Study Protocol

Effect of communicating structured benefit and harm information in European patient leaflets on expectations about new medicines: a randomized controlled trial

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Introduction

The patient information leaflet, also known as the package leaflet, is a written summary of the information available on medicines designed to help patients use their medications safety and appropriately. It is the primary tool through which regulatory agencies communicate essential information to patients, and it is included with every prescription medicine in Europe. Patient information leaflets are the most widely distributed source of printed medicine information in Europe, and are also available electronically via the electronic Medicines Compendium and the websites of the European Medicines Agency (EMA).

Although widely available, many people find regulated patient information leaflets unhelpful because they do not meet people's information needs – particularly their need to understand how well a medicine works.[1–3] In order to make informed, evidence-based decisions aligned with their preferences, patients need clear information about the potential benefits, harms, and uncertainties of drugs, including treatment alternatives.[3,4] However, much of this information is either inadequately communicated or entirely absent from current patient leaflets. Leaflets often omit the goal of treatment (e.g., whether the treatment is palliative or curative) and provide no data on the magnitude and relevance of expected benefits.[5] While side effects are listed, they are rarely accompanied by data on frequency, severity,[6–8] or how these risks compare to other treatments.

Patients consistently express interest in receiving written information about prescription drugs at the point of care that more effectively addresses their informational needs.[1,2] The European Medicines Agency (EMA) recently proposed a series of reforms aimed at improving the clarity and usefulness of patient information leaflets. One key proposal is the introduction of a 'key information section'; a concise summary at the beginning of the leaflet that includes qualitative statements about the goal of treatment, main benefits, contraindications, and the most serious side effects.[9]

To inform the EMA's consultation on improving patient information leaflets, we developed a key information section that summarizes the main benefits and harms of a medicine. Its design was informed by evidence on effective health communication. Recognising that qualitative statements alone could be misinterpreted by patients,[4,8,10] we incorporated a structured summary table presenting quantitative information on treatment effects and side effects. Previous research shows that patients not only want this type of information,[1,2] but they also understand it, and can use it to make more informed decisions.[4,11–13]

To evaluate the impact of structured benefit-harm information in patient leaflets, we will conduct a randomized controlled trial with a nationally representative sample of adults in the United Kingdom (UK). The trial will evaluate whether including qualitative or quantitative information about drug benefits and harms improves individuals' expectations and understanding of a newly approved drug. Participants will be randomly assigned to one of three groups: (1) the standard patient information leaflet (control), (2) a leaflet incorporating the EMA's proposed key information section with qualitative statements, or (3) a leaflet with a key information section that includes both qualitative and quantitative information on the drug's benefits and harms.

Methods

This study received ethics approval from the London School of Economics and Political Science. The protocol was registered prior to recruiting participants (ClinicalTrials.gov) and the study will be reported in accordance with the CONSORT guidelines for randomized controlled trials.

Randomization

Participants will be individually randomized with equal allocation to 1 of 3 versions of a patient information leaflet: (1) the standard patient information leaflet (control), (2) a leaflet incorporating the EMA's proposed key information section with qualitative statements, or (3) a leaflet featuring a key information section that summarises quantitative data on the drug's main benefits and harms in addition to qualitative statements. We will use Qualtrics to randomize participants and to administer the survey.

Participants

Adults 18 years and older, fluent in English, and residing in the UK will be invited to participate in this survey. Participants will be recruited by Cint, a market research company that identifies participants from hundreds of research panel providers that use different methods for recruitment. We plan to recruit a nationally representative census-matched sample of adults according to age, sex, and education. Informed consent will be obtained from participants before initiating the survey; participants will be directly compensated by the survey company after completion. No identifying information about participants will be recorded.

Interventions

Participants in the control group will receive the standard patient information leaflet for a recently approved cancer drug, obtained electronically from the EMA website. There are 2 experimental conditions.

For participants randomized to receive the EMA's proposed key information section with qualitative statements, we developed a version based on the draft proposal published by the EMA.[9] The proposed key information section summarizes the goal of treatment, main benefits, contraindications, and most serious side effects. To ensure accuracy of our interpretation, we sought feedback from the EMA. The final version tested in the trial incorporated their suggestions.

Next, we developed a key information section that includes quantitative data on the drug's main benefits and side effects, modeled on the Drug Facts Box – a tabular summary format for prescription drugs, designed to resemble a nutrition label.[13] The key information section presents qualitative information about the drug (including its indication and treatment goal), and how it was studied (the comparator treatment and number of patients enrolled in the clinical trial that supported the drug's approval). It supplements this with quantitative data the drug's benefits and side effects. Data on the drug's benefits and side effects were sourced from European Public Assessment Reports (EPARs). Further details are provided in the appendix.

Procedure

Upon entering the study, participants will be randomized to 1 of 3 versions of a patient leaflet. The patient leaflet is for tivozanib (Fotivda), a cancer drug approved by the EMA for the treatment of advanced kidney cancer. An electronic version of the patient leaflet along with a download link will be displayed alongside each multiple-choice question. Participants will first complete a practice question designed to test their ability to scroll through and navigate the leaflet. Participants who answer the practice question incorrectly will be excluded from the study at this stage.

The first set of questions is designed to evaluate participants' expectations, perceived magnitude, and understanding of the drug's benefits and side effects based on the information provided in the patient leaflet. To assess expectations, we will ask participants about the likelihood that patients with advanced kidney cancer would be cured, live longer, or

feel better if they were treated with tivozanib. They will also be asked about the perceived magnitude of the tivozanib's benefits and side effects.[13–15]

To assess understanding, we will ask participants 3 questions: (1) the approved indication of tivozanib, (2) the most common serious side effect associated with treatment, and (3) the recommended dose of treatment. Answers to all 3 questions can be found in the standard patient leaflet. Information about the drug's indication is also included in both key information sections; information about the most common serious side effect is presented in the EMA's proposed key information section with qualitative statements. Participants randomized to the key information section with both qualitative statements and quantitative data will receive 2 additional questions: one asking them to identify the difference in overall survival between tivozanib and standard treatment, and another asking about the difference in serious side effects.

Next, all participants will be asked a series of questions to assess their satisfaction with the information presented in the version of the patient leaflet they were assigned. Before ending the survey, we will ask participants for information about their demographics: their age, sex, highest level of educational attainment, and personal experience with cancer (whether themselves, an immediate family member or close friend had been diagnosed with cancer).

Primary outcome

The primary outcome of the study is participants' expectations about the drug's benefits and side effects. We selected tivozanib as the test treatment because it is representative of many recently approved cancer drugs. Tivozanib is not curative for advanced kidney cancer and, at the time of approval, it demonstrated no additional overall survival or quality of life benefit relative to standard treatment (sorafenib). Owing to the lack of information about drug benefits in the standard patient leaflet and the limited information quantifying side effects, we hypothesized that participants would overestimate the benefits and underestimate the side effects of tivozanib.[14]

We assessed 3 questions related to participants' expectations about treatment outcomes: whether participants expected that tivozanib was curative, extended overall survival, or improved quality of life. We selected these 3 outcomes because research shows that patients undergoing cancer treatment value these outcomes the most.[15,16] For the primary analysis, we will compare the proportion of participants in each group who had accurate expectations for at least 2 of the 3 treatment outcomes with tivozanib (defined as responding "definitely no" or "probably no" to these questions).

Secondary outcomes

Participants' understanding of the information presented in the patient leaflet, their perceived magnitude of the drug's benefits and harms, and their satisfaction with the information are secondary outcomes of the trial. To assess understanding, we will compare the proportion of correct responses to each comprehension question across the randomized groups. To assess participants' perceived magnitude of the drug's benefits and harms, we will compare the proportion of participants in each group who responded that (1) the benefits of tivozanib were large, (2) the side effects were not concerning, and (3) the benefits of tivozanib outweighed the side effects. To assess satisfaction, we will compare the proportion of participants in each group who provided positive ratings about the leaflet (e.g., reporting that the leaflet was helpful and easy to understand).

Quality control

We will use several strategies to enhance the reliability and validity of the survey response data. First, we have included 2 attention check questions at different points throughout the survey. The first question will validate that participants can navigate the online survey and scroll through the patient leaflet; the second question will ask participants to select a specific

answer to ensure that they are paying attention. Participants that answer either question incorrectly will be excluded from the study at that stage. We will also exclude participants that (1) do not complete the survey, (2) complete the survey but straight-line their responses, and (3) participants that complete the survey in under 180 seconds.

Statistical analysis

The sample size and power calculations for this trial were informed by previous studies.[13] This trial is powered to detect an absolute difference of 10% between groups (60% vs 50%) with 90% power and a two-sided alpha of 0.05. We plan to adjust for 3 pairwise comparisons for the primary outcome, comparing each of the intervention arms with one another. Therefore, we aimed to recruit 700 participants per group and considered Bonferroni-corrected p values <0.0167 to be statistically significant.

We will use X^2 tests to compare the difference in proportions between groups. Logistic regression models will be used for adjusted analyses, controlling for participant demographics. We will conduct additional subgroup analyses to explore heterogeneity of treatment effects based on participants' sex, age, education level, and personal experience with cancer.

Appendix

eMethods

Development of the EMA's proposed key information section with qualitative statements
The EMA published its proposal for a key information section in patient leaflets in July 2024.[9] The content of this proposed section was based on surveys conducted with patients, members of the public, and healthcare professionals, focusing on what they considered to be 'key information' about a medicine. According to the EMA's draft, the key information section should include: the indication and goal of treatment / main benefits (with cross reference to section 1 of the current patient leaflet), contraindications and important precautions (section 2), and most serious side effects / main risks (section 4).

Since the guidance and template for the EMA's proposed key information section had not been finalized by the time of the trial, we developed a version for testing based on the content of the EMA's draft proposal. Statements about the goal of treatment, benefits, contraindications, and side effects were sourced from the EMA's medicines overview and patient information leaflet. To ensure the accuracy of the version used in the trial, we shared our draft with the EMA and incorporated their feedback into the final version tested.

Development of the key information section with qualitative and quantitative information
We designed the key information section that includes both qualitative and quantitative information based on evidence-based principles for communicating health information to patients and members of the public. Patients need information about the benefits, harms, and uncertainties of drugs in order to make informed decisions consistent with their preferences. This includes qualitative descriptions of the intention of treatment (e.g., whether it is palliative or curative),[17] and quantitative data on the effect of treatment on clinically meaningful outcomes.[15] Presenting this information in a structured format helps support better comprehension.[10,13]

We based the design of the key information section on the Drug Facts Box – a tabular summary format developed to communicate drug benefits and harms to the public.[13] We adapted the design considerably to align with the EMA's consultation on the proposed key information section and to address gaps in the presentation of prescription drug information in current European patient leaflets.

The key information section that includes both qualitative and quantitative information on drug benefits and harms is divided into 2 parts: general information about the drug, and data on treatment outcomes. The general information section begins with a header describing the drug name and approved indication ("*Key information about*…"), followed by 2 subheadings. The first subheading ("*What is Fotivda and what is it used for"*) includes 3 bullet points.

The first bullet point describes the indication of the drug as approved by the EMA. The second describes the intention of treatment, indicating whether treatment is curative or is intended to delay disease progression and extend survival. The third bullet summarizes the main benefits demonstrated in clinical trials, including whether the drug was associated with clinically relevant outcomes for patients. This section concludes with another subheading which summarizes the key features of the clinical trial which supported the drug's approval ("*Benefits and side effects of Fotivda"*). A brief sentence provides information about the comparator treatment used in the clinical trial and the number of participants enrolled.

Next, the key information section presents data on treatment outcomes in a tabular format. The columns correspond to the treatments administered in the clinical trial and the rows correspond to the outcomes measured. For each outcome, the table displays the absolute

difference between the two treatments; the results for the new drug; and results for the comparator treatment.

To present information on drug benefits, we included data on outcomes that are clinically meaningful for patients with the condition, as well as the primary outcome of the clinical trial that supported the drug's approval. In oncology trials, clinical outcomes typically include overall survival and quality of life. Therefore, if the trial's primary outcome was a surrogate endpoint (e.g., progression-free survival), the included 3 rows of benefit information: overall survival, quality of life, and the surrogate endpoint. If the primary outcome was overall survival, only 2 rows were included: overall survival and quality of life.

For tivozanib, the primary endpoint of the pivotal study was progression-free survival. To reduce confusion with overall survival, we described progression-free survival in plain language as *"how long did people have before the cancer grew or spread", while* overall survival was described as "*how long did people live?"*.[18] Because the improvement in overall survival was not statistically significant between tivozanib and sorafenib at the time of approval, we reported the absolute difference between the two treatment in the corresponding column of the table but noted that the observed difference may be due to chance.

For data on quality of life, we used any measure of global health-related quality of life reported in the EPAR, given that quality of life outcomes are inconsistently measured and reported in cancer drug trials.[19] In the case of tivozanib, quality of life was measured using a 108-point scale. Because the difference in quality of life between tivozanib and sorafenib was not statistically significant, we reported the absolute difference in the table but noted that the observed difference may be due to chance.

The final outcome reported in the table is the percentage of patients who experienced severe side effects. Severe side effects were defined as grade 3 (severe events requiring hospitalization or prolongation of hospitalization) and grade 4 (life threatening) adverse events, according to the common terminology criteria for adverse events (CTCAE). We reported the overall proportion of patients who experienced these adverse events rather than the proportion determined to be treatment related by trial investigators. We excluded grade 5 adverse events (death) since these were relatively rare and could be misinterpreted.

<u>Drug information</u>
Tivozanib (Fotivda) was approved by the EMA in 2017 for the treatment of advanced kidney cancer. The primary outcome of the clinical trial that supported tivozanib's approval showed an additional benefit in progression-free survival of 2.8 months compared to sorafenib (11.8 months vs 9.1 months). Overall survival and overall health related quality of life were secondary outcomes in the trial but neither showed a statistically significant difference between the two treatments. Severe harms (defined as life threatening or requiring hospitalization [grade 3 and 4]) were more common with tivozanib (70%) than with sorafenib (64%).

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Figure 1: Patient leaflet for tivozanib and key information sections tested in the trial

Package leaflet: Information for the patient

Fotivda 890 microgram hard capsules
Fotivda 1340 microgram hard capsules
tivozanib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Fotivda is and what it is used for

The active substance in Fotivda is tivozanib, which is a protein kinase inhibitor. Tivozanib reduces the supply of blood to the cancer, which slows down the growth and spread of cancer cells. It works by blocking the action of a protein called vascular endothelial growth factor (VEGF). Blocking the action of VEGF prevents the formation of new blood vessels.

Fotivda is used to treat adults with advanced kidney cancer. It is used where other treatments such as interferon-alpha or interleukin-2 have either not yet been used or have not helped to stop your disease.

2. What you need to know before you take Fotivda

Do not take Fotivda:
- If you are allergic to tivozanib or any of the other ingredients of this medicine (listed in section 6);
- If you are taking St. John's Wort (also known as *Hypericum perforatum*, a herbal remedy used for treatment of depression and anxiety).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Fotivda:
- if you have **high blood pressure**
  Fotivda can increase your blood pressure. Your doctor will monitor your blood pressure regularly and, if it is too high, may either give you a medicine to lower it, or reduce your dose of Fotivda. However, if your blood pressure remains too high, your doctor may decide to interrupt or to stop treatment with Fotivda. If you are already taking a medicine to treat high blood pressure, and your doctor reduces the dose of Fotivda or interrupts or stops treatment, you will be regularly checked for low blood pressure.

- if you have or have had an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall.

KEY INFORMATION

What is Fotivda and what it is used for
- Fotivda is a medicine for treating adults with advanced kidney cancer. Fotivda may be used in previously untreated patients or in those whose disease has got worse despite treatment with another medicine that works in a different way.
- Fotivda does not cure advanced kidney cancer.
- Fotivda may increase how long people live without their disease getting worse. However, it does not cure advanced kidney cancer.

For further information about Fotivda and its uses, see section 1.

What you need to know before you take Fotivda
- Do not take Fotivda if you are allergic to the active ingredient, tivozanib, or if you are taking St. John's Wort (a herbal remedy for depression).
- Talk to your doctor if you have high blood pressure, have had an aneurysm (a bulge in a blood vessel), have had blood clots or have any of the signs or symptoms of heart failure.

For further information, see section 2.

Most important side effects with Fotivda
- The most common side effect with Fotivda is high blood pressure (which occurs in almost half of patients and can be serious in a quarter of patients).
- Other common side effects are voice changes, tiredness and diarrhoea (which occur in about a quarter of patients).

For the full list of possible side effects, see section 4.

To understand all information about using this medicine, it is very important that you read the rest of this leaflet.

Key information about **Fotivda for renal cell carcinoma** (kidney cancer)

What is Fotivda and what it is used for:
- Fotivda (tivozanib) is a medicine to treat adults with advanced kidney cancer that has come back after previous treatment or has spread to another part of the body.
- Fotivda does not cure advanced kidney cancer.
- Fotivda may increase the time until a test shows the cancer has grown or spread, but it has not been shown to extend how long people live.

Benefits and side effects of Fotivda:
In a study involving 517 people, Fotivda was compared to sorafenib, a standard treatment for kidney cancer. What difference did Fotivda make?

		Fotivda		Standard treatment
How long did people live?	People given Fotivda lived **2.6 months less**. However, this finding may be due to chance.	28.2 months	vs	30.8 months
How did people feel?	People given Fotivda felt **1.1 points worse** on a 108-point scale. However, this finding may be due to chance	4.8 points worse	vs	3.7 points worse
How long did people have before the cancer grew or spread?	People given Fotivda had **2.8 months longer** before the cancer grew or spread.	11.9 months	vs	9.1 months
How common were serious side effects?	People given Fotivda had **6% fewer** serious side effects (disabling, life-threatening, or requiring hospitalization).	64%	vs	70%

Note: Left panel shows the standard patient leaflet for tivozanib (control); upper right panel shows the EMA's proposed key information section with qualitative statements; lower right panel shows the key information section containing both qualitative and quantitative information.

EMA patient leaflet survey

About this study
Every prescription medicine comes with written information for patients about the medicine and how to use it. It is called the patient information leaflet. This is what the patient leaflet looks like.

[leaflet image]

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About this study
Researchers in the UK, US, and Australia are interested in what people think about the patient leaflet and how it could be improved. This study is funded by King's College London in the United Kingdom.

The survey takes about 15 minutes to complete.

Consent
Participation in this survey is voluntary. The survey is anonymous – that means we will not record your name or any information that could connect you to your answers.

If you have any questions regarding this study, please contact the researcher, Avi Cherla, at a.j.cherla@lse.ac.uk. If you have any concerns regarding the conduct of this research, please contact the LSE research ethics managers via research.ethics@lse.ac.uk.

Instructions
Please try to answer all the questions even if you are not completely sure about an answer. Once you complete a question, you will not be able to go back and change your answer.

By selecting next, you agree that you:

- Are 18 years or older
- Live in the United Kingdom
- Are fluent in reading, writing and speaking in English
- Have read and understand the instructions
- Consent to participating in the survey

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Section A: Previous experience using the patient leaflet

1. If you are currently prescribed or have ever been prescribed a medicine, how often do you read the patient leaflet?
    - Often
    - Sometimes
    - Rarely
    - Never

2. If you are currently prescribed or have ever been prescribed a medicine, how often do you talk to your doctor about the information you see in the patient leaflet?
    - Often
    - Sometimes
    - Rarely
    - Never

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Section B: Participants' expectations and understanding of treatment using the patient leaflet

Imagine that your doctor prescribes you a new medicine. When you pick up the medicine from the pharmacy, you read the patient leaflet included in the box.

This patient leaflet is for a medicine called Fotivda. You can zoom in and scroll through every page of the leaflet. You can also download it here: Fotivda.pdf

You will be shown the patient leaflet for Fotivda on every page for the next few questions, along with an option to download the leaflet. Please use the information in the leaflet to answer the questions.

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3. This first question is practice. Scroll to section 3 of the leaflet and find the first word.
    - Always [**correct**]
    - Serious
    - Patient
    - Chance

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4. What is Fotivda used for?
    - To treat adults with breast cancer
    - To treat adults with heart failure
    - To treat adults with advanced kidney cancer [**correct**]
    - To treat adults with advanced lung cancer
    - Not sure

----- end of page----

5. Does Fotivda cure advanced kidney cancer?
    - Definitely yes
    - Probably yes
    - Probably no
    - Definitely no

----- end of page----

6. Do people with advanced kidney cancer live longer when treated with Fotivda?
    - Definitely yes
    - Probably yes
    - Probably no
    - Definitely no

----- end of page----

7. Do people with advanced kidney cancer feel better when treated with Fotivda?

- Definitely yes
- Probably yes
- Probably no
- Definitely no

----- end of page----

8. Compared to standard treatment, how long did people given Fotivda live? **[Key information table group]**
    - 6 months **less** than people given standard treatment
    - 2.6 months **less** than people given standard treatment **[correct]**
    - About the same as people given standard treatment
    - 2.6 months **longer** than people given standard treatment
    - 6 months **longer** than people given standard treatment
    - Not sure

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9. Overall, how large are the benefits of Fotivda?
    - Very large
    - Large
    - Moderate
    - Small
    - Very small to none

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10. To confirm that the survey is functioning correctly, please select 'Standard treatment', below.
    - Fotivda
    - Advanced kidney cancer
    - Standard treatment **[correct]**
    - Neither Fotivda or standard treatment

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11. Compared to standard treatment, how common were serious side effects with Fotivda? **[Key information table group]**
    - 22% **less** common than with standard treatment
    - 6% **less** common than with standard treatment **[correct]**
    - About the same as standard treatment
    - 6% **more** common than with standard treatment
    - 22% **more** common than with standard treatment
    - Not sure

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12. What is the most common serious side effect of Fotivda?
    - Rapid or irregular heart beat
    - High blood pressure [**correct**]

- Diarrhoea
- Muscle spasms
- Not sure

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13. How concerning are the side effects of Fotivda?
    - Extremely concerning
    - Very concerning
    - Somewhat concerning
    - Not at all concerning

----- end of page----

14. Do you think the benefits of Fotivda outweigh the side effects?
    - Definitely yes
    - Probably yes
    - Probably no
    - Definitely no

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15. What is the recommended dose of Fotivda during the first 3 weeks of treatment? **[All groups]**
    - One 890 microgram capsule daily
    - One 1340 microgram capsule daily **[correct; answer in section 3 of PIL]**
    - Two 1340 microgram capsules daily
    - Two 890 microgram capsules daily
    - Not sure

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Section C: Participants' satisfaction with the patient leaflet

You're almost done. What was your experience of using the patient leaflet for Fotivda?

16. Was it easy to find information about Fotivda using the leaflet?
    - Very easy
    - Easy
    - Difficult
    - Very difficult

17. Was it easy to understand the information?
    - Very easy
    - Easy
    - Difficult
    - Very difficult

Please rate your agreement with the following statements.

18. The leaflet helped me think about the benefits of Fotivda.
    - Strongly agree
    - Agree
    - Disagree
    - Strongly disagree

19. The leaflet helped me think about the side effects of Fotivda
    - Strongly agree
    - Agree
    - Disagree
    - Strongly disagree

20. The leaflet helped me think of questions I would like to ask my doctor
    - Strongly agree
    - Agree
    - Disagree
    - Strongly disagree

21. Overall, did you find the patient leaflet for Fotivda:
    - Very helpful
    - Helpful
    - Unhelpful
    - Very unhelpful

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Section D: Demographics

Thank you for taking the time to respond to this survey. These last 5 questions are to help us better understand you.

22. How old are you?
    - 18 to 24
    - 25 to 44
    - 45 to 64
    - 65 and older

23. What is your sex?
    - Male
    - Female
    - Other

24. What is the highest level of education that you have completed?
    - Less than 5 GCSE's A* to C (or equivalent i.e., level 1 diploma/ certificate /BTEC /NVQ)
    - 5 or more GCSE's A* to C (or equivalent i.e., level 2 diploma/ certificate/ BTEC/ NVQ, O-Levels)
    - 2 or more A-Levels (or equivalent I.e., level 3 diploma/ certificate/ BTEC)
    - Undergraduate degree or higher

25. What is your approximate yearly income?
    - Less than £20,000
    - £20,000 to £34,999
    - £35,000 to £44,999
    - £45,000 and above

26. Have you, a close friend, or immediate family member (i.e. your partner, parents, siblings, or children) ever been diagnosed with cancer? (Select as many that apply)
    - I have been diagnosed (currently, or in the past)
    - An immediate family member has been diagnosed with cancer
    - A close friend has been diagnosed with cancer
    - To my knowledge, none of my close friends or family, or myself, has been diagnosed with cancer

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---------- end of survey message ----------