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Messages about Black-Box Warnings

A Comparative Analysis of Reports from the FDA and Lay Media in the US

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Abstract

Background: The US FDA and lay media are important sources of information for the public about the risks of adverse events associated with drugs, yet the quality of FDA and US lay media reports about medication 'black-box' warnings, which highlight potentially severe adverse events from medications, is unknown.

Objective: To determine and compare the content of FDA and US lay media reports about medication black-box warnings.

Methods: We assessed FDA and US lay media reports about medication black-box warnings published or aired between 1 January 2003 and 31 December 2007 for the presence of six core message components, including (i) the affected drug's brand name; (ii) generic name; (iii) treatment indication; (iv) reason for the black-box warning; (v) clinical recommendations for patients, such as warning signs and symptoms of the adverse effect addressed by the black-box warning; and (vi) encouragement to discuss the issue with a healthcare provider, and additional characteristics.

Results: FDA reports presented more core information than lay media reports (median 5 vs 3 message components; $p < 0.001$). FDA reports were more likely to mention generic names (84.6% vs 18.1%; $p < 0.001$) of affected drugs, while lay media reports less frequently detailed clinical recommendations for patients (43.9% vs 96.2%; $p < 0.001$). Only 10.6% of lay media reports encouraged patients to seek additional information from their healthcare provider, compared with 48.1% of FDA reports ($p < 0.001$).

Conclusions: FDA and US lay media reports about medication black-box warnings presented different information. This may reflect a difference in underlying motivation for reporting of news about risks of adverse drug events. It may also indicate a lack of agreement and understanding about the best methods to communicate risk information to the public, thus indicating areas for future research.

Background

Fifty-six percent of American adults (more than 122 million people) sought information about a personal health concern in 2007.[1] Traditional media sources, such as newspapers and television broadcasts, serve as the primary source of personal health information for 40% of Americans.[2] Yet the media acts as more than a passive delivery vehicle for information. Their portrayal and framing of health issues clearly has profound effects on consumer behaviour.[3-10]

Health media coverage spans a wide range of topics, from the findings of scientific studies to the federal regulation of medications, such as 'black-box' warnings issued by the US FDA. Black-box warnings highlight any 'special problems' of a medication, particularly those that may lead to death or serious injury.[11] The technical language of these warnings and their prominent location on prescriber drug labelling are meant to explicitly guide prescribers' practices. Yet lay media communications may emphasize certain aspects of the black-box warning without mentioning other areas of concern. For example, many press reports about a recent black-box warning describing the risk of suicidality among youths taking antidepressants discussed personal stories from families whose children committed suicide.[12,13] However, while reasons for concern existed, these reports did not mention the lack of definitive data supporting actual causation.[14] Without full contextualization, health news may over- or under-emphasize both the risks of health hazards and the generalizability of study findings.[15-19] This may result in distorted portrayals of risk and evoke emotions or 'mental noise', which can additionally influence risk perception, the ability of an individual to process information, and subsequent health behaviours.[20]

Prior studies about black-box warnings have focused on their influence on physician prescription practice[21,22] but not on public reporting of black-box warnings. In order to gain insight into the nature of reporting of serious adverse drug risks to lay audiences, we used a risk communication framework to determine and compare the content of FDA and US lay media reports about medication black-box warnings.

Methods

Data Sources

In order to capture lay media reports with the broadest exposure across the US, this study included reports from the top ten most circulated daily US newspapers, based on statistics from the US Audit Bureau of Circulations,[23] which collectively have a total circulation of over 11 million subscriptions (*USA Today, Wall Street Journal, New York Times, Los Angeles Times, Chicago Tribune, Washington Post, Houston Chronicle, New York Post, Philadelphia Inquirer,* and *Detroit Free Press*); the five most viewed network television news stations (ABC, NBC, CBS, FOX and CNN);[24] and the Associated Press, the largest newswire service in the world.[25] Articles and transcripts were obtained from online media databases, including Lexis-Nexis (http://www.lexis-nexis.com), NewsBank (http://www.newsbank.com), Factiva (http://www.factiva.com) and the *Los Angeles Times* archives (http:// pqasb.pqarchiver.com/latimes). All databases archived all published articles from their respective sources during the study period. Publicly released FDA reports, including press

releases, public health advisories and talk papers, were obtained from online archives on the FDA website (http://www.fda.gov).

Reports from the lay media databases were identified through date-limited searches using a search query designed to maximize recall and precision. The query employed various combinations of 'black box warning', 'black box label', and 'Food and Drug Administration'. Any reports that discussed an FDA-issued black-box warning for a specific drug or group of drugs in the body of the report were included in the study. All included reports discussed black-box warnings for which both an FDA report and a lay media report were published (table I). Any duplicates and reports that did not address FDA-issued black-box warnings for drugs were excluded. All FDA reports issued during the study period were reviewed based on the same inclusion and exclusion criteria. All included FDA and lay media reports were published or aired between 1 January 2003 and 31 December 2007.

Report Coding

A coding sheet was developed based on risk communication theory, with assistance from health communication experts at the Annenberg School of Communication at the University of Pennsylvania. In consulting with these experts and clinicians, we also delineated six core message components for media consumers that would provide essential, basic information about drugs affected by black-box warnings. These core message components include information about (i) the brand name of the affected drug; (ii) generic name; (iii) treatment indication; (iv) reason for the black-box warning; (v) clinical recommendations for patients, such as warning signs and symptoms of the adverse effect addressed by the black-box warning; and (vi) encouragement to discuss the issue with a healthcare provider.

We also coded all reports for the presence of additional message components, including quantitative descriptions of risk (including frequency of events, relative and absolute risks, and odds of the adverse event); mention of the data supporting the black-box warning; the study methods utilized to generate the supporting data; the methodological strengths and weaknesses of the study; supportive and dissenting expert testimonials; supporting and dissenting personal stories from patients (exemplars); any benefits of treatment for the underlying disease; and any uncertainty about the causal relationship between the drug of interest and the adverse event. (Because the FDA has the authority to issue black-box warnings on the basis of 'reasonable evidence of an association' between an adverse event and a medication, 'a causal relationship need not have been proved'.)[11]

Each variable of interest was marked as present or absent. Additional information, including date of publication or airing, word count and primary focus (health, business or legal), was also recorded. The FDA's black-box warnings could affect either an entire class of medications (e.g. antidepressants and paediatric suicidality) or individual medications. Therefore, each report was also categorized as discussing a medication affected by either a class-wide or individual, drug-specific, black-box warning. A random 10% sample of all identified reports was coded by two independent coders to ensure consistency in coding (kappa statistic = 0.91). Any discrepancies in coding were resolved by consensus. The remaining sample was split among these two coders.

Analysis

We calculated descriptive statistics and compared the content of FDA reports with that of lay media reports using two-sided Fischer's exact tests. A summary component score was created ranging from 0–6, providing 1 point for the presence of each core message component. We subsequently compared the scores of the FDA and lay media reports using a Wilcoxon rank-sum test as the distributions of scores were not normally distributed. In order to account for the focus of the articles, we repeated this analysis including only articles with a primary focus of health.

Linear regression was used to examine the impact of media format (newspapers, television or Associated Press), primary focus, word count, type of black-box warning (class-wide or individual

Table I. Reporting of black-box warnings issued by the US FDA between 2003 and 2007

Affected drug or drug class	Reporting of black-box warning	
	FDA report[a]	lay media report[b]
Abacavir	No	No
Acitretin	No	No
Adalimumab	No	No
Alemtuzumab	No	No
Alosetron	No	No
Angiotensin receptor antagonists	No	Yes
Antivirals for hepatitis B	No	Yes
Antidepressants[c]	Yes (PR, TP, PHA)	Yes
Antipsychotics[c]	Yes (TP, PHA)	Yes
Aprotinin	Yes (PR, PHA)	No
Stimulants for attention-deficit hyperactivity disorder[c]	Yes (PR, PHA)	Yes
Bevacizumab	No	No
Bicillin®	Yes (TP)	No
Bosentan	No	No
Cetuximab	No	No
Dactinomycin	No	No
Docetaxel	No	No
Doxorubicin	No	No
Epirubicin	No	No
Erythropoiesis-stimulating agents[c]	Yes (PR, PHA)	Yes
Estrogens[c]	Yes (PR)	Yes
Fentanyl[c]	Yes (PR, PHA)	Yes
Gadodiamide	No	No
Ibritumomab tiuxetan	No	No
Idursulfase	No	No
Infliximab	No	No
Isotretinoin	Yes (PR, PHA)	No
Itraconazole	No	No
Lenalidomide	No	Yes
Lindane	Yes (TP, PHA)	No
Long-acting β-adrenergic receptor agonists[c]	Yes (TP, PHA)	Yes
Mifepristone[c]	Yes (PR, PHA)	Yes
Methadone[c]	Yes (PR, PHA)	Yes
Methotrexate	No	No
Methoxsalen	No	No
Mitoxantrone	No	No
Morphine	No	No
Mycophenolate mofetil	No	Yes
Nevirapine	Yes (PHA)	No
Non-steroidal anti-inflammatories[c]	Yes (PR, TP, PHA)	Yes
Omalizumab	No	No
Perflutren	No	No
Phytomenadione	No	No

Continued next page

Table I. Contd

Affected drug or drug class	Reporting of black-box warning	
	FDA report[a]	lay media report[b]
Progesterone[c]	Yes (TP)	Yes
Raloxifene	No	No
Sirolimus	No	No
Sodium oxybate	No	No
Tamoxifen	No	No
Tenofovir	No	No
Teriparatide	No	Yes
Tinidazole	No	No
Tipranavir	No	No
Tysabri®[c]	Yes (PR)	Yes
Telithromycin[c]	Yes (PHA)	Yes
Thalidomide	No	No
Topical calcineurin inhibitors	No	Yes
Thiazolinediones[c]	Yes (PR)	Yes
Tolcapone	No	Yes
Trastuzumab	No	No
Tretinoin	No	No
Warfarin	No	Yes
Zidovudine	No	No

a FDA reports limited to press releases, talk papers or public health advisories.

b Includes reports from selected newspapers, television broadcast news programmes and newswire services.

c Reports included in analyses.

PHA = public health advisory; **PR** = press release; **TP** = talk paper.

medication) and number of reports generated for each black-box warning on the scores of the lay media reports. As word count was not normally distributed, we categorized this variable into quartiles. In order to examine the relationship between FDA reports and the respective lay media reports about the same black-box warning, we included two additional independent variables in our regression model: (i) the summary score of the corresponding FDA report; and (ii) the duration of time between the publication date of the FDA report and the publication date of the relevant lay media reports.

All test results were considered statistically significant based on *a priori* level of $p \leq 0.05$. We computed all statistics utilizing Stata version 10.0 (StataCorp LP, College Station, TX, USA). As a significant percentage of lay media reports were about antidepressants, we performed a secondary analysis excluding all reports about antidepressants to assess the robustness of our findings. The study protocol was reviewed and exempted by the University of Pennsylvania Internal Review Board.

Results

FDA and US Lay Media Reports about Black-Box Warnings

Fifty-two FDA and 551 US lay media reports about black-box warnings met the inclusion criteria for this study. After 2003, during which only 14 reports about black-box warnings (2.3%) were published or aired, a significant increase in media reporting of medication black-box warnings occurred (table II). The vast majority of these reports concentrated on the health aspects of the black-box warnings, although some articles focused primarily on the business or legal sequelae of the medication's black-box warning (87.6% vs

6.6% vs 5.8%, respectively). While the mean word count was 638 words, the individual word counts ranged from 38 to 7291 words. During the study period, while the class-wide and individual black-box warnings affected over 150 unique medications, most reports focused on the class-wide black-box warnings for antidepressants, non-steroidal anti-inflammatories, stimulants for the treatment of attention-deficit hyperactivity disorder and thiazolinediones. The median number of reports per black-box warning was 7 but ranged from 2 to 192.

Core Message Components

While over 98% of FDA and US lay media reports included descriptions of the treatment indication for the affected drugs and the reason for the black-box warning, FDA reports more frequently detailed their specific brand (98.1% vs 87.7%, respectively; $p = 0.02$) and generic names (84.6% vs 18.1%, respectively; $p < 0.001$). While 96.2% of FDA reports detailed specific clinical recommendations for healthcare providers and patients, such as concerning symptoms that may be attributable to a medication, 43.9% of lay media reports provided similar information ($p < 0.001$). Only 10.6% encouraged affected patients to seek additional information about the black-box warning from their healthcare provider compared with 48.1% of FDA reports ($p < 0.001$) [table III].

Overall, FDA reports included a median of five of the six core message components compared with only three components in US lay media reports ($p < 0.001$). When only lay media reports with a primary health focus ($n = 469$) were considered, the median quality score remained unchanged (three components).

Table II. Baseline characteristics of included US FDA and US lay media reports

Characteristic	No. (%)
Media format	
FDA report	52 (8.6)
newspaper	298 (49.4)
television	120 (19.9)
Associated Press	133 (22.1)
Year of publication or airing	
2003	14 (2.3)
2004	123 (20.4)
2005	158 (26.2)
2006	131 (21.7)
2007	177 (29.4)
Primary focus	
health	528 (87.6)
business	40 (6.6)
legal	V35 (5.8)
Mean word count	638 (range 38–7291)
Medications receiving black-box warning	
non-steroidal anti-inflammatories	103 (17.1)
thiazolinediones	70 (11.6)
antidepressants	192 (31.8)
stimulants for attention-deficit hyperactivity disorder	75 (12.4)
others	163 (27.1)
Median number of reports per warning	7 (range 2–192)

Additional Message Components

Specific quantitative enumeration of risk, encompassing frequency of adverse events as well as relative and absolute risks, appeared in 46.8% of US lay media reports compared with 36.5% of FDA reports ($p = 0.24$). However, FDA reports mentioned the data triggering the black-box warning more consistently than lay media reports (96.1% vs 77.3%, respectively; $p = 0.001$) and also included more information about the study methodology producing the data (71.2% vs 24.5%, respectively; $p < 0.001$). Descriptions of study strengths (0.0% vs 0.01%, respectively; $p = 0.99$) and weaknesses (7.7% vs 5.6%, respectively; $p = 0.52$) were rare.

Distinct differences in the usage of expert testimonials and exemplars in the form of personal stories and examples also emerged. Twenty-five percent of FDA reports cited experts, all of whom were FDA employees, and supported the black-box warnings. In comparison, 78.0% of US lay media reports utilized a diversity of advocates and clinicians to provide expert testimonials representing both support and dissent with the issuance of the black-box warning ($p < 0.001$). Twenty-five percent of lay media reports also included personal

Table III. Message components of US FDA press releases and US lay media reports about drug black-box warnings

Characteristic	FDA [n (%)] (n = 52)	Lay media [n (%)] (n = 551)	p-Value
Core message components			
Brand name of drug	51 (98.1)	483 (87.7)	0.02
Generic name of drug	44 (84.6)	100 (18.1)	<0.001
Treatment indication	51 (98.1)	549 (99.6)	0.24
Reason for the black-box warning	51 (98.1)	545 (98.9)	0.45
Clinical recommendations	50 (96.2)	242 (43.9)	<0.001
Encouragement to seek healthcare provider	25 (48.1)	64 (10.6)	<0.001
Median number of included core message components (interquartile range)	5 (5–6)	3 (2–3)	<0.001
Additional message components			
Quantitative description of risk	19 (36.5)	258 (46.8)	0.24
Mention of supporting data	50 (96.1)	426 (77.3)	<0.001
Mention of supporting data – methods	37 (71.2)	135 (24.5)	<0.001
Mention of supporting data – strengths	0 (0.0)	2 (0.01)	0.99
Mention of supporting data – weaknesses	4 (7.7)	31 (5.6)	0.52
Expert testimonials	13 (25.0)	430 (78.0)	<0.001
Supportive expert testimonials	11 (21.2)	173 (31.4)	<0.001
Dissenting expert testimonials	0 (0.0)	72 (13.1)	<0.001
Exemplars	0 (0.0)	135 (24.5)	<0.001
Supportive exemplars	0 (0.0)	78 (14.2)	<0.001
Dissenting exemplars	0 (0.0)	22 (4.0)	<0.001
Any uncertainty of causality	18 (34.6)	212 (38.4)	0.88
Benefits of disease treatment	10 (19.2)	179 (32.5)	0.08

stories from patients in their reports, while FDA reports uniformly did not ($p < 0.001$).

Reflecting the ability of the FDA to issue black-box warnings in the absence of definitive evidence of a causal relationship between a medication and an adverse event, approximately one-third of all included reports mentioned the FDA's uncertainty regarding causality. However, if uncertainty was noted in the FDA reports, only 45.1% of the lay media reports about the same black-box warnings noted the uncertainty. Additionally, US lay media more frequently incorporated messages about the benefits of disease treatment in their reports than the FDA (32.5% vs 19.2%, respectively; $p = 0.08$).

Multivariate Analysis of US Lay Media Reports

Compared with the articles in the lowest quartile of word count (range 38–344), reports in the highest quartile (range 829–2445) included 0.5 additional core components (95% CI 0.09, 0.93). Type of media format, primary focus of the article, type of black-box warning (class-wide vs specific medication) and number of reports about the same black-box warning showed no association with the number of core components included by lay media reports. Additionally, neither the score of the corresponding FDA report for each lay media report nor the duration of time between the publication date of lay media reports and the publication date of the respective FDA report showed any association with the number of included core message components in the lay media reports (table IV).

Secondary Analysis Excluding Reports about Antidepressants

In a secondary analysis excluding reports about antidepressants, we found only one significant difference in our results: US lay media reports now reported brand names of the affected drugs as frequently as FDA reports (96.5% vs

Table IV. Multivariate analysis of inclusion of core message components about black-box warnings in US lay media reports

Independent variables	Beta coefficient (95% CI)
Number of core components in FDA reports	–0.01 (–0.06, 0.05)
Days between publication of FDA and lay reports	0.01 (–0.01, 0.02)
Media format[a]	
newspapers	–0.05 (–0.42, 0.32)
television	0.18 (–0.27, 0.63)
Primary focus[b]	
business	0.06 (–0.52, 0.65)
legal	0.34 (–0.25, 0.94)
Word count[c]	
second quartile	0.09 (–0.31, 0.50)
third quartile	0.09 (–0.31, 0.49)
fourth quartile	0.51 (0.09, 0.93)
Class-wide medication warning[d]	–0.30 (–0.81, 0.21)
Number of reports about same drug warning	–0.01 (–0.02, 0.01)

a Reference group is the Associated Press.

b Reference group is a health focus.

c Word count is categorized into quartiles; reference group is the first quartile.

d Reference group is a warning for a single, specific medication.

100%, respectively; p = 0.38). This difference did not alter the mean summary scores or the results of the regression analysis (data not shown).

Discussion

Our study of FDA and US lay media reports about medication black-box warnings has shown important differences in the presentation of information from the federal agency overseeing the use of pharmaceutical drugs and lay media organizations. FDA reports, including press releases, public health advisories and talk papers, consistently provided more core messages about affected drugs to consumers. They often explicitly detailed the generic and brand names of the medications, recommendations for patients and encouragement for patients to seek additional advice from their personal healthcare provider. While US lay media reports rarely provided similar recommendations and encouragement, they did report brand names, treatment indication and reason for the black-box warning for the affected medications. They also often incorporated both supportive and dissenting opinions from a variety of experts, such as advocates, clinicians and researchers, in their reporting. Lay media also utilized human interest stories.

Consistent with a recent study of news media reporting of medication research,[26] we found US lay media reports infrequently included generic drug names. While many patients refer to their drugs by their brand names, others may only know these same drugs by their generic names.[27] Therefore some patients may not be aware that a news story has personal implications if only medication brand names are mentioned. As prior research demonstrated that mass media influences the use of healthcare services,[10] we also believe in the importance of encouraging patients to seek additional information and advice from their personal healthcare provider. This provides opportunities to discuss the impact of a black-box warning on an affected patient in the context of individual risk factors, to clarify misinformation and engage the patient in the healthcare decision-making process.

When considering FDA and lay media reports focusing on the same black-box warning, we found little consistency in the relationship between included message components in the two report types. Not only did the temporal proximity of the publication dates of the lay media reports and the relevant FDA report have little impact on the frequency of reporting of core message components, the number of reports generated about the black-box warning also had little impact. There was also surprisingly little correlation between the number of core components present in FDA reports and the number of components included in lay media reports. The primary focus of the report, whether health, business or legal, showed little relationship with the frequency core message components that appeared in lay media reports. Only articles in the highest quartile of word count had significantly higher summary component scores compared with those articles in the lowest quartile of word

count. Overall, this set of findings suggests that the primary focus of the report, the timing of the lay media report in relation to the FDA report, and the amount of information presented in the corresponding FDA report had little impact on the frequency with which US lay media reports included core message components about drugs affected by black-box warnings.

As almost one-third of the included reports focused on the black-box warning for antidepressants, we repeated our analyses excluding these reports. In this secondary analysis, we found that US lay media reports now reported brand names of the affected drugs as frequently as FDA reports. Reasons why lay media reports did not reference the specific drug names of antidepressants are unclear, but may be related to presumed public familiarity with trade names of antidepressants such as Prozac® (fluoxetine). The remainder of our results remained unchanged, supporting the robustness of our initial findings.

The factors affecting the content of news articles are clearly complex. First, one must consider the intended audience for the report. While lay media reports are intended to be distributed to the general public, FDA press releases are intended primarily for lay media sources, public health advisories for healthcare professionals and talk papers for the public. The different intended audiences for the various FDA communications, even though they may address black-box warnings for the same drug, could influence the communication style and specific elements chosen for mention. Additionally, while inclusion of information in an FDA press release may emphasize the importance of those news elements from the FDA's perspective, reporters may not believe that the same elements need to be communicated to the public. Lay media reporters often have limited space to communicate the news. This limitation forces news writers to balance the need to present basic, factual information about a black-box warning with stories from exemplars and expert opinions. Lay media reporters may additionally be influenced by the motivations of their employers to sell their respective products, such as newspapers and television viewership. It is also likely that they approach reporting from the perspective of informing consumers by engaging them with exemplars and experts rather than the clinician's and regulator's perspective of helping patients interpret complex medical information and applying that information to their health decision making. Finally, lay media reporters may utilize FDA communications to inform their reports as well as potentially supplement them with information from a variety of other sources, including experts, advocates, pharmaceutical companies, scientific literature and other lay media outlets, all of which may additionally influence their selection of message components for inclusion in the report and their presentation of the news story.

However, differences in the reported elements about black-box warnings in these FDA and US lay media reports may reflect more than the differences in perspectives. They may reflect a lack of agreement and understanding about the best methods to communicate risk information to the public. Prior research has demonstrated that the use of personal examples of adverse health events may enliven news stories, engage listeners and readers, and enhance understanding of the presented health information.[28] However, use of exemplars in the news can significantly alter perceptions of risk despite inclusion of baseline risk statistics, probably because of the more relatable and memorable nature of the personal stories.[29] Additionally, as only 18% of health journalists receive specialized training in health reporting,[30] a lack of adequate training may compound the problems caused by these knowledge gaps in risk communication.

As this study did not include reports from additional media formats, such as radio broadcasts, independent internet reports, local television news broadcasts or smaller newspapers, the results cannot be generalized to all lay media reports. The sample focused exclusively on US reports and medications regulated by the FDA (brand names of drugs can vary from country to country) and therefore cannot be extrapolated to media reports about adverse drug event warnings in other countries. Additionally, since the six elements selected as core message components were based on consultation with health

communication experts, the items identified as core messages may not reflect the most essential components of health communication messaging from the FDA, health reporter or public perspectives. Also, the study did not capture alternative methods of FDA communications, such as listserv announcements, that may qualitatively differ from the included FDA reports. However, the study did include nationally distributed media reports accessible in print, broadcast and online forms (e.g. from included newspaper and television station websites) that were widely accessible to a significant portion of the adult US population. Our study is also the first, to our knowledge, to closely examine and compare FDA and US lay media reporting about medication black-box warnings.

Conclusions

FDA and US lay media reports about medication black-box warnings present different information. While detailed information about generic names of the affected drugs and encouragement for patients to seek additional advice from their healthcare providers frequently appeared in FDA reports, this information appeared infrequently in lay media communications. However, lay media reports did employ significant use of concordant and discordant personal stories and expert opinions, while FDA reports included only supportive expert testimonials. While both source institutions may have the goal of providing information to the public, they differ in the ways they convey that information. As the likelihood of discovering serious adverse drug effects, some probably necessitating black-box warnings, is high,[31] exploring methods of effective risk communication to the lay public about these emerging adverse event risks is a significant public health issue. Further research is necessary to understand the effectiveness of these different media reports in communicating information to the public, the specific elements that enhance and detract from the intended messages and, ultimately, the impact, both positive and negative, on health behaviours.

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