

Most off-label antidepressant prescriptions lack strong scientific evidence

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Pills. Credit: Public Domain

Most off-label antidepressant prescriptions lack strong scientific evidence, finds a study published by *The BMJ* today.

Off-label use occurs when a drug is prescribed for a different condition, given to a different patient group (e.g. children) or in a different dose or formulation than in the approved label.

Antidepressant use has increased substantially in the UK and in other western countries such as Canada and the USA. In fact, the number of antidepressants dispensed in England increased by 3.9 million (6.8%) between 2014 and 2015 - more than any other class of prescription drugs.

Around a third of antidepressants are prescribed for "off-label" conditions, most commonly pain, insomnia and migraine, but it is unknown to what extent these prescriptions are supported by scientific evidence.

To address this issue, a team of researchers decided to examine off-label indications for antidepressants in primary care and assess the level of scientific support for these off-label prescriptions.

Using data from an electronic prescribing system, they tracked over 100,000 antidepressant prescriptions written by 174 [primary care](#) physicians for over 20,000 adults between 1 January 2003 and 30 September 2015 in Quebec, Canada.

Overall, 29% of all antidepressant prescriptions were written for an off-

label indication. Tricyclic antidepressants (TCAs) had the highest prevalence of off-label indications, while selective serotonin reuptake inhibitors (SSRIs) and serotonin-noradrenaline reuptake inhibitors (SNRIs) were less likely to be prescribed off-label.

Among all off-label antidepressant prescriptions, only 16% (4,977 out of 31,319) were directly supported by strong [scientific evidence](#) backing the drug's use for the indication. For 40% (12,386) of off-label prescriptions, there was no strong evidence backing the drug's use for the indication, but there was strong evidence for another drug in the same class.

For the remaining 44% (13,956) of off-label prescriptions, neither the prescribed drug nor any other drugs in the class had strong evidence for the indication.

The researchers point to several factors that could contribute to physicians prescribing antidepressants for off-label indications, including difficulties keeping track of new indications for specific products, constraints on drug insurance plans, and perceptions that alternative treatment options may carry more risks than taking [antidepressants](#).

They stress that their study included some limitations that could influence the generalisability of the findings, but say their results "highlight an urgent need to produce more evidence on the risks and benefits of off-label antidepressant use and to provide physicians with this evidence at the point of prescribing."

And they conclude that technologies such as indication based e-prescribing systems and electronic health records "have the potential to become essential components of effective post-market drug surveillance systems for monitoring and evaluating off-label antidepressant use."

In a linked editorial, researchers at the University of Dundee argue that the strength of evidence matters more than the presence or absence of a specific licence.

As this research shows, off-label prescribing is common, often poorly supported by evidence, or relies heavily on extrapolating evidence from one situation to another, write Dr. Daniel Morales and Professor Bruce Guthrie. But they point out that these pitfalls are not confined to off-label drugs.

They suggest that, for all prescribing, patients (or their parents or carers) should be given enough information to allow them to make an informed decision to take a medicine (or not). "This should include whether the intended use is off-label, but more importantly prescribers should discuss the strength of the [evidence](#) base underlying their recommendation."

More information: Off-label indications for antidepressants in primary care: descriptive study of prescriptions from an indication based electronic prescribing system, www.bmj.com/content/356/bmj.j603

Editorial: Off-label prescribing of antidepressants, www.bmj.com/content/356/bmj.j849

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