

Communicating the risk of side effects to patients: an evaluation of UK regulatory recommendations.

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Abstract

BACKGROUND: All licensed medicines in the European Union must be provided with a Patient Information Leaflet that includes a list of all known side effects. Among patients who read the leaflet, the side effects section is the most often read. A UK government regulatory publication recommends providing medicine side effect risk information in a combined format, using verbal descriptors accompanied by numerical information.

OBJECTIVES: This study, with users of an existing popular patient information website, investigates the effectiveness of presenting medicine side effect risk information in different forms.

DESIGN: Participants were randomly allocated to one of the three formats for representing risk information (verbal descriptors, e.g. 'common'; absolute frequencies, e.g. 'less than 1 in 10 people'; and a combination of verbal descriptors and frequency bands, e.g. 'common (affects less than 1 in 10 people)').

METHODS: Participants (n = 187) were recruited from users of the Cancer Research UK patient information website. They were asked to imagine that they had to take a cancer treatment (tamoxifen), estimate the risks of four side effects occurring, and complete Likert scales relating to their satisfaction with the information supplied and perceived likelihood of various outcomes.

RESULTS: Those in the absolute frequency format demonstrated greater accuracy in estimating the likelihood of having two of four side effects than the other two formats. They were also more accurate at estimating the likelihood of themselves or the average person having any side effect from taking tamoxifen. Participants in the absolute frequency format rated the risk to health from tamoxifen as lower than those in the other two formats, were more satisfied with the information they received than those in the verbal format, and felt there would be less impact of the information on tamoxifen use than those in the combined format.

CONCLUSIONS: These findings fail to confirm that the recommended use of combined descriptors for medicine side effects is unequivocally superior to absolute frequency alone. They also add weight to the growing body of research highlighting the deficiencies in using verbal descriptors for conveying side effect risk, and the strength of using absolute frequency descriptors.