

**STUDY REPORT SUMMARY**

**ASTRAZENECA**

**PHARMACEUTICALS**

**FINISHED PRODUCT:** Not applicable

**ACTIVE INGREDIENT:** Not applicable

**Study No: NIS-CFR-XXX-2012/1**

**LEVEL OF CONCORDANCE BETWEEN PATIENTS PERCEPTION AND PHYSICIANS ASSESSMENT OF CARDIOVASCULAR RISK**

**Developmental phase:** Not applicable

**Study Completion Date:** 19/05/2014

**Date of Report:** 03/04/2015

**OBJECTIVE:**

Primary objective

To compare patients' perception of their cardiovascular risk (CVR) before reading the Medical Information Leaflet (MIL) on cardiovascular risk factors with physicians' assessment of CVR.

Secondary objectives

- a) To describe patients' perception of CVR before and after reading the Medical Information Leaflet
- b) To assess the level of concordance (before and after reading the Medical Information Leaflet) between patients' perception of CVR and their actual CVR

c) To describe the profiles of those patients whose self-assessment of their CVR (before reading the Medical Information Leaflet) is concordant with their actual CVR, and to compare these with the profiles of patients whose self-assessments are discordant

d) To describe the risk factors (RFs) considered by those patients whose self-assessment of their CVR (before reading the Information Leaflet) is concordant with their actual CVR, and to compare these with the cardiovascular risk factors (CVRFs) considered by patients whose self-assessments are discordant.

## **METHODS:**

This is a national, non-interventional, prospective study to be conducted on a nationwide population sample representative of 200 general practitioners from 30 October 2013 to 18 April 2014. Epidemiology Research Associates (ERAs) will be dedicated to this study and will provide logistic assistance to the physicians.

The physicians will enroll for a day the first 4 patients seen in medical visits who meet the screening criteria (50 years old and over and in primary prevention of cardiovascular events without a pathological vascular sonography). A sample of 786 patients were included and analyzed in this survey.

Data will be collected during face-to-face visits on a case report form (CRF) and self-administered questionnaires (to be completed by the physician and the patient, respectively).

Physicians and patients fill out a questionnaire; the patients had to fill out a first part of questionnaire before reading the MIL and the second part, after reading it.

Patients had to assess their own cardiovascular risk before and after reading the MIL. The physician assessed the cardiovascular risk for each patient. For both the risk was assessed

according to a qualitative scale (low/moderate/high). Moreover, physicians provided some clinical information in order to calculate an objective score with the SCORE scale.

### **Statistical analysis**

Monovariate analysis. Quantitative data were described by the means and standard deviations (SD) and categorical data by the numbers in each category and corresponding percentages.

All comparisons between two populations were carried out by the Student's t test for quantitative data, and by the Z test and the Chi-square test for the comparison of percentages and numbers, respectively, in the case of categorical data. Differences between patients population aged 65 years old or younger and patients population older than 65 years were considered statistically significant when the probability value was less than 0.05 (bilateral test).

## **RESULTS**

Among 786 patients, 46% of them are men and 54% are women, 65 years old and older in average (SD 9.6), 235 aged 65 years or less and 245 older than 65. The cardiovascular risk according the physicians' assessment was low moderate, high for 37%, 43%, 20%.

### **Principle objective:**

The rate of consistency between risk perceptions made by physicians and those made by patients is 38%, with no significant difference according to patient age (39% consistency amongst those 65 years or younger and 38% amongst those over 65).

## Secondary Objectives

After reading the MIL, the majority of patients retain the same perception of their risk that they held before (table 1).

	Before reading	After reading
<b>Aged 65 years or less</b> n=235		
Low	31%	25%
Moderate	39%	44%
High	17%	26%
No answer	13%	5%
<b>Older than 65</b> n=245		
Low	27%	26%
Moderate	44%	53%
High	11%	13%
No answer	18%	8%

Table 1: Patient assessment CVR before and after the reading MIL

The 4th axis of analysis focused on the differences in profiles between patients whose self-assessment is consistent with their actual CVR (n=77) and patients whose self-assessment is inconsistent with their actual CVR (n=127).

Before reading the MIL, patients of 65 years or younger whose self-assessment is consistent with their actual CVR are more often regular smokers (29% vs 13%), patients without early coronary disease (75% vs. 61%). In contrast, patients whose self-assessment is inconsistent with their actual CVR are more likely to have left their primary studies (24% vs. 13%), more often suffer from treated type 2 diabetes (31% vs 13%) and more likely to have kidney disease (8% vs. 1%).

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Concerning patients over 65, before having read the MIL, it's women who show greater consistency between their self-assessment and their actual CVR (66% vs 52%). On the other hand, it's men who are more likely to show inconsistencies between their self-assessment and actual CVR (48% vs. 34%), more frequently suffering from non-treated type 2 diabetes (7% vs. 1%) and treated type 2 diabetes (32% vs. 7%).

Lastly, the final analysis focused on evaluating the factors increasing cardiovascular risk before and after reading the MIL. The 4 principal factors of risk cited don't change after reading the MIL. Nevertheless, we note a relative consideration for age (+3 points) concentrated on those over 65, a slight decrease in importance given to cardiac pathologies (-2 points) and to unhealthy lifestyles (-4 points).