

An examination of Potential Names for a Recall Notification Campaign



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My area of research:



- Human Factors: Concerns designing products, equipment, and environments considering people's abilities and limitations. Human Factors and Ergonomics Society (hfes.org)

- Warnings and hazard perception

Purposes of warnings are:

- 1) to inform / convey info
- 2) to promote correct behavior & reduce inappropriate behavior
- 3) to prevent or reduce injury, health problems, & property damage

Safety communications:

- Media: labels, manuals, inserts, pamphlets, signs, posters, video, internet etc.
- Modality: visual, auditory

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Warning research has examined aspects:

- that attract attention (e.g., print size, color, symbols)
- that enhance understanding (e.g., giving hazard, consequence, and instructions information)
- that affect beliefs, motivation & behavior (e.g., injury severity info, cost of compliance, social influence)

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• Differences:

- **Warnings:** given on or with product at time of purchase
- **Recalls:** after the product has left manufacturer

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• Research on the Wording of Warnings

– Signal Words

- Intended to attract attention, & express hazard level

- Danger



- Warning



- Caution



American National Standards Institute (ANSI) Z535

- Research: Alternative terms
 - Deadly to Notice

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• Also research on other aspects of wording:

(A) Emphasis terms:

- Extremely important that
 - Absolutely necessary that
 - vs. important or necessary vs. no emphasis term
- Mandatory vs. Recommended that

(B) Explicitness (saying specifically what the issue or instruction is)

- Current research: applied similar techniques for names of recall notifications

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– Participants

- Parts 1 & 2: N = 94
 - Undergraduates at two universities (NC and CA) (N = 31, $M_{age} = 24.5$, $SD = 6.0$)
 - Nonstudent adults in central NC (N = 63, $M_{age} = 44.4$, $SD = 11.7$;
- Part 3: N = 143 ($M_{age} = 25.7$ years, $SD = 11.4$)

• Part 1

- Participants given scenario / background on recalls:

Imagine you are in charge of notifying the public about a product, which after having left the manufacturer, is discovered to be potentially unsafe. Assume it could be a food product, a medicine, or a medical device -- such as contaminated canned meat, substandard antibiotics, or a defective blood-sugar meter.

- Also told that the FDA or the manufacturer (called Company-X may be doing the recall)
- Participants given 61 potential names of recall notices and rated them using 9-point scale: (0) not at all appropriate, (2) somewhat appropriate, (4) appropriate, (6) very appropriate and (8) extremely appropriate.

Table 1. Mean Appropriateness Ratings (and SD) for Names/Titles of Recall Notices Ordered from Highest to Lowest (n = 94)

Name	Mean	SD	Name	Mean	SD
FDA Urgent Recall Notice	5.72	2.00	Product Warning Alert	5.17	2.24
FDA Public Safety Warning	5.70	1.98	FDA Unsafe Product Notice	5.13	2.35
Urgent Product Recall Bulletin	5.57	2.14	Urgent Recall Bulletin	5.12	2.18
Product Danger Alert	5.54	2.16	FDA Health and Safety Alert	5.05	2.22
FDA Urgent Recall	5.51	2.18	FDA Alert	5.04	2.20
Public Safety Warning	5.49	2.12	FDA Unsafe Product Advisory	5.03	2.27
Urgent Recall Notice	5.46	2.08	FDA Health and Safety Bulletin	5.03	1.98
Urgent Recall	5.46	2.32	Company-X Urgent Recall	5.02	2.36
Product Danger Notice	5.36	2.25	Product Warning	5.00	2.16
Urgent Product Recall	5.31	2.13	Company-X Urgent Recall Notice	4.99	2.34
FDA Recall Warning	5.23	2.01	FDA Warning	4.95	2.16
Unsafe Product Notice	5.22	2.12	FDA Recall	4.90	2.25
FDA Safety Warning	5.18	1.92			

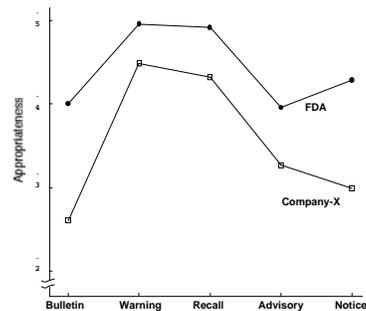
Table 1. Continued

Name	Mean	SD	Name	Mean	SD
Recall Notice	4.82	2.44	Safety Alert	4.30	2.37
Public Safety Notice	4.79	2.20	Product Recall Bulletin	4.28	2.26
FDA Safety Alert	4.74	2.13	FDA Notice	4.28	2.30
Safety Warning	4.72	2.15	Public Safety Bulletin	4.21	2.36
Product Recall Notice	4.70	2.22	Recall Bulletin	4.18	2.52
Unsafe Product Advisory	4.69	2.21	Safety Advisory	4.12	2.18
Public Safety Alert	4.66	1.99	Safety Alert Bulletin	4.10	2.15
Urgent Notice	4.63	2.34	Safety Bulletin	4.06	2.40
Recall Warning	4.62	2.15	Safety Recall Bulletin	3.99	2.12
Health and Safety Alert	4.60	2.39	FDA Bulletin	3.99	2.38
Product Alert	4.57	2.33	FDA Advisory	3.95	2.32
Product Recall Warning	4.56	2.22	Product Advisory	3.94	2.40
Company-X Warning	4.47	2.30	FDA Safety Bulletin	3.85	2.26
Company-X Recall Notice	4.40	2.40	Company-X Advisory	3.26	2.35
Health and Safety Bulletin	4.39	2.40	Company-X Notice	3.14	2.36
Product Warning Notice	4.39	1.99	Company-X Notice	2.98	2.49
Safety Notice	4.36	2.21	Company-X Bulletin	2.60	2.31
Company-X Recall	4.31	2.33			

A different group of participants rated individual component words a recall campaign name (n = 143)

Words	Mean	SD
Urgent	6.37	1.61
Recall	6.26	1.83
FDA	6.00	2.13
Danger	5.97	2.06
Warning	5.87	1.68
Unsafe	5.80	1.93
Alert	5.71	1.77
Safety	5.34	2.09
Health	5.33	2.02
Product	4.71	2.35
Advisory	4.62	2.00
Notice	4.05	2.20
Public	3.99	2.28
Bulletin	2.87	2.06

Figure 1. Mean ratings of appropriateness for word pairs involving entities and root words



Part 2 WHAT ABOUT SURGICALLY-IMPLANTED MEDICAL DEVICES?

- Participants told about the potential problem of using the name *recall* for surgically-implanted medical devices:

Some medical devices are surgically implanted inside a human body, such as heart pacemakers. Suppose that after some of these devices have been implanted it is discovered that some of them may have defects and need to be taken out of service. . . There is some concern that people told of a 'recalled' implanted device may panic unnecessarily. Here is the issue: Because users cannot simply "return" their surgically implanted device and may become anxious, do you think the word 'recall' should be used in these notices?

- Rated 3 items using 9-point rating scale: (0) do not agree at all, (2) somewhat agree, (4) agree, (6) very much agree, and (8) completely agree.

Part 2: Items that were rated concerning the use of the term 'recall' for surgically-implanted medical devices

- (a) Use the word 'recall' for everything
- (b) Use the term 'recall' for everything except use a different term for surgically-implanted devices.
- (c) Don't use the term 'recall' but rather use another term that fits *all* kinds of products (including surgically-implanted ones).

Table 3. Means and standard deviations for items concerning the use of the term "recall" with respect to medical devices (n=94)

Mean	SD	Item
3.50	2.9	Use the word 'recall' for everything
5.09	2.7	Use the term 'recall' for everything except use a different term for surgically implanted devices.
2.55	2.8	Don't use the term 'recall' but rather use another term that fits <i>all</i> kinds of products (including surgically-implanted ones).

Discussion

- Certain words were highly rated:**
 - Urgent
 - Recall
 - Danger
 - FDA
- Certain names were highly rated:**
 - FDA Urgent Recall Notice,
 - FDA Public Safety Warning
 - Urgent Product Recall Bulletin
 - Product Danger Alert
 - Public Safety Warning
 - FDA Urgent Recall
- If just want very brief, 2-word name:**
 - Urgent Recall

Participants indicated that something other than the word Recall for surgically-implanted medical devices was permissible

- Study was not designed to determine what that name might be.
- Suggests that exceptions may be okay than trying to cover everything through a single standard which could "water-down" the notification

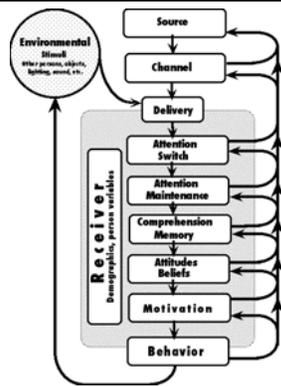
Some simple testing can aid risk communication decisions

ACKNOWLEDGMENT

- Thanks to Nancy Ostrove and Bradford Stone of the U.S. FDA for their comments.



Communication-Human Information Processing (C-HIP) Model



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Do Not



Get Pregnant

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Image 1



Image 2



Image 3



Image 4



Image 5



Image 6

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FDA Code of Federal Regulations 21 CFR 330.10 Paragraph A4(v):

Labeling shall be clear and truthful in all respects and may not be false or misleading in any particular. It shall state the intended uses and results of the product; adequate directions for proper use; and warning against unsafe use, side effects, and adverse reactions *in such terms as to render them likely to be read and understood by the ordinary individual including individuals of low comprehension under customary conditions of purchase and use.*

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