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Communicating the benefits and harms of anticancer drugs

Are patients getting all the information they need?

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Informed consent is a central tenet of ethical clinical practice and shared decision making, and it requires that patients have easy access to independent and comprehensive information about medicines. For instance, is accurate information about benefits and harms available, is it complete, and is it presented in ways that ensure patients understand the benefits and harms from key research findings and the extent of remaining uncertainties?

In a linked paper, Davis and colleagues (doi:10.1136/bmj-2022-073711) set out to answer these questions for new anticancer drugs approved by the European Medicines Agency (EMA) between 2017 and 2019.[1] Firstly, they evaluated the content of European public assessment reports (EPARs), looking at information targeted at clinicians (through a summary of product characteristics), patients (information leaflets), and the public (public summaries). Then they used a non-systematic review of literature, UK and EU guidance documents, frameworks, and taxonomies to determine what information about drug benefits and harms is most important to patients and the public. Their findings suggest that there is much room for improvement in the sources provided, particularly in patient information leaflets.

The authors evaluated 29 anticancer drugs that received a first marketing authorisation for 32 separate cancer indications in 2017-19. Most (23/32, 72%) of the indications were not associated with any direct survival benefit; instead, approval was on the basis of surrogate outcomes, such as progression-free survival or tumour response. Moreover, 88% (28/32) of indications had been approved for non-curative intent—for patients with advanced stage or metastatic disease. The authors also found that patient information leaflets lacked important information necessary for patients to make informed decisions, including how a drug was evaluated, key findings from research studies, and the benefits expected from treatment. Overall, 41% (13/32) of information leaflets did not report the drug's indication or target population.

Public summaries fared slightly better: at least 75% reported how the drug was studied and the benefits patients might expect during treatment. Information in EPARS—which contain everything required for EMA approval—and information provided to doctors typically included comprehensive information on type of drug, indication, and study results. Importantly, none of the public summaries or patient information leaflets and only a quarter of summaries for clinicians contained information on quality of life. Communication of any remaining uncertainty about safety and effectiveness was variable; and was poor to very poor in some uncertainty domains. Only 3% of patient information leaflets mentioned a need for further long term data.

The takeaway message from Davis and colleagues' study is that information about drugs is rarely communicated well—and particularly not communicated well to patients. More is, however, to be gleaned from this study. Firstly, although not the primary focus, the authors' review of taxonomies describing the interests of patients in how benefits and harms are communicated shows that patients are interested in the same information as clinicians and that patients are asking the right questions about their treatment. Furthermore, some consensus exists on the kind of information patients want and need to make informed decisions. Nevertheless, although EMA provides templates for pharmaceutical companies detailing the information they should provide to patients and clinicians,[2] it is still unclear whether this information fully meets patients' needs or expectations.

Secondly, key information within comprehensive EPARs clearly fails to reach information sources for patients. However, it is unclear whether this gap is interfering with shared decision making. We do not know, for example, whether this information reaches patients in some other way. Is information making its way to patients through discussions with clinicians? Through internet searches? Accuracy will be an even greater concern for some of these routes, and more research must be done to answer these questions—a knowledge gap that patients, clinicians, and agencies could work together to address. Clinicians who are informed by both patients and EMA are in a better position to guide interventions with patients' full support.

Thirdly, although substantial information on drugs is already out there, these sources tend to be static, and they will likely benefit in the future from being digitalised and embedded in electronic medical records and clinical workflows. The covid-19 pandemic prompted EMA to develop new ways to present information about benefits and harms of vaccines, such as visual representation of risk, that potentially could be applied to other types of medicines.[3]

Finally, oncology is a field characterised by good continuity of care and close relationships between patients and clinicians in both primary and secondary care, which may help compensate for limitations in publicly available sources of information about drugs. Whether Davis and colleagues' findings extend to non-cancer treatments remains unclear. The trust between patients and healthcare providers remains pivotal in ensuring that patients are fully informed

about benefits and harms of drugs. 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.

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1 Davis C, Wagner AK, Salcher-Konrad M, etal. Communication of anticancer drug benefits and related uncertainties to patients and clinicians: document analysis of regulated information on prescription drugs in Europe. *BMJ* 2023;380:e073711.

2 European Medicines Agency. QRD product-information annotated template (English) version 10.3 ANNEX I, SUMMARY OF PRODUCT CHARACTERISTICS. 2022. https://www.ema.europa.eu/documents/template-form/qrd-product-information-annotated-template-english-version-103_en.pdf (accessed 18 Feb 2023).

3 AstraZeneca's COVID-19 vaccine: benefits and risks in context. https://www.ema.europa.eu/en/documents/chmp-annex/annex-vaxzevria-art53-visual-risk-contextualisation_en.pdf (accessed 27 Feb 2023).