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Comparison of two methods of presenting risk information to patients about the side effects of medicines.

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Abstract

OBJECTIVE: To determine whether the use of verbal descriptors suggested by the European Union (EU) such as "common" (1-10% frequency) and "rare" (0.01-0.1%) effectively conveys the level of risk of side effects to people taking a medicine.

DESIGN: Randomised controlled study with unconcealed allocation.

PARTICIPANTS: 120 adults taking simvastatin or atorvastatin after cardiac surgery or myocardial infarction.

SETTING: Cardiac rehabilitation clinics at two hospitals in Leeds, UK.

INTERVENTION: A written statement about one of the side effects of the medicine (either constipation or pancreatitis). Within each side effect condition half the patients were given the information in verbal form and half in numerical form (for constipation, "common" or 2.5%; for pancreatitis, "rare" or 0.04%).

MAIN OUTCOME MEASURE: The estimated likelihood of the side effect occurring. Other outcome measures related to the perceived severity of the side effect, its risk to health, and its effect on decisions about whether to take the medicine.

RESULTS: The mean likelihood estimate given for the constipation side effect was 34.2% in the verbal group and 8.1% in the numerical group; for pancreatitis it was 18% in the verbal group and 2.1% in the numerical group. The verbal descriptors were associated with more negative perceptions of the medicine than their equivalent numerical descriptors.

CONCLUSIONS: Patients want and need understandable information about medicines and their risks and benefits. This is essential if they are to become partners in medicine taking. The use of verbal descriptors to improve the level of information about side effect risk leads to overestimation of the level of harm and may lead patients to make inappropriate decisions about whether or not they take the medicine.