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## Influences on older people's decision making regarding choice of topical or oral NSAIDs for knee pain: qualitative study

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### ABSTRACT

**Objective** To explore the factors that influence older people's decision making regarding use of topical or oral ibuprofen for their knee pain.

**Design** Qualitative interview study nested within a randomised controlled trial and a patient preference study that compared advice to use oral or topical non-steroidal anti-inflammatory drugs (NSAIDs) for knee pain in older people. **Setting** 11 general practices.

**Participants** 30 people aged ≥50 with knee pain.

**Results** Participants' decision making was influenced by their perceptions of the associated risk of adverse effects, presence of other illness, nature of their pain, advice received, and practicality. Although participants' understanding of how the medications worked was sometimes poor, their decision making about the use of NSAIDs seemed logical and appropriate. Participants' model for treatment was to use topical NSAIDs for mild, local, and transient pain and oral NSAIDs for moderate to severe, generalised, and constant pain (in the absence of other more serious illness or risk of adverse effects). Participants showed marked tolerance and normalisation of adverse effects.

**Conclusion** Participants had clear ideas about the appropriate use of oral and topical NSAIDs. Taking such views into account when prescribing may improve

adherence, judgment of efficacy, and the doctor-patient relationship. Tolerance and normalisation of adverse effects in these patients indicate that closer monitoring of older people who use NSAIDs might be needed.

### INTRODUCTION

In a randomised controlled trial and parallel patient preference study we found that advice to, or the decision to, preferentially use topical or oral NSAIDs for knee pain had equivalent effects on the pain.<sup>1-3</sup> To help set the results of that study in context we conducted a nested qualitative study to examine what influenced participants' decisions about taking part in the study and their use of topical or oral ibuprofen for their knee pain.

### METHOD

Details of our methods and the clinical results are available elsewhere.<sup>1-3</sup> Participants for the qualitative study came from 11 practices across the UK.

**Rationale behind the decisions**—We explored the rationale behind patients' decisions to take part in the preference study or the randomised trial and, for those in the preference study, their decisions to choose topical or oral medication. We conducted telephone

interviews with a purposive sample of participants according to which study they had joined and their choice or allocation of treatment. These interviews lasted about 45 minutes.

*Patients' experiences of and beliefs about adverse effects*—A second purposive sample was interviewed according to the participants' choice of treatment or allocated treatment in the trial and whether it had had an adverse effect.<sup>3</sup> These interviews took place in the participants' home or at their general practice; they lasted about one hour. We aggregated information from both groups for the analysis.

*Interview process*—We developed topic guides, DC undertook the preference interviews, and YA undertook the interviews on adverse effects. All the interviews were tape recorded, anonymised, and transcribed.

*Data analysis*—We developed a thematic framework by mapping ideas and opinions articulated in the transcripts and conflating these into sub-themes and themes (see [bmj.com](http://bmj.com) for further details).

## RESULTS

We conducted 30 interviews, 15 telephone interviews about medication preference and 15 face-to-face interviews about adverse effects. Eighteen participants were men. Sixteen participants used topical NSAIDs and 14 used oral NSAIDs. We interviewed five participants aged 50-60 years, 16 aged 61-70, and 10 aged over 70.

We grouped the 14 sub-themes into five themes: the nature of pain, mechanism of action and resulting effectiveness of medications, risk assessment of adverse effects, practicality of use, and advice and information about NSAIDs.

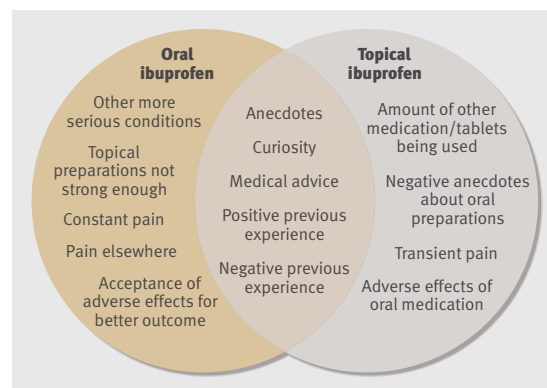
### Nature of pain

Constant pain was believed to be caused by structural, irreversible damage to bones and cartilage and was therefore considered to require stronger medication such as oral NSAIDs. Transient pain was believed to be caused by weakness in the knee and personal responsibility for pain—for example, from overuse. Those with transient pain considered their pain less degenerative and thought that topical preparations were preferable.

### Mechanism of action and resulting effectiveness of treatment

Topical preparations were considered to have a localised rather than a generalised effect and would take effect more quickly. Participants' beliefs about how topical preparations worked were enhanced by the visual feedback of the topical preparation disappearing into the skin. Topical preparations were assumed to have a lower dose of the active ingredient and were considered less toxic. This appealed to patients with digestive and other systemic problems.

Oral preparations were thought to have a more general rather than a local effect. Participants were less



Factors influencing patient preferences for topical or oral ibuprofen

confident about understanding the mechanism of action of the tablets. Oral preparations were seen as toxic to everywhere but the knees, and more powerful than the topical preparations. Those with multiple sites of pain were happier to take oral preparations because the drug might help other areas while it circulated around the body.

“I’d be rubbing the stuff all over me if I had gel” (patient 9).

Neither route of administration was expected to be a cure. Topical preparations were considered effective in the short term for mild to moderate knee pain and oral preparations in the medium to long term for severe knee pain. The exception was the presence of additional illness. Participants then worried about the number of drugs taken and the interaction between them.

### Risk assessment of adverse effects

Nearly all were sceptical about whether it was possible to experience adverse effects from topical preparations. Oral preparations, however, were considered to be harmful to those parts of the body that were not in pain.

Mild adverse effects that were seen as tolerable and were acceptable as a risk included things like a rash, an “acidic stomach,” or a mild change in bowel habits—for example, diarrhoea once a week. Participants would not tolerate adverse effects if they were continuous and unmanageable; these included things like swelling, headache, dizziness, or visual problems.

Because they were part of a trial, our participants may have been more willing to tolerate adverse effects. Participants did not necessarily communicate these symptoms to their general practitioner.

### Practicality of use

The practicality of taking the drug was a consideration for those in the preference study. Some wanted a simple, convenient “quick fix” and others did not want to deal with the time and “mess” of the topical preparations.

**WHAT IS ALREADY KNOWN ON THIS TOPIC**

Non-steroidal anti-inflammatory drugs (NSAIDs) are effective but can produce serious adverse effects

For older patients with knee pain advice to use oral or topical NSAIDs results in equally effective relief

Patients may be prepared to forgo some effectiveness of treatment to avoid adverse effects

**WHAT THIS STUDY ADDS**

Choice of topical or oral treatment depends on perceived risk of adverse effects, nature of pain, the presence of other illness, practicality, and medical advice

General practitioners' and patients' perceptions of the importance of adverse effects from oral NSAIDs may differ

Closer monitoring for potential adverse effects is required

**Advice and information about NSAIDs**

Advice and "information" was obtained through consultations and from those with medical knowledge, narratives from others, advertisements, promotional literature and articles in magazines. The validity and accuracy of information was rarely questioned. Patients generally trusted the advice of their general practitioner implicitly; this had the effect of increasing how much they would tolerate adverse effects.

"If it was a doctor who said, 'We'll try you on so and so, I would try it'" (patient 7).

We found that participants' comprehension depended on the use of lay terminology and effective face-to-face communication. Few participants remembered the content of written instructions and many actively avoided reading about adverse effects for fear of experiencing them through the power of suggestion. Participants believed that because they were in a study they would be well looked after.

The figure shows the main factors that influenced people's choices about NSAID medication.

**DISCUSSION**

Participants with mild transient knee pain, considered to be caused by weakness or mild degeneration, preferred treatment with topical preparations. Oral medication was preferred by those with more serious, constant, or widespread pain. Our quantitative data also supported this finding.<sup>2</sup> Exceptions to preferring oral medication were the presence of more serious illness and intolerance of oral treatment. The four main issues identified from our emergent concepts are described below.

**Participants' lack of understanding and knowledge**

Participants' understanding about pain and the mode of action of treatment was generally limited. Although we thought we had presented adequate information about the study, participants were still unclear about it and about the drugs used.<sup>4-6</sup> This has implications for the consent process if participants are not making informed decisions about joining studies of this nature.

**Trust and the research process**

Like others, we found older people were relatively trusting of their general practitioners' advice and decisions about their health care,<sup>7</sup> and had a high level of trust in the trial process. In addition, participants tended to normalise general malaise. This, coupled with poor understanding of important adverse effects, could lead to an increase in serious adverse effects and unplanned hospital admissions. In older people this is compounded by the increased prevalence of comorbidities and the high proportion taking multiple medications.<sup>8</sup> Our results add to a growing body of research that indicates a need to monitor elderly patients closely to ensure that reported "normalised" and "accommodated for" adverse effects are really minor.<sup>9</sup>

**Perception of risk from NSAIDs**

Study participants reported indigestion, fatigue, and breathlessness but did not necessarily associate them with NSAID use. There seem to be differences between perceptions of practitioners and patients of adverse effects of oral NSAIDs.<sup>10-12</sup> The risk of adverse effects influences choice; patients may often opt for less effective treatments first to avoid the toxicity of other more effective medication, which has implications for how their use and adverse effects are monitored.<sup>13</sup>

**Education**

Increasing patients' knowledge through education about the causes of knee pain, mode of action of treatment, and adverse effects improves both adherence and informed choice.<sup>5,14</sup>

**Strengths and limitations**

Our sample was selected on the basis of the study they participated in and, for some, the presence of adverse effects. They were all English speaking and predominantly white British. Both telephone and face-to-face interviews produced a large amount and range of quality data, but we have to recognise that this research is based on a fairly healthy pre-screened population of older people with knee pain. However, the trial they participated in was a pragmatic one and the issues raised are congruent with those found in some other studies on this topic.<sup>12,15</sup>

**Conclusion**

Patients' decisions about topical or oral treatment for their knee pain were logical and based on the nature of pain, risk of adverse effects, advice, and practicalities. Practitioners need to monitor their patients appropriately for adverse effects. Shared decision making is preferable to encourage adherence to the treatment process and positive perception of the drug used.

We thank Lynette Edwards for comments on earlier drafts of this paper and to all our interviewees for giving up their time for this study. Full details of the study team are given elsewhere.<sup>4</sup>

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## Mannequins have feelings too

In the world of reality television, C-list and would-be celebrities act as guinea pigs for whatever social experiment takes the producer's fancy. Extended periods of isolation, food rationing, verbal abuse, exposure to potentially harmful animals—nothing, it seems, is deemed ethically out of bounds.

Thankfully, the ethical guidelines governing medical research bear no resemblance to those apparently operating in television. But, as a clinician struggling to get my first research project off the ground, I am wondering if we haven't drifted too far to the other extreme of "ethical correctness."

My particular study is to assess the ability of paramedics to use a new airway device. The aim is to establish that the device is suitable for paramedics in a simulated scenario using a mannequin, a pilot study to a future trial with live participants. There seemed to be few ethical issues, but, not wishing to practise "off piste," I sought advice from my local ethics committee, which assured me that I did need ethical approval because of inclusion of NHS staff.

I therefore had no alternative to making an application. Reading the 55 page ethics form was time consuming enough, let alone answering the questions, meeting with R&D department staff and statisticians, as well as designing protocols and consent forms. Many of the questions are irrelevant to the study, concentrating on aspects such as potential hazards to participants (in this case, mannequins). It has also been infiltrated by rogue elements such as statistics, which have distracted us from the real aims of the ethics committee. Surely the form should concentrate on identifying potential ethical issues and how the author intends to address them.

We are in danger of losing sight of the ultimate goal of medical research, which is to improve patient care and outcomes. In particular, small scale studies conducted by clinicians are crucial in providing practical solutions at a local level—my study, for instance, will not win a Nobel Prize, but it may just save a life. There is a need to ensure ethical standards, but simple, non-invasive studies, such as my own, being required to complete a lengthy ethics application is patently a case of over-vigilance. It has taken

considerable motivation to maintain enthusiasm for this project, and I am sure many would have given up in their quest for ethical approval. The risk is that research will become the sole preserve of full time academics and that smaller scale, but none the less important, research by clinicians will not be done.

How do we balance patient safety and a duty to perform high quality research against an ethics application procedure so arduous that it inhibits research? The ideal is a process that encourages good research alongside the protection of patients, by asking questions that researchers ought to have considered anyway in planning their project. This requires moving away from a "one size fits all" application, which has become clumsy and largely irrelevant, to a more flexible system. An alternative might be further levels of application for differing levels of invasiveness or scale. My attempts to explain my simple study design have been difficult over the telephone and via the application form. The application process could be streamlined by a face to face discussion with a nominated ethical judge, who is empowered to give or withhold approval.

Ultimately, the experience has been a valuable one, whether or not my study receives ethical approval. Perhaps there is an ethics committee that has approved the next *Big Brother* series. I only wish that I were privy to the consent form.

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We welcome articles up to 600 words on topics such as *A memorable patient*, *A paper that changed my practice*, *My most unfortunate mistake*, or any other piece conveying instruction, pathos or humour. Please submit the article on <http://submit.bmj.com>. Permission is needed from the patient or a relative if an identifiable patient is referred to. We also welcome contributions for "End-pieces," consisting of quotations of up to 80 words (but most are considerably shorter) from any source, ancient or modern, which have appealed to the reader.