Study finds 'important shortcomings' in official cancer drug information

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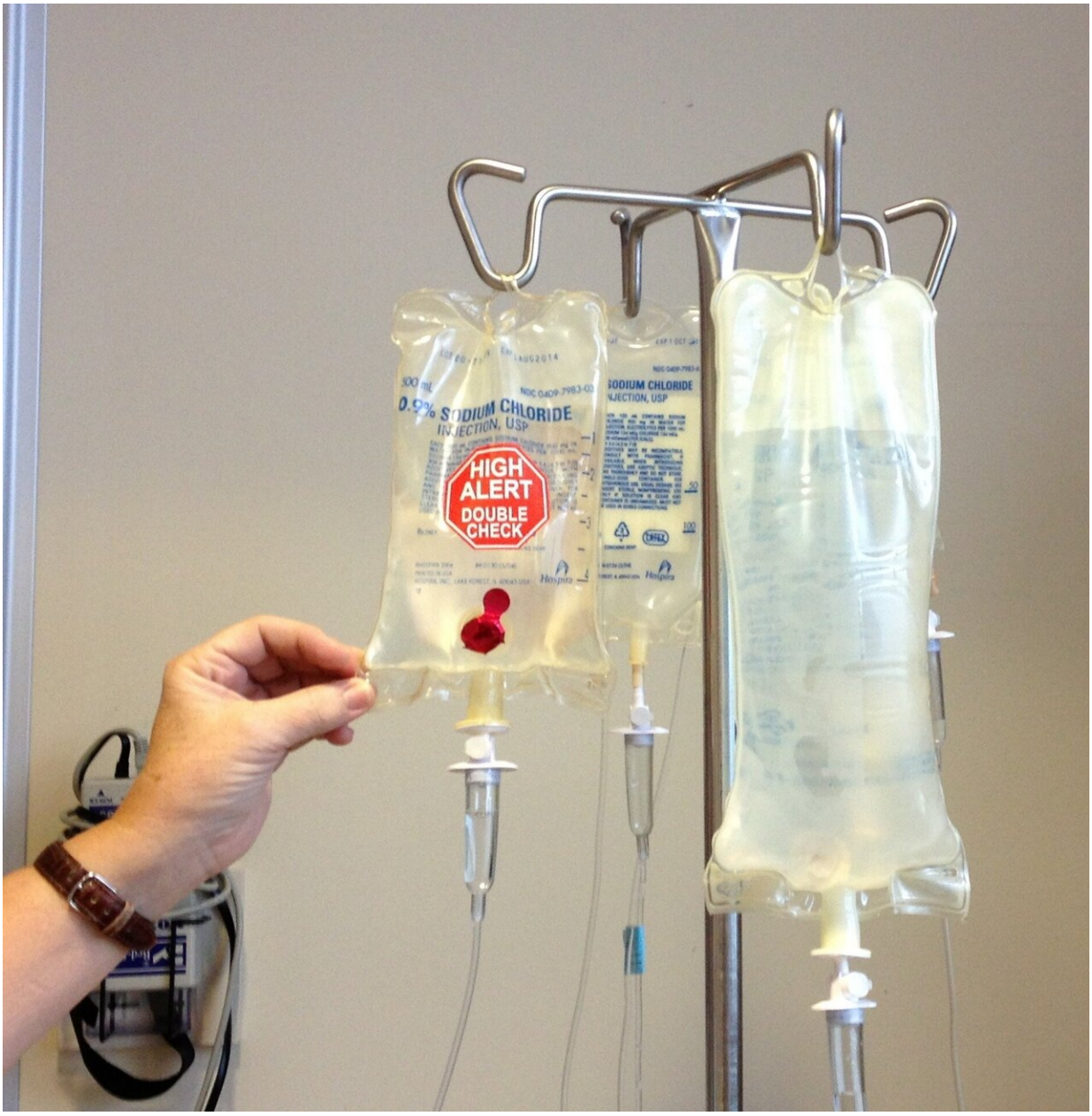

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Important information about cancer drug benefits, and related uncertainties, is frequently omitted from official prescription drug information sources for clinicians and patients in Europe, finds an analysis published by *The BMJ* today.

Despite the commitment of medicines regulators to shared decision making and person centered care, the researchers say better information on the benefits and potential harms of medicines are needed to help inform treatment decisions, especially for patients with time limiting conditions such as advanced cancer.

To receive and participate in medical care, patients need high quality information about treatments, tests, and services, including information about the benefits of and risks from prescription drugs. Previous studies have looked at how information on drug risks and adverse effects is communicated to patients, but research on communication of drug benefits is limited.

To address this, researchers set out to assess the extent to which information about cancer drug benefits, and related uncertainties, is communicated to patients and doctors in regulated prescription drug information sources in Europe.

They reviewed official written and electronic information for clinicians (through a summary of product characteristics), patients (information leaflets) and the public (public summaries) for 29 new cancer drugs approved by the European Medicines Agency (EMA) during 2017-2019.

They then compared the information on drug benefits reported in these sources with the information available in regulatory assessment documents (known as European public assessment reports or EPARs), which contain everything required for drug approval.

They found that both patient and public facing information sources were often lacking in relevance. For example, information on drug benefits was not reported in any patient leaflets, while other—potentially less relevant information for patients (e.g., how a drug works in the body)—was consistently included.

They also found instances where the reporting of a study design and study findings was inconsistent with the information reported in EPARs and potentially misleading.

Important gaps and uncertainties in the evidence base were also rarely reported, particularly those that might be relevant and useful for patients, such as whether a drug extended survival or improved quality of life.

Finally, scientific concerns about the reliability of evidence on drug benefits, which were raised by European regulatory assessors for almost all drugs in the study sample, were rarely communicated to clinicians, patients, or the public.

The researchers acknowledge that their review may not have captured all information about each trial or drug benefits and uncertainties that might be relevant and useful for patients. What's more, they included only new cancer drugs and it's not clear whether these findings extend to other disease areas.

Nevertheless, this was a comprehensive review of documents which they say "identified important shortcomings in the communication of information on drug benefits and related uncertainties in regulated

sources."

The findings "highlight the need to improve the communication of the benefits and related uncertainties of anticancer drugs in regulated information sources in Europe to support evidence informed decision making by patients and their clinicians," they conclude.

The takeaway message from this study is that information about drugs is rarely communicated well—and particularly not communicated well to patients, say *BMJ* editors in a linked editorial.

It also raises questions about whether this knowledge gap is interfering with shared decision making and whether new ways to present information such as visual representation of data on benefits and harms—used for COVID-19 vaccines—could be applied to other types of medicines.

"The trust between patients and healthcare providers remains pivotal in ensuring that patients are fully informed about benefits and harms of drugs," they write. "But regulatory agencies should pay closer attention to important gaps in information for patients, and further research should aim to determine more precisely where these gaps occur and to work with patients to fill them."

More information: Communication of anticancer drug benefits and related uncertainties to patients and clinicians: document analysis of regulated information on prescription drugs in Europe, *The BMJ* (2023). DOI: 10.1136/bmj-2022-073711

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