 83 items	Degree, clinician-rated	Interview and physical exam
Clinical diagnostic scale (Aithal et al., 2000)	Any medications	Hepatotoxic adverse effects	Causality	Interview

Methods

The protocol of the study was approved by the University of Maryland Institutional Review Board. A convenience sample of 61 consecutive psychiatric patients was enrolled from an outpatient rehabilitation clinic. All patients were taking at least one psychotropic medication. Medication compliance was carefully followed by clinic staff, so with some degree of certainty, we could be sure that patients were actually taking prescribed medications.

Instruments

The Side Effect Survey (SidES), a two part survey designed for this study, was self-administered by study participants.

The survey assesses the patient's perception of the presence and severity of specific symptoms. Responses identify medication side effects experienced (Symptom Checklist) by the participant and the five medication side effects (symptoms) that were most severe for the patient. The scale contains a checklist of 150 items that are known symptoms of medication side effects associated with the most commonly prescribed medications. The symptom list was based on the medication side effects of the "Top 200 Most Prescribed Drugs in 2003" ("Top 200 Most Prescribed Drugs in 2003", n. d.) listed in the Micromedex database ("Micromedex Healthcare Series", n. d.). The checklist of possible symptoms is divided into functional sections by organ system. Symptom severity is quantified using one of 3 options (mild, moderate, or severe). Patients then indicate whether they believe the symptom is a drug side effect and if so to which medication(s) they attribute the symptom. At the end of the checklist, participants were asked to identify any other symptoms they believed to be medication side effects that were not listed in the survey and indicate the severity of these symptoms. In the second part of the assessment, patients were asked to select the five medication side effects that were the most bothersome, rate the level of distress caused by them, and indicate the duration (number of days symptoms persisted).

The SidES questionnaire allows inquiry about the side effects of all medications that a patient takes and allows several configurations of data reporting. Information about a specific medication or group of medications, symptoms or group of symptoms, symptom severity, and symptom duration can be extracted from the data supplied in the survey. SidES quantifies symptom scores, which are calculated as the sum of the patient rating of their distress from the five most severe medication side effects, and the sum of the numbers of days during the last two weeks they had these symptoms. The scale is provided in the attachment.

The Udvalg for Kliniske Undersogelser (UKU) Side Effect Rating Scale was used independently as a control for comparison to SidES. The UKU is a clinician-administered scale that is accepted as a standard tool for side effect assessment

in psychiatric settings and is thoroughly detailed in existing literature. The UKU was administered to study participants by an experienced interviewer.

Results

Socio-demographic characteristics of the sample are provided in the Table 2. The study sample exhibited a variety of Axis I psychiatric diagnosis: schizophrenia (36.1%, 22 subjects), schizoaffective disorder (24.6%, 15 subjects), bipolar disorder (23.0%, 14 subjects), major depressive disorder (11.5%, 7 subjects). One person (0.02%) had a psychotic disorder (not specified), two others had ADHD (0.03%). Twelve subjects (19.7%) had concurrent personality disorder, and 34 subjects (54.1%) had a history of substance abuse.

Table 2. Sociodemographic characteristics of the sample

Parameter	Mean ± Standard Deviation or Percentage
Age (years)	40.2 ± 11.2
Gender	42.6% female (26 subjects)
Education (years)	11.5 ± 1.9
Race	
– African-American	45.9% (28 subjects)
– Caucasian	50.8% (31 subjects)
– Asian	3.3% (2 subjects)
Employment status	80.3% unemployed (50 subjects)

The average number of medications per patient was 4.5 ± 2.2, and of those medications 3.0 ± 1.5 were psychotropic medications. Medications taken by more than 10% of the sample were: Quetiapine (24.2%, 16 patients), Olanzapine (21.2%, 14 patients), Divalproex (19.7%, 13), Trazodone (18.2%, 12), Aripiprazole (15.2%, 10), Risperidon (15.2%, 10), Escitalopram (13.6%, 9), and Sertraline (12.1%, 8). Majority of the patients (71.7%, 43) reported some medication side effects. The most frequent side effects, defined as present in 15% or more of the patients, are shown in Table 3.

Table 3. The most frequent medication side effects (present in 15% or more patients)

	Percent	N
SidES		
Dry mouth	40.0%	24
Weight gain	33.3%	20
Extreme thirst	30.0%	18
Increased appetite	23.3%	14
Tiredness or fatigue	20.0%	12
Nightmares	18.3%	11
Day sleepiness	16.7%	10
Increased duration of sleep	16.7%	10
Blurred vision	15.0%	9
UKU		
Reduced salivation	28.3%	17
Sleepiness/sedation	23.3%	14
Orthostatic dizziness	23.3%	14
Weight gain	16.7%	10
Increased duration of sleep	15.0%	9
Tremor	15.0%	9

Reliability and validity of SidES

The overall reliability of SidES was good (Table 4). The Cronbach-alpha for the Symptom Checklist was above 0.90. The validity of SidES was analyzed through a comparison of corresponding items in SidES and the UKU Side Effect Rating Scale. It is important to recall that these scales rate symptoms from different perspectives. The UKU scale is a clinical assessment by a trained investigator evaluating the severity of reported symptoms. The SidES scale is a patient self-assessment that measures perceived degree of distress from the symptom. Therefore, we could not expect full correspondence between these scales. For most symptoms (41 of 48 items), correlation between similar items were significant at $p < 0.01$. Two symptoms' correlations were significant at $p < 0.05$: photosensitivity (the study was conducted mostly in the winter and early spring when cases of sunburn were rare), and dystonia with slurred speech. Two other symptoms, increased pigmentation and galactorrhea, were not reported and subsequently not analyzed. For emotional indifference, psychological dependency, and physical dependency the ratings of clinicians and patients were markedly different. Patient more frequently perceived their medications as addictive, and less frequently recognized clinically significant apathy. The global assessment item of the UKU scale and the total distress score in SidES correlated at $p < 0.01$ (assessed by a patient $r = 0.75$, assessed by a doctor $r = 0.56$).

Table 5. Correlations between SidES total scores and number of medications taken by patients

Scores	Number of Medications	
	Psychotropic	Total
Total Distress	$r = 0.35, p = 0.006$	$r = 0.49, p < 0.0001$
Total Number of Days	$r = 0.37, p = 0.004$	$r = 0.43, p < 0.001$
UKU global assessment (patient)	$r = 0.23, p = 0.07$	$r = 0.32, p = 0.01$
UKU global assessment (doctor)	$r = 0.24, p = 0.07$	$r = 0.29, p = 0.03$

Total scores of SidES and number of medications

The patient rating of medication side effects using SidES correlated with the total number of medications and number of psychotropic medications (Table 5). The correlation between SidES score and the total number of medications was stronger than the correlation of the SidES score with the number of psychotropic medications. The discrepancy most likely reflects the fact that the questionnaire asked about side effects from all medications taken by the patient and not only psychotropic drugs. Table 5 shows correlation data for both SidES and UKU scores with medication.

Medication side effects perception

The UKU scale and SidES include ratings of symptom severity and the perception or assessment (depending on who administers the survey) that a symptom is a side effect. Patients perceive more symptoms than those identified by clinicians. Comparing a set of similar items in UKU and SidES, the total number of symptoms present was 13.9 ± 1.2 in SidES (patient assessed) and 9.4 ± 6.4 in UKU (provider assessed). The difference is significant with $p > 0.0001$. Patients more frequently perceived the symptoms that they had as side effects of their medications. The total number of symptoms identified as medication side effects by a clinician or a patient (UKU vs. SidES, taking into account only similar items) were significantly different (2.31 vs. $4.46, p < 0.001$).

Discussion

Post marketing evaluation of FDA-approved medications is a topic of heated debate (Psaty et al., 2004). Life-threatening adverse events are only the tip of the iceberg which harbors numerous, non-serious adverse drug reactions below the surface. Even in clinical trials adverse effects are reported inconsistently (Loke & Derry, 2001). One of the options to improve reporting on medication safety in clinical trials can be use of standardized rating scales (Ioannidis & Lau, 2002). While life-threatening adverse reactions are reported more consistently (Ahmad, 2003) less serious side effects are often ignored, even in the context of clinical trials (Michels, 1999). However, because non life-threatening medication side effects, are significantly more widespread than life-threatening events they can indirectly pose a significant threat to the patient by imposing symptoms that may be unpleasant or require treatment and decreasing medication compliance (Croog et al., 1986; Fitzgerald, 1976; Fleischhacker et al., 1994).

Problems with the evaluation of medication side effects are numerous. General inquiry about medication side effects, by survey or interview, elicits information about significantly distressing events and symptoms that affect daily functioning. Some researchers argue that questions about specific symptoms are minimally useful for both clinical trials and clinical practice because they do not reveal any additional medically serious events compare to general inquiry (Rabkin et al., 1992). Some medication side effects are difficult to uncover without direct closed ended questioning. For example, the incidence of sexual dysfunction associated with Fluoxetine therapy was 7.8-16% in different studies using self-reported data and 17-75% on direct questioning (Michels, 1999). An extensive and detailed list of all possible medication side effects (Trotti & Bentzen, 2003) can be very useful for large-scale clinical trials, but not practical for smaller research trials or integration into clinical practice.

Restricting the list of possible medication side effects to only a particular group of medications (e.g. neuroleptics) or a specific set of medication side effects (e.g. extrapyramidal) is a possible solution to the lack of practicality of conventional tools for adverse drug reaction assessment. This limited approach has the advantages of a relatively shorter list of symptoms and increased specificity for the symptoms or medication side effects being studied. Many psychiatric patients with schizophrenia and other psychotic disorders frequently take neuroleptics along with mood stabilizers or antidepressants. It may be possible to develop a separate scale for each group of medication used, but this is not practical. The use of hypothetical, "group-specific" scales would increase the difficulty of assessing side effects resulting from combined therapy. Specific side effect surveys would also limit the utility of these tools for general medical practice research where a wide variety of drugs may be prescribed. Another approach that could be used in the near future is

electronic questionnaires that change the list of symptoms according to the medications a patient takes.

The score of SidES correlated well with the total number of medications that the patients took. It is likely that patients taking more medication have more medication side effects (symptoms) and an increased likelihood of perceiving these symptoms as severe. This hypothesis is supported by the fact that the clinical (UKU) and patient (SidES) assessments of medication side effects were significantly correspondent. It is also important to point out that the health status of patients who require some number of medications can predispose them to having medication side effects of varied severity. It could be also that the more severely ill patients (who likely take more medication) have symptoms that they explain as medication side effects, when in reality most of these symptoms are caused by their health condition.

Patients perceived more symptoms when performing self-assessment and more frequently attributed them to side effects of their treatment when compared to clinical assessment results. That is consistent with observations from previous studies. Based on this study data, it is impossible to say if this phenomenon is specific to psychiatric patients or applicable to any groups of patients. Although exaggerated, the patient perception of adverse drug reactions seen in SidES corresponds with the clinical assessment of reported symptoms using the UKU.

Conclusion

In this study, SidES demonstrated good psychometric properties. It accurately assesses the patient perception of medication side effects from their treatment and lends insight as to how patients relate symptoms to a particular medication and which symptoms are more intrusive than others. As indicated in previous studies, patients likely perceive more symptoms than clinicians may detect and more frequently attribute them to medication side effects (Lindstrom et al., 2001). SidES is an effective tool for the self-assessment of adverse drug reactions. Further study of the overall impact of medication side effects and tools for their assessment could be useful in evaluating medication non-compliance and the development of safer medications and treatment regimens.

References

- Ahmad SR. Adverse drug event monitoring at the Food and Drug Administration. *J Gen Intern Med.* 2003 Jan;18(1):57-60.
- Aithal GP, Rawlins MD, Day CP. Clinical diagnostic scale: a useful tool in the evaluation of suspected hepatotoxic adverse drug reactions. *J Hepatol.* 2000 Dec;33(6):949-52.

- Andersson O. Registration of side effects by means of a questionnaire. *Acta Med Scand Suppl.* 1979;628:29-32.
- Carelle N, Piotto E, Bellanger A, Germanaud J, Thuillier A, Khayat D. Changing patient perceptions of the side effects of cancer chemotherapy. *Cancer.* 2002 Jul 1;95(1):155-63.
- Clyde DJ. SAFTEE: data system for side effect assessment scale. *Psychopharmacol Bull.* 1986;22(1):287
- Corso DM, Pucino F, DeLeo JM, Calis KA, Gallelli JF. Development of a questionnaire for detecting potential adverse drug reactions. *Ann Pharmacother.* 1992 Jul-Aug;26(7-8):890-6.
- Croog SH, Levine S, Testa MA, Brown B, Bulpitt CJ, Jenkins CD, Klerman GL, Williams GH. The effects of antihypertensive therapy on the quality of life. *N Engl J Med.* 1986 Jun 26;314(26):1657-64.
- Day JC, Wood G, Dewey M, Bentall RP. A self-rating scale for measuring neuroleptic side-effects. Validation in a group of schizophrenic patients. *Br J Psychiatry.* 1995 May;166(5):650-3.
- Dott SG, Weiden P, Hopwood P. An innovative approach to clinical communication in schizophrenia: the approaches to schizophrenia communication checklists. *CNS Spectrums.* 2001; 4: 333-338.
- Edwards, I., Aronson J. Adverse drug reactions: definitions, diagnosis, and management. *The Lancet.* 2000 October 7;356:1255-59.
- Fitzgerald JD. The influence of the medication on compliance with therapeutic regimens. In: Sackett DL, Haynes RB, eds: *Compliance with therapeutic regimens.* Baltimore: Johns Hopkins University Press, 1976.
- Fleischhacker WW, Meise U, Gunther V, Kurz M. Compliance with antipsychotic drug treatment: influence of side effects. *Acta Psychiatr Scand Suppl.* 1994;382:11-5.
- Gandhi TK, Weingart SN, Borus J, Seger AC, Peterson J, Burdick E, Seger DL, Shu K, Federico F, Leape LL, Bates DW. Adverse drug events in ambulatory care. *N Engl J Med.* 2003 Apr 17;348(16):1556-64.
- Ioannidis JP, Lau J. Improving safety reporting from randomised trials. *Drug Saf.* 2002;25(2):77-84.
- Jordan S., Knight J., Pointon D. Monitoring adverse drug reactions: scales, profiles, and checklists. *International Nursing Review.* 2004 (51) 208-221.
- Kalachnik, JE. Measuring side effects of psychopharmacologic medication in individuals with mental retardation and developmental disabilities. *Mental Retardation and Developmental Disabilities Research Reviews.* 1999 5;4:348-359.
- Lindstrom E, Lewander T, Malm U, Malt UF, Lublin H, Ahlfors UG. Patient-rated versus clinician-rated side effects of drug treatment in schizophrenia. Clinical validation of a self-rating version of the UKU Side Effect Rating Scale (UKU-SERS-Pat). *Nord J Psychiatry.* 2001;55 Suppl 44:5-69.
- Lingjaerde O, Ahlfors UG, Bech P, Dencker SJ, Elgen K. The UKU side effect rating scale. A new comprehensive rating scale for psychotropic drugs and a cross-sectional study of side effects in neuroleptic-treated patients. *Acta Psychiatr Scand Suppl.* 1987;334:1-100.
- Loke YK, Derry S. Reporting of adverse drug reactions in randomised controlled trials - a systematic survey. *BMC Clin Pharmacol.* 2001;1:3.
- Michels KB. Problems assessing nonserious adverse drug reactions: antidepressant drug therapy and sexual dysfunction. *Pharmacotherapy.* 1999 Apr;19(4):424-9.
- Micromedex Healthcare Series. Retrieved May 19, 2006 from <http://www.thomsonhc.com>
- Munetz MR, Benjamin S. How to examine patients using the Abnormal Involuntary Movement Scale. *Hosp Community Psychiatry.* 1988 Nov;39(11):1172-7.
- Psaty BM, Furberg CD, Ray WA, Weiss NS. Potential for conflict of interest in the evaluation of suspected adverse drug reactions: use of cerivastatin and risk of rhabdomyolysis. *JAMA.* 2004 Dec 1;292(21):2622-31. Epub 2004 Nov 22.
- Rabkin JG, Markowitz JS, Ocepek-Welikson K, Wager SS. General versus systematic inquiry about emergent clinical events with SAFTEE: implications for clinical research. *J Clin Psychopharmacol.* 1992 Feb;12(1):3-10.
- Simpson GM, Angus JW. A rating scale for extrapyramidal side effects. *Acta Psychiatr Scand Suppl.* 1970;212:11-9.
- Top 200 Most Prescribed Drugs in 2003. Retrieved May 19, 2006 from the Mosby Drug Consult website http://www.mosbysdrugconsult.com/DrugConsult/Top_200/.
- Trotti A, Bentzen SM. The need for adverse effects reporting standards in oncology clinical trials. *J Clin Oncol.* 2004 Jan 1;22(1):19-22.

Attachment
The Side Effect Survey, Version 2.0 (SidES 2.0)

ID _____ Name: _____ Date: _____ Interviewer: _____

In this questionnaire, you will be asked about the medications you have taken and your health problems.

Medication list

First we would like to ask what medications you are taking.

1. What medications did you take during **the last month**? Include all prescription and over-the-counter medications, like vitamins, sleeping pills, pain relievers or cold medicines.
2. For how long have you taken this medication?
3. Are you taking this medication currently?

	Medications	Average Daily Dosage (mg)	Disease/ condition	How long? (Y-years, M-months, D-days)	Taking currently?
1				Y M D	Yes No
2				Y M D	Yes No
3				Y M D	Yes No
4				Y M D	Yes No
5				Y M D	Yes No
6				Y M D	Yes No
7				Y M D	Yes No
8				Y M D	Yes No
9				Y M D	Yes No
10				Y M D	Yes No
11				Y M D	Yes No
12				Y M D	Yes No

SIDE EFFECTS

	Medications	Average Daily Dosage (mg)	Disease/ condition	How long? (Y-years, M-months, D-days)	Taking currently?
13				Y M D	Yes No
14				Y M D	Yes No
15				Y M D	Yes No
10				Y M D	Yes No
11				Y M D	Yes No
12				Y M D	Yes No
13				Y M D	Yes No
14				Y M D	Yes No
15				Y M D	Yes No
16				Y M D	Yes No
17				Y M D	Yes No
18				Y M D	Yes No
19				Y M D	Yes No
20				Y M D	Yes No
21				Y M D	Yes No
22				Y M D	Yes No
23				Y M D	Yes No
24				Y M D	Yes No

Specific Inquiry

Now we would like to ask you about any symptoms you have had during the LAST TWO WEEKS (unless another period is indicated). Some of these symptoms could be side effects caused **by your medication(s)**.

A side effect is an **undesirable effect of your medication**. It can be, for example, nausea, headache, skin rash or other symptoms that cause you pain, discomfort, physical or emotional suffering. You can assume that the problem is caused by your medication(s) if:

1. It begins or significantly increases when you begin to take your medication or increase your medication dosage
OR
2. It decreases or disappears when you decrease the dosage of your medication or stop taking your medication
OR
3. It starts or increases after you finish taking your medication
OR
4. It starts when you decrease the dosage of your medication or stop taking it, but it is not related to increased activity of your disease.

PLEASE ANSWER THE FOLLOWING QUESTIONS FOR EACH OF THE SYMPTOMS LISTED IN THE TABLE BELOW:

1. **During the LAST TWO WEEKS**, did you have any of the symptoms or health problems listed in the table below? In the **'Presences'** column, circle "No" if you **have not had this symptom at all**. You can stop here and go to the next symptom then.
2. If you have had this symptom during the last two weeks please grade the amount of distress caused by this symptoms in the column **'Distress'** as either: 'none', 'mild', 'moderate' or 'severe'
 - **None:** If this symptom despite on its presence was not bothersome for you at all
 - **Mild:** If you can easily ignore it or it was mildly bothersome
 - **Mod (Moderate):** If it was tolerable for you or moderately bothersome
 - **Sev (Severe):** If it was hardly tolerable or intolerable for you or it was very bothersome
3. Do you think that this symptom that you have had could be a side effect of your medication(s)? Please circle 'No', 'NS' (Not sure), or 'Yes' in the **'Side Effect Column'**.
4. If you answered 'Yes' or 'Not Sure' on the previous question, do you know which medication(s) may be causing this symptom? Circle the number in the **'Medications'** column that corresponds with the number of the medication(s) on the medication list which you filled out in the medication list of this survey, or choose "DK" (do not know).

	Symptoms	Presence	Distress (Mod – moderate, Sev – severe)	Side Effect (NS – not sure)	Medications (DK – do not know)
100	GENERAL				
101	Fever or chills	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
102	A feeling of general discomfort and being unwell.	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
103	Swollen glands	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
104	High blood pressure (if measured)	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
105	Low blood pressure (if measured)	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK

SIDE EFFECTS

	Symptoms	Presence	Distress (Mod – moderate, Sev – severe)	Side Effect (NS – not sure)	Medications (DK – do not know)
106	Appetite decrease	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
107	Appetite increase	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
108	Weight loss	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
109	Weight gain	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
110	Higher than normal body weight	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
111	Lower than normal body weight	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
200	SKIN AND HAIRS	Presence	Distress	Side Effect	Medications
201	Acne	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
202	Itching	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
203	Rash or hives	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
204	Other skin irritation or inflammation	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
205	Skin bruising	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
206	Heavy bleeding or oozing from cuts or wounds	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
207	Impaired skin healing	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
208	Increased sweating	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
209	Oily skin or hairs	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
210	Dry skin	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
211	Severe sunburn or skin photosensitivity	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
212	Skin flashing (red skin)	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
213	Blue, cold or pale skin	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
214	Skin stretching	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
215	Skin shriveling and thinning	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
216	Yellowing of the skin	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
217	Increased pigmentation (darkening) of the skin	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
218	Excessive hair growth	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
219	Hair loss	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
300	HEAD				
301	Headache	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK

	Symptoms	Presence	Distress (Mod – moderate, Sev – severe)	Side Effect (NS – not sure)	Medications (DK – do not know)
302	Face swelling or puffy face	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
303	Face pain	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
304	Dizzy spells when getting up from the bed or standing up	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
305	Feeling of spinning or rota- ting, or that things around you are rotating	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
306	Other lightheadedness or dizziness	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
400	<i>EYES AND VISION</i>	Presence	Distress	Side Effect	Medications
401	Blurred vision	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
402	Double vision	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
403	Dry eyes	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
404	Eye irritation or pain	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
405	Excessive eye discomfort in bright light	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
406	Red eyes	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
407	Yellowing of the eyes	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
408	Worsened eyesight	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
409	Abnormal movements of the eyeballs	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
500	<i>EARS AND HEARING</i>	Presence	Distress	Side Effect	Medications
501	Decreased hearing	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
502	A ringing or buzzing sound in the ears or head	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
503	Earache	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
504	Feeling of pressure or full- ness in the ears	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
505	Ear discharge	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
600	<i>SLEEP</i>	Presence	Distress	Side Effect	Medications
601	Difficulty falling asleep	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
602	Interrupted sleep	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
603	Day sleepiness	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK

SIDE EFFECTS

	Symptoms	Presence	Distress (Mod – moderate, Sev – severe)	Side Effect (NS – not sure)	Medications (DK – do not know)
604	Increased duration of sleep	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
605	Decreased duration of sleep	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
606	Nightmares or vivid dreams	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
700	<i>MOOD AND MIND</i>	Presence	Distress	Side Effect	Medications
701	Depression	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
702	Abnormally elevated mood	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
703	Mood swings	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
704	Anxiety, inner unrest or tension	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
705	Tiredness or fatigue	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
706	Memory problems	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
707	Concentration difficulty	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
708	Loss of consciousness	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
709	No motivation or feeling of indifference	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
710	Irritability	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
711	Addiction or dependence on medication	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
712	Sedation (a dulled level of alertness during the day)	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
713	Confusion (a lack of clear and orderly thought and behavior during the day)	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
800	<i>MOUTH</i>	Presence	Distress	Side Effect	Medications
801	Dry mouth	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
802	Increased thirst	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
803	Sore tongue or mouth, mouth ulcers	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
804	Bleeding gums	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
805	Other gum problems	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
806	Worsening dental problems	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
807	Increased spit (salivation) in the mouth	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
808	Bad taste in the mouth or taste abnormality	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK

	Symptoms	Presence	Distress (Mod – moderate, Sev – severe)	Side Effect (NS – not sure)	Medications (DK – do not know)
900	<i>NOSE AND THROAT</i>				
901	Nasal drying or burning	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
902	Nose bleeds	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
903	Nasal congestion or runny nose	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
904	Throat irritation or sore throat	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
905	Hoarseness	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1000	<i>CHEST AND BREATHING</i>	Presence	Distress	Side Effect	Medications
1001	Coughing	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1002	Chest pain	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1003	Shortness of breath	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1004	Wheezing	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1005	Rapid heartbeat	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1006	Slow heartbeat	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1007	Irregular heartbeat	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1009	Sneezing	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1010	Yawning (more frequently than usual)	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1011	Hiccups (more frequently than usual)	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1012	Excessive phlegm (mucous) production	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1013	Blood in the phlegm (mucous)	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1100	<i>DIGESTION AND STOMACH</i>	Presence	Distress	Side Effect	Medications
1101	Difficulty swallowing	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1102	Nausea	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1103	Vomiting	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1104	Heartburn	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1105	Abdominal (belly) pain, discomfort or cramping	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1106	Diarrhea	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1107	Constipation	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK

SIDE EFFECTS

	Symptoms	Presence	Distress (Mod – moderate, Sev – severe)	Side Effect (NS – not sure)	Medications (DK – do not know)
1108	Blood in the stool	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1109	Other stool discoloration	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1110	Bloating (excessive gas in the bowel)	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1111	Abdominal (belly) swelling	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1112	Rectal itching or pain	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1200	<i>MOVEMENTS</i>	Presence	Distress	Side Effect	Medications
1201	General weakness	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1202	Restlessness, inability to sit still	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1203	Slow movements	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1204	Slurred speech	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1205	Muscle spasms	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1206	Epileptic seizures	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1207	Instability when walking	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1208	Falls	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1209	Tremors (hand, head or leg shaking)	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1210	Clumsiness, shaky and unsteady movements	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1211	Abnormal involuntary mo- vements (like twitching, tics)	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1212	Muscle rigidity or stiffness (difficult to begin move- ments)	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1300	<i>BONES AND JOINTES</i>				
1301	Back pain	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1302	Joint pains	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1303	Joint swelling	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1304	Hand or arm swelling	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1305	Leg swelling	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1306	Muscle pains or cramps	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1307	Numbness, tingling, or a burning feeling in the arms or legs	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK

	Symptoms	Presence	Distress (Mod – moderate, Sev – severe)	Side Effect (NS – not sure)	Medications (DK – do not know)
1308	Joint stiffness	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1309	Bone fractures	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1310	Bone pain	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1311	Arm pain or cramps	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1312	Leg pain or cramps	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1400	<i>URINATION</i>	Presence	Distress	Side Effect	Medications
1401	Painful urination	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1402	Increased frequency of urination	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1403	Blood in the urine	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1404	Other changes in the color of urine	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1405	Difficulty urinating or urinary retention	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1406	Urinary incontinence, involuntary dribbling or leaking of the urine	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1407	Significantly smaller volume of urine than usual	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1408	Significantly larger volume of urine than usual	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1500	<i>SEXUAL AND REPRODUCTIVE HEALTH</i>	Presence	Distress	Side Effect	Medications
1501	Increased sexual desire	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1502	Decreased sexual desire	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1503	Genital discomfort, itching or pain	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1504	Problems with achieving orgasm	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1505	Pain during sexual intercourse	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1506	Nipple discharge	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
The three following symptoms on this page are ONLY FOR MEN					
1507	Problems with performing sexual act (disorder of erection)	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1508	Abnormal, continuous and painful erections	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1509	Excessive development of the breasts	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK

SIDE EFFECTS

	Symptoms	Presence	Distress (Mod – moderate, Sev – severe)	Side Effect (NS – not sure)	Medications (DK – do not know)
The symptoms on this page are ONLY FOR WOMEN. If you are a man, please go to the next section (OTHER SYMPTOMS)					
1510	Breast pain	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1511	Breast swelling	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1512	Vaginal dryness	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1513	Abnormal vaginal discharge	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
Please, when answer if you had the following problems during the last two months :					
1514	Abnormal absence of periods	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1515	Irregular vaginal bleeding	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1516	Heavy vaginal bleeding	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1517	Decreased amount or duration of menstrual flow	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1518	Premenstrual tension	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
1519	Menstrual cramps	No Yes	None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK

OTHER SYMPTOMS. During the last two weeks, did you have any other health problems that are not mentioned above? Any other pain? Injury? Bleeding? Swelling? Unpleasant sensation or discomfort in your body? Disruption of normal functions or appearance of your body? If yes, please, describe them below. If no, go to the next page.

1500	OTHER SYMPTOMS	Distress (Mod – moderate, Sev – severe)	Side Effect (NS – not sure)	Medications (DK – do not know)
1		None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
2		None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
3		None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
4		None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
5		None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
6		None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
7		None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK

8		None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
9		None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
10		None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
11		None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
12		None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
13		None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK
14		None Mild Mod Sev	No NS Yes	1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 DK

SIDE EFFECTS

General Inquiry

- Have you had any side effects from your medications during the last two weeks? Please, circle your answer.

No Yes

- If you answer **No**, you can stop here. If you had some side effects, please select FIVE side effects caused by your medications that were most bothersome for you.
- If you have two or several symptoms, that are closely related, happen at the same time, and are about the same for you (e.g., weight gain and increased appetite, nausea and vomiting, or dry mouth and increased thirst), please, place them in one line.

#1	
#2	
#3	
#4	
#5	

Now please answer the following questions about the amount of distress that you suffer from these side effects and the number of days that you suffered during the last two weeks. Please, circle your answer. If it is difficult to answer about the duration of some side effects, such as weight gain, dependence on medication, or menstrual problems, please circle 'NA' (not applicable).

SE	DISTRESS: How much did you suffer from this symptom either emotionally or physically? Use color card 1 (yellow-red) to answer.	DAYS: How many days did you have this side effect DURING THE LAST TWO WEEKS ?
1	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 NA
2	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 NA
3	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 NA
4	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 NA
5	0 1 2 3 4 5 6 7 8 9 10	0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 NA

Overall Severity

Now we would like to know your opinion about all the side effects of your medications DURING THE LAST TWO WEEKS. **Circle your answers.**

1. How much did you suffer from all of your side effects either emotionally or physically?
Use color card 1 (yellow-red) to answer..

0 1 2 3 4 5 6 7 8 9 10

2. How much did the SIDE EFFECTS disrupt your normal life activities during the last two weeks?
Use color card 2 (green-blue) to answer.

0 1 2 3 4 5 6 7 8 9 10

Instructions

The scale is intended for use in potentially any group of patients taking medications. Currently it has been used in three groups of patients (with psychiatric disorders, asthma, and inflammatory bowel disease). The scale is administered under a supervision of a trained research assistant. The final scores of the scale are calculated using the following algorithm (See Table 1). The color cards should be separated and

Table 1. Structure and final scores of the side effect survey used in the study.

Scale	What Measures	Final Scores
Specific Inquiry	Patients are asked to select from the symptom checklist the symptoms that they had during the last two weeks, which of them could be medication side effects, and which medications could cause them.	Side effects index (SEI) calculated as a sum of all rating of individual side effects (not including symptoms that patients do not attribute as side effects or not sure if it is caused by their medication) in the symptom checklist. The potential score ranges from 0 (no side effects) to 450 (if a patient has all listed symptoms as side effects in a severe degree)
General Inquiry	Patients are asked to name their five most distressing medication side effects, and estimate the severity of distress they experienced from them (on 0 to 10 scale) and how many days they had them during the last two weeks (from 0 to 14 days).	Side effect-related general distress (GDIS) calculated as a sum of individual estimates of distress: from 0 (no side effects) to 50 (very severe side effects). General duration of Side Effects (GDUR) calculated as a sum of individual estimates of duration in days: from 0 to 70.
Overall Rating	Patients are asked to rate their medication side effects overall: amount of distress and disability they caused them.	Two scores: 0-10 overall distress (ODIST), and 0-10 overall disability (ODISA).

COLOR CARD 1: Select the number of your choice

0	None Not bothersome at all
1	Minimal Easy to ignore or minimally bothersome
2	
3	Mild Mildly bothersome
4	
5	Moderate Tolerable or moderately bothersome
6	
7	Severe Hardly tolerable or very bothersome
8	
9	Very severe Intolerable or extremely bothersome
10	

COLOR CARD 2: Select the number of your choice

0	None Had no negative impact on your activities.
1	Minimally Minimally difficult or disrupted
2	
3	Slightly Slightly difficult or disrupted
4	
5	Moderately Moderately difficult or disrupted
6	
7	Severely Very difficult or disrupted
8	
9	Very severely Extremely difficult or impossible to do
10	