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Explaining all without causing unnecessary harm: Is there scope for positively framing medical risk information?

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Declaration of interest

We declare no conflicts of interest.

Contributor statement

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Highlights

- Clinicians in the UK are now legally required to tell patients about every risk involved in any prescribed medical treatment
- Informing patients of all risks such as side-effects however, may unintentionally increase the incidence of the very side-effects that are warned about
- Positively framing risk information could be a solution to this dilemma, and we argue this should also be considered by other countries

Abstract

Clinicians in the United Kingdom are now legally obliged to tell patients about every risk involved in prescribed medical treatments. Although important for informed consent, warning patients of risks such as side-effects can increase the incidence of these very side-effects, through the nocebo effect. Positively framing risk information could be a potential solution to this dilemma, and preliminary data has shown it is effective in healthy volunteers receiving a sham drug. Future research is needed to test its effectiveness in a clinical population.

Keywords: Risk communication; positive framing; side-effects; nocebo effects

In 2015 the UK Supreme Court passed a challenging legal judgement [1] requiring clinicians to tell patients about every risk involved in any prescribed medical treatment, and making clear that clinicians do not have the power to decide what information a patient should be given. This is an important judgement from a communication point of view, as explaining the risks involved in medical treatments is necessary in order for patients to make informed decisions about whether to adhere to a certain medicine regimen or agree to a medical procedure. The ruling was based upon the case of birthing complications arising from a patient's medical condition which was not initially disclosed. The risk information however for any prescribed medical treatment is wide-ranging and complications only make up a part of this. Another important part which is particularly essential for prescribed medications, concerns side-effects. This poses a dilemma. Although provision of information about side-effects is a necessary component to lead to informed consent, at the same time it may unintentionally increase the incidence of the very side-effects that are warned about, through a psychological phenomenon known as the nocebo effect [2].

Nocebo effects are defined as the experience of symptoms in response to a sham exposure [3] and are thought to explain many of the side-effects that patients experience and attribute to their medications [2]. Nocebo effects can occur to any medication whether available over-the-counter or prescribed for a specific medical condition. They tend to manifest as non-specific symptoms similar to those that people experience in everyday life, e.g. headache, nausea, fatigue, and which are then attributed to the medication [4]. They primarily occur through negative expectations, if patients expect to get side-effects from a sham noxious exposure they will have an increased chance of experiencing them [5]. These expectations can be generated from a variety of sources such as media reports, conversations with friends and family, and warnings of side-effects in doctor-patient consultations or patient information

leaflets (PILs). Most recently, for example, media attention has highlighted the high rates of statin-associated side-effects such as muscle pain reported in clinical practice, despite the low rates observed in clinical trials [6]. This discrepancy could be nocebo-related, driven by warnings about adverse effects communicated by clinicians and by media reports, elevating anxiety, expectation and hence experience of side-effects among patients [7].

Side-effects can be a worrisome burden to patients, decreasing their well-being and affecting medication adherence and the resulting therapeutic benefit, as has been shown in antiretroviral therapy for human immunodeficiency virus [8]. They are also an important determinant of non-adherence for all types of medication [9]. It has been estimated that over 200,000 patients stopped taking their statin medication in the 6 months after adverse media coverage about statin side-effects, and as a result we can expect more than 2,000 additional cardiovascular events across the UK over the next decade [10]. As such, not only do side-effects affect patients but they also have ramifications for healthcare services, costing the NHS billions in additional healthcare costs [11] as the result of lowered adherence.

One way to reduce side-effects is to reduce nocebo effects. The current literature discusses withholding side-effect information in an effort to reduce expectations and therefore nocebo induced side-effects [12].Even though this process might reduce side-effects, it does not adhere to the ruling of the UK Supreme Court. One potential resolution to this apparent impasse in the UK is the use of positive framing. The framing effect represents a type of cognitive bias, in which people react to a described probability in different ways depending on how it is presented; e.g. as a loss (negative) or as a gain (positive) [13]. This use of message framing has been extensively studied in a number of decisional domains and has

been shown to influence consumer choice [14], preferences for therapies [15], and engagement in health behaviours [16].

Currently medication side-effect information must be communicated in PILs, listing side-effects in terms of how common they are, with the associated number of people who will be affected (e.g. 'Common, 1 in 10 people will be affected'). Reframing side-effects positively would involve presenting side-effect risk information in terms of the number of people who will not be affected (e.g. 'Uncommon, 9 in 10 people will not be affected'). Positive framing is an example of libertarian paternalism [17], which often uses 'nudge' techniques to guide people's choices in a way that will improve outcomes, without withholding any information, and therefore without infringing informed consent or patient autonomy. In a randomised controlled trial of 203 healthy volunteers we found that positively framing side-effects in PILs compared to current practice significantly reduced the proportion of participants experiencing symptoms and attributing them to a sham drug (39.2% in the positively framed condition compared to 54.5% in the control condition, OR= 0.66, 95% CI 0.46,0.93) [18].

Given that the current way we communicate side-effect information in PILs in the UK and throughout Europe has been shown to result in people grossly overestimating the risk of side-effects [19], positive framing has the potential to be a cost-effective intervention that could be easily introduced into PILs in order to rectify this. Future research is needed to test this use of positive framing within a clinical population and to assess peoples' understanding of positively framed side-effect information to see if it leads to more realistic expectations of side-effects compared to the current way we communicate. It is also possible interactions may exist, for example with people who have higher health literacy being less susceptible to positive framing than those with lower health literacy.

Regardless, since the UK is now moving into an era where the full presentation of risk information is mandatory, it will be important to find ways of doing this without jeopardising important therapeutic outcomes. Although this is less of an issue for other countries at this time, the use of positively framing side-effect risk should also be considered beyond the UK when communication about side-effects is necessary, in order to minimise the risk of nocebo effects occurring.

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