Drug Safety in the Digital Age

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Accessibility
Under these circumstances, and however anomalous it may seem, the idea of bringing death with dignity to the ICU is highly germane. I believe that not only should the barriers between family and patient in the unit be minimized (and indeed many ICUs have now implemented such policies), but the process of decision making should also more fully reflect the principles of palliative care. Such an ICU culture would not only promote aggressive treatment but also help patients and their families make wise decisions about managing the end of life. This approach, as Cook and Rocker observe, may seem paradoxical, but it is nevertheless altogether essential.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

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Drug Safety in the Digital Age

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The Internet is increasingly redefining the ways in which people interact with information related to their health. The Pew Internet Project estimates that more than half of all Americans sought health information online in 2013, mostly through search engines such as Google and websites such as Wikipedia and WebMD.

In this digital age, engaging with new media offers an unparalleled opportunity for medical and public health professionals to find information they need and to interactively reach out to patients and their support networks. One domain where these capabilities may have far-reaching effects that are currently undefined is drug safety. As the volume of health-related information on the Internet has grown, important questions have emerged. How are messages from regulators — for example, warnings against using a drug in a specific patient population — diffused digitally? And are the messages still accurate when they reach the general population?

To explore these questions, we selected new drug-safety communications related to prescription medicines that were issued by the U.S. Food and Drug Administration (FDA) over a 2-year period between January 1, 2011, and December 31, 2012 (see Table S1 in the Supplementary Appendix, available with the full text of this article at NEJM.org). Despite debates over its credibility, Wikipedia is reportedly the most frequently consulted online health care resource globally: Wikipedia pages typically appear among the top few Google search results and are among the references most likely to be checked by Internet users. We therefore evaluated Google searches and Wikipedia page views for each drug in our sample. We also examined the content of Wikipedia pages, looking specifically for references to safety warnings. To control for secular trends, we examined results from a 120-day window around the date of the announcement (from 60 days before the announcement to 60 days after it) and constructed a baseline period for comparison that ran from 60 days to 10 days before the period of interest began.

We identified safety warnings for 22 prescription drugs that are indicated for a range of clinical conditions, including primary hypertension, chronic myelogenous leukemia, and hepatitis C. Collectively, these drugs triggered 13 million searches on Google and 5 million Wikipedia page views annually during the study period. FDA safety warnings were associated with an 82% increase, on average, in Google searches for the drugs during the week after the announcement and a 175% increase in views of Wikipedia pages for the drugs on the day of the announcement, as compared with baseline trends (see line graph and Fig. S1 in the Supplementary Appendix).

Did users find accurate information on the drugs’ safety? We found that 41% of Wikipedia pages pertaining to the drugs with new safety warnings were updated within 2 weeks after the warning was issued with information provided in the FDA an-
Effect of Food and Drug Administration Warnings on Google and Wikipedia Traffic.

Drugs associated with 22 warnings were examined. Google search volumes were normalized, since Google does not report these data in absolute terms. Google search volumes are available on a weekly basis, whereas Wikipedia page views are calculated on a daily basis. The 2-day change (from the day of the announcement to the next day) in Wikipedia page views and the 1-week change in Google search volumes were statistically significant (P<0.001).

Announcements (see Fig. S3 in the Supplementary Appendix). The Wikipedia pages for drugs that were intended for treatment of highly prevalent diseases (affecting more than 1 million people in the United States) were more likely to be updated quickly (58% were updated within 2 weeks) than were those for drugs designed to treat less-prevalent conditions (20% were updated within 2 weeks, P=0.03; see Fig. S2 in the Supplementary Appendix).

Overall, 25% of Wikipedia pages were updated more than 2 weeks after the FDA warning was issued (average, 42 days), and 36% of pages remained unchanged more than 1 year later (as of January 2014). For example, the FDA issued a safety communication on January 13, 2012, that brentuximab vedotin (Adcetris), used to treat Hodgkin's lymphoma and systemic anaplastic large-cell lymphoma, had been linked to two cases of progressive multifocal leukoencephalopathy. As a result, the FDA placed a new black-box warning about this risk on the drug label, a move that was followed by a 50% increase in Google searches for the drug during the ensuing week and a 141% increase in views of the drug’s Wikipedia page. However, there was still no mention of the new black-box warning on Wikipedia 2 years later, a discrepancy that substantiates concerns raised by previous studies over the reliability of online drug information.

These findings have practical implications. As clinicians seek to promote patient-centered care and shared decision making, patients’ preferences and knowledge increasingly figure into patient care. Patients may be better prepared to voice their preferences regarding treatment options after they weigh relevant information, including information about potential risks. They may also be more knowledgeable about when to seek medical care for symptoms that may represent an adverse drug reaction. Physicians can provide some of the critical information when they prescribe a drug, but the survey shows that many patients still independently consult additional resources.

Public health officials have historically focused on printed drug labels and “Dear Health Care Provider” letters from the FDA, but new technologies offer the opportunity to reach patients and physicians more efficiently and effectively. We believe the first step should be improving the accessibility of drug information available through the FDA’s website. Currently, safety communications are housed on the MedWatch portal, whereas electronic drug labels containing information on efficacy, dosage, and contraindications are located in the Drugs@FDA database — and there is no obvious link between these two resources. In addition to centralizing these disparate data sources, the agency could make its website more consumer-friendly by better integrating social media. Although the FDA has posted (tweeted) safety communications on Twitter since 2010 and its main drug-related Twitter account (@FDA_Drug_Info) currently has roughly 140,000 followers, the agency’s drug-safety–specific Twitter account (@FDAMEDWatch) has just 20,000 followers. Enabling FDA site visitors to quickly share...
safety communications on common social media platforms such as Twitter and Facebook would broaden the virtual reach of the agency’s messages.

Another approach to promoting accurate dissemination of drug-safety information is active participation in the online curation of medical information. In 2008, the FDA partnered with WebMD to bring public health announcements to all registered users and to quickly integrate this information into WebMD’s suite of Web pages. A digital strategy for drug safety could expand this model to include other sites that are highly frequented by the public, including websites for disease-specific patient-support and patient-advocacy organizations. Our findings also suggest that there may be a benefit to enabling the FDA to update or automatically feed new safety communications to Wikipedia pages, as it does with WebMD.

Clinicians and researchers could contribute to this effort. In September 2013, the University of California, San Francisco, became the first U.S. medical school to offer academic credit for editing medical content on Wikipedia, a project that could be scaled to the national level to

**Given the frequency with which patients seek information on the Internet, taking advantage of electronic media appears to be a promising means for the FDA to ensure that patients have ready access to accurate and comprehensive information, including timely updates pertaining to drug-safety issues.**

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When Representative Paul Ryan (R-WI) attracted national attention by joining Senator Ron Wyden (D-OR) in proposing a sweeping privatization of Medicare, he was variously vilified and praised for suggesting that Medicare should be converted from a defined-bene-