



Thinking creatively about evaluating interactions
between people and packaging with the goal of
improving health: The Packaging HUB

Laura Bix

Acknowledgements

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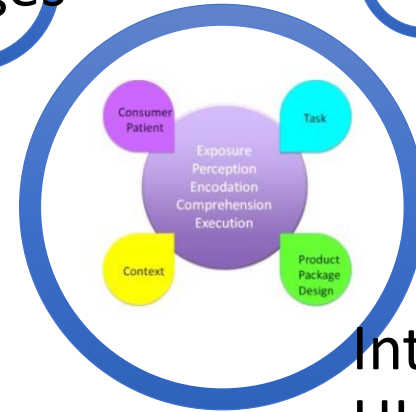
THE OHIO STATE
UNIVERSITY
WEXNER MEDICAL CENTER



Objectives

Provide some context on the move toward User Centered Design (UCD)

- Trends in healthcare
- Megatrends that are driving these changes



Introduce the Mission of the HUB

- Some of the work that we do



Environments				
Functions		Physical	Atmospheric	Human
	Protection	Cushions Corner Posts Anti Slip Agents	Barrier Materials O ₂ Absorbers Anti Static Agents Wet Strength Materials UV Absorbers UV Blockers	Child Resistant Closures Tamper Evident Features Sterile Barriers
	Communication	Bar Codes RFID Shock Indicators Symbols Text	Microbial Indicators O ₂ Indicators TTIs	Warnings Directions for Safe Use Indicators of Safety and Quality
	Utility	Stretch Wrap Strapping Dual Ovenable Materials	Edible Films Anti Slip	Senior Friendly Packaging Handles Grips Size Limits Pour spouts

Approach to the Design of Products

Product-centered design
(PCD)

The properties of the product determine
which users can use it

"The product has to do that"

User-centered design
(UCD)

The users functional capabilities determine
which product properties are adequate

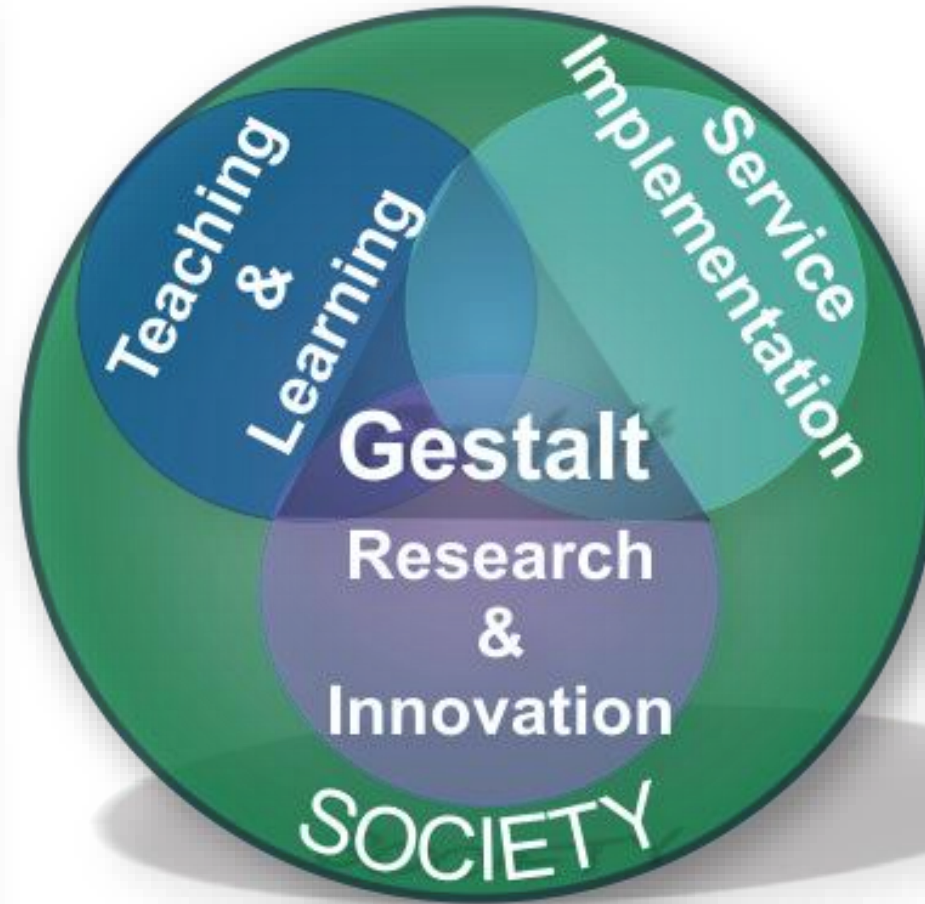
"The user has to be able to do that with
the product"

Source: Keates S, Clarkson J (2004). "Chapter 11: Countering design exclusion" in "Countering Design Exclusion: An Introduction to Inclusive Design". London, Springer-Verlag: 141-156.



HUB Researchers employ a user-centered approach to package design, informed by science, with the goal of improving health outcomes

MISSION



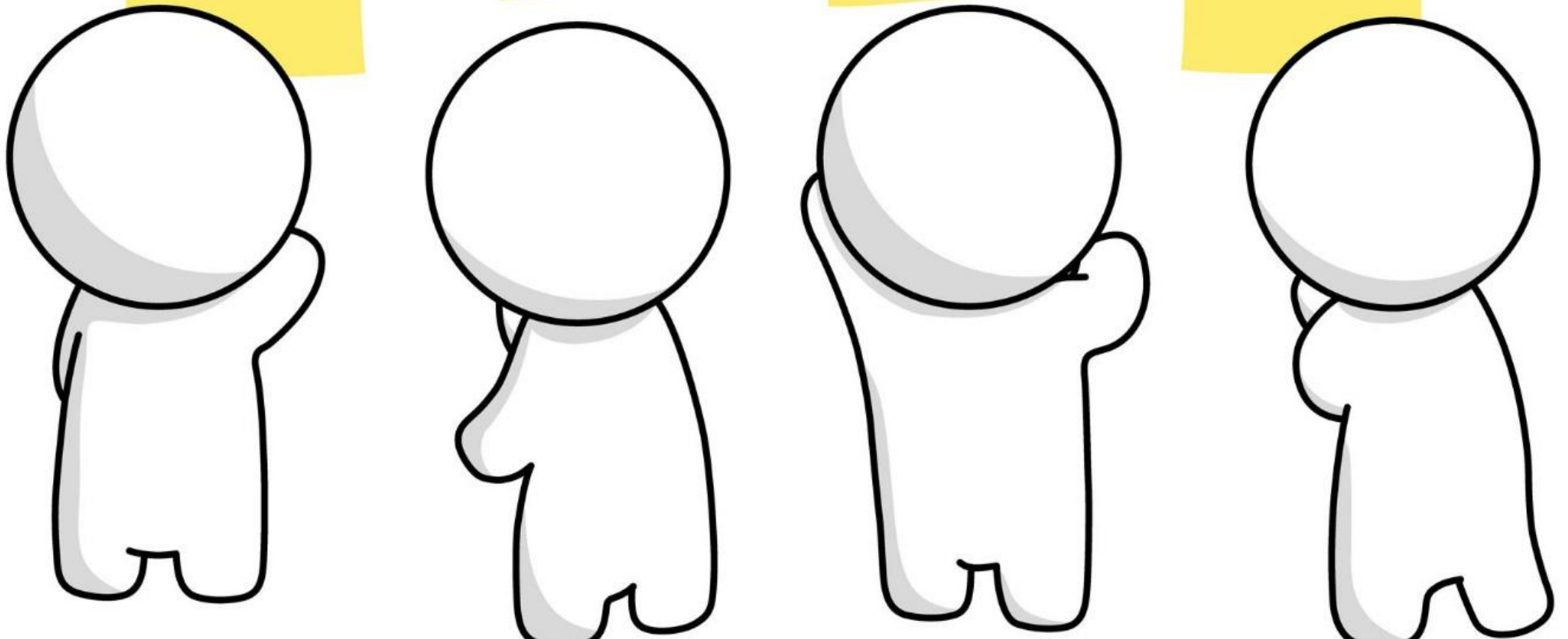
ENGAGED PROCESS

- Create a cohort of scientists and industry professionals that embrace a user-centered approach to package design
- Enhance accessibility of packaging by changing the packaging industry's approach to design
- Increase adherence to medical regimens
- Reduce the prevalence of medication errors
- Reduce the rate of hospital acquired infections
- Reduce the frequency of unintentional exposure to medication by children

IMPACT

Our Process for Making a Difference

Use cross functional thinking and
objective evaluations of performance
to create products that are safer and
perform in all contexts of healthcare



Forbes Predicts 5 Megatrends for Healthcare

- Formation of **Accountable Care Organizations**
 - (Move from silos to an entire system of entities centered on patient health)
- Move **from fee for service** (based on volume and complexity) **to one based more directly on health outcomes**
 - (Move from sick care to healthcare)
- **Rewarding better health outcomes** and quality
 - Required reporting of quality and patient satisfaction to CMS (Medicare Advantage Model-Stars program- those with the highest ratings receive additional payments)
- **Health Information Technology** (healthIT) Incentives
- New generation of **Physicians**
 - Connected



A system comprised of
fragmented, siloed
entities focused on a
single product,
procedure, or process



Evolution in care delivery



We are on the cusp of “a new era of medical product development,” one where medical treatments are tailored to the characteristics, needs, and preferences of patients.

Tailored therapies

Targeted gene therapies

3D printed customized parts

Paving the way for personalized medicine 2013 [Available from:

<http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/PersonalizedMedicine/UCM372421.pdf>

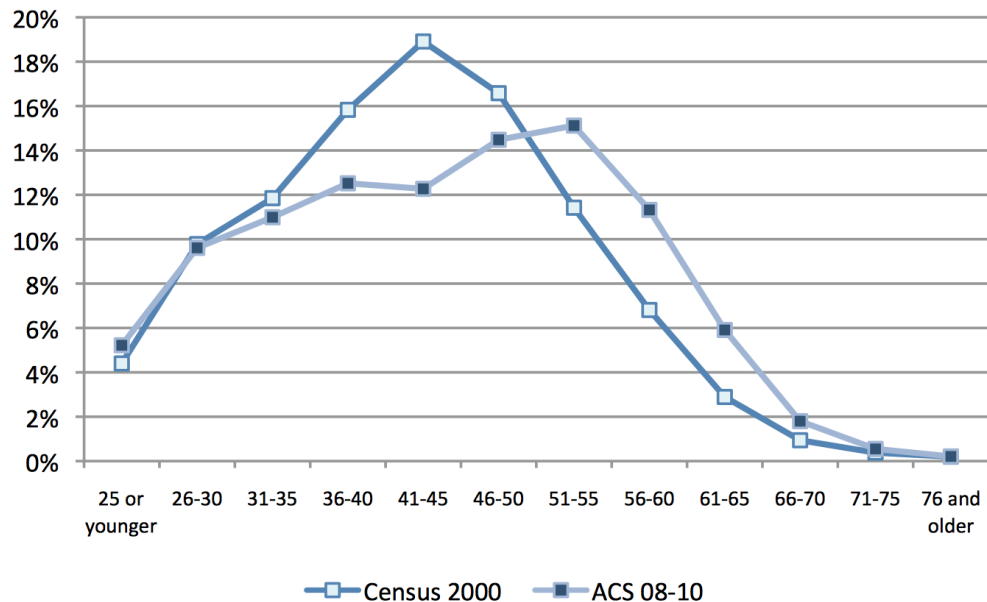


Drivers of Change

Population Aging

- 20% of the US population will be over the age of 65 by 2030
- 5% of the US population will be over the age of 85 by 2050

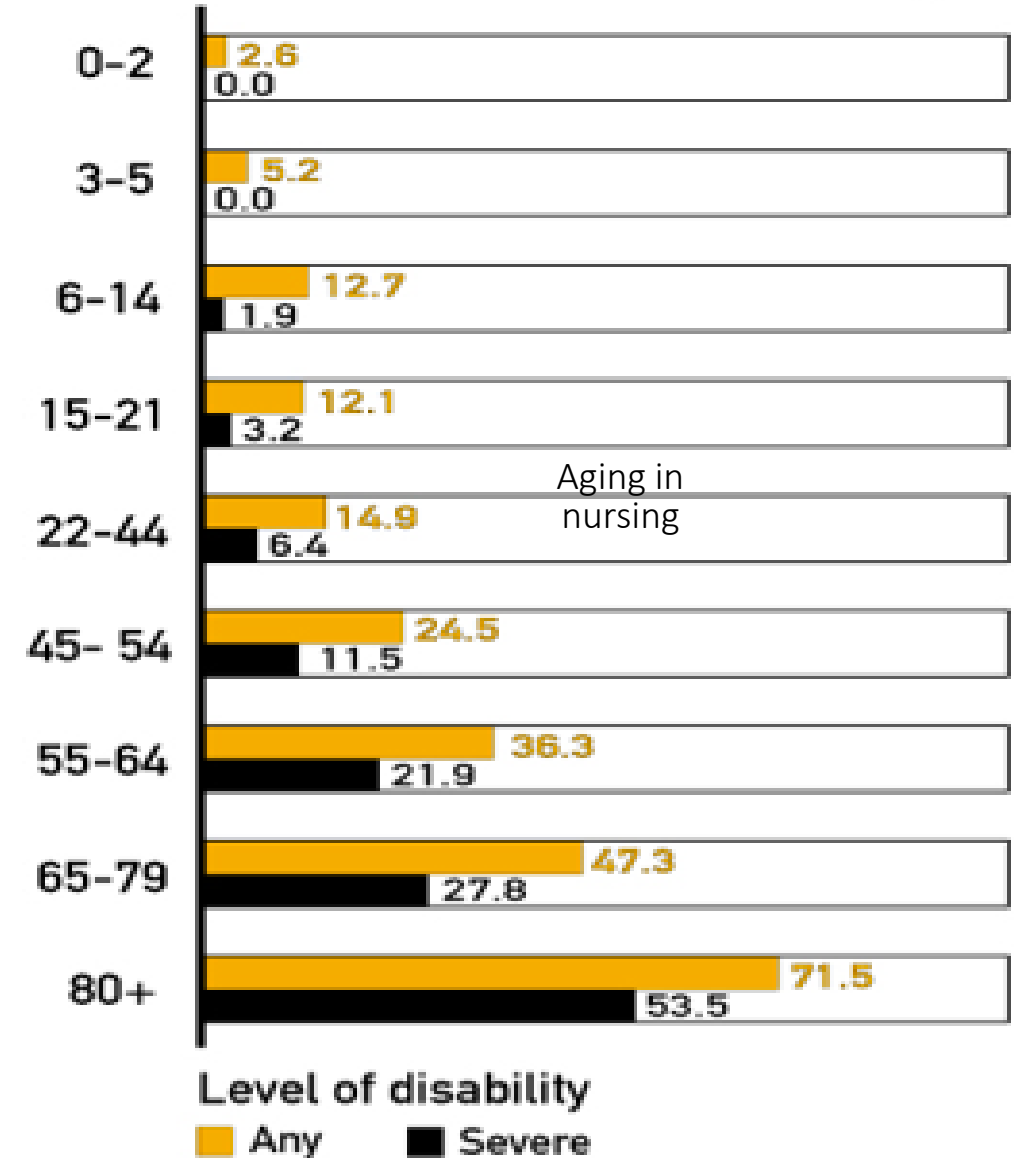
Figure 9. Age Distribution of RNs, in Five-Year Increments



Data Sources: HRSA analysis of the ACS 2008-2010 three-year file and Census 2000 Long Form 5% sample

Disability prevalence by age

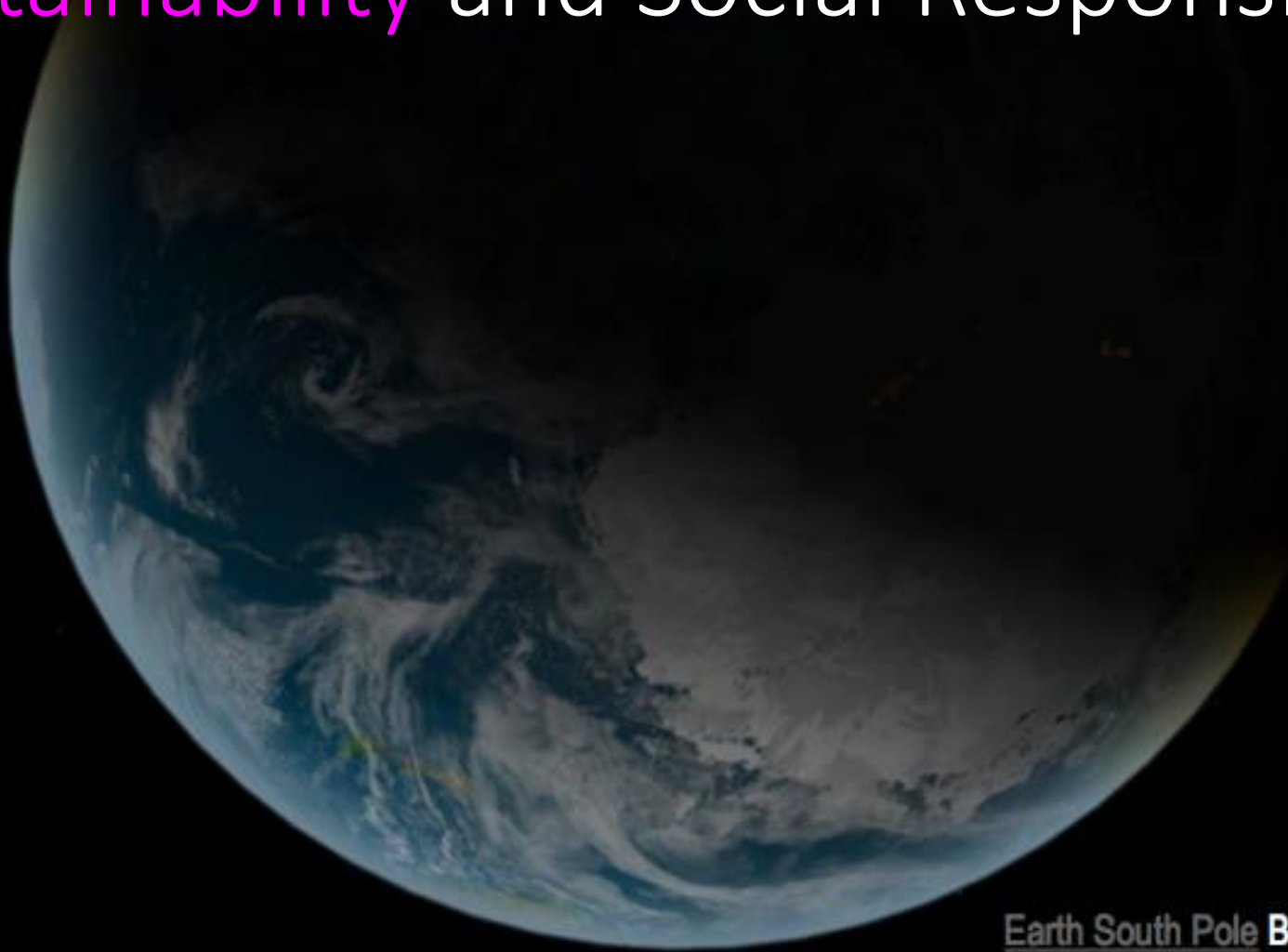
Percent with specified level of disability



Source

U.S. Bureau of the Census, Current Populations Reports, Household Economic Studies Report '97

Sustainability and Social Responsibility



Earth South Pole By FlyingSinger

Packaging Plays a More Prominent Role in Reaching and Retaining Customers

- Escalating competition for customers
 - Customer expectations are increasing
 - Customization
 - Diverse range of product choices available
- Changes in Advertising
 - Remote Control
 - Fragmentation
 - Filtering
- Viral/Social media Movement

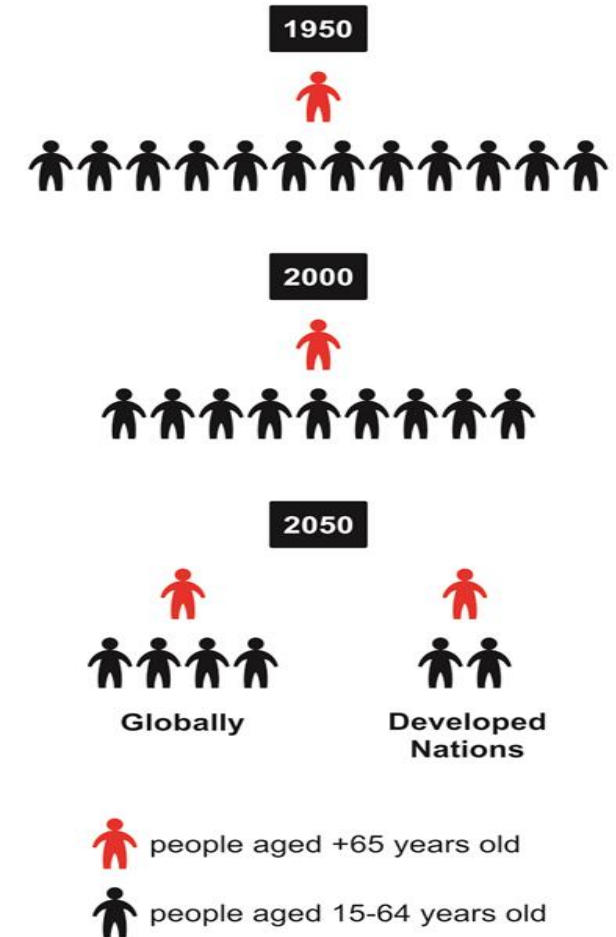
Twee



patientslikeme

Trends aggravating difficulties in aging

- Reductions in the **Potential Support Ratio (PSR)**⁴
- Increased polypharmacy, complexity in regimen
- Shifts from **acute care** to **ambulatory care**
- Shifts from **acute disease** to **chronic disease**
- Shifts from long term care to home care
 - **80-90%** of long term care provided by families



⁴. Wiggins, David (March 5, 2013). "Making good design great: Inclusive Design; It's Normal to be Different." 2nd World Seminar on Accessible and Inclusive Design. Gouda, Netherlands

Shifting role of the caregiver



- 1,167 non-paid caregivers
 - 46% cared for people 5-9 prescriptions/day
 - 18% cared for people ≥ 10 prescriptions/day
 - 69% of those cared for took 1-4 OTCs or supplements as well
- Triple Burden
 - Personal Care
 - Household Chores
 - Medical Tasks

Medical Tasks

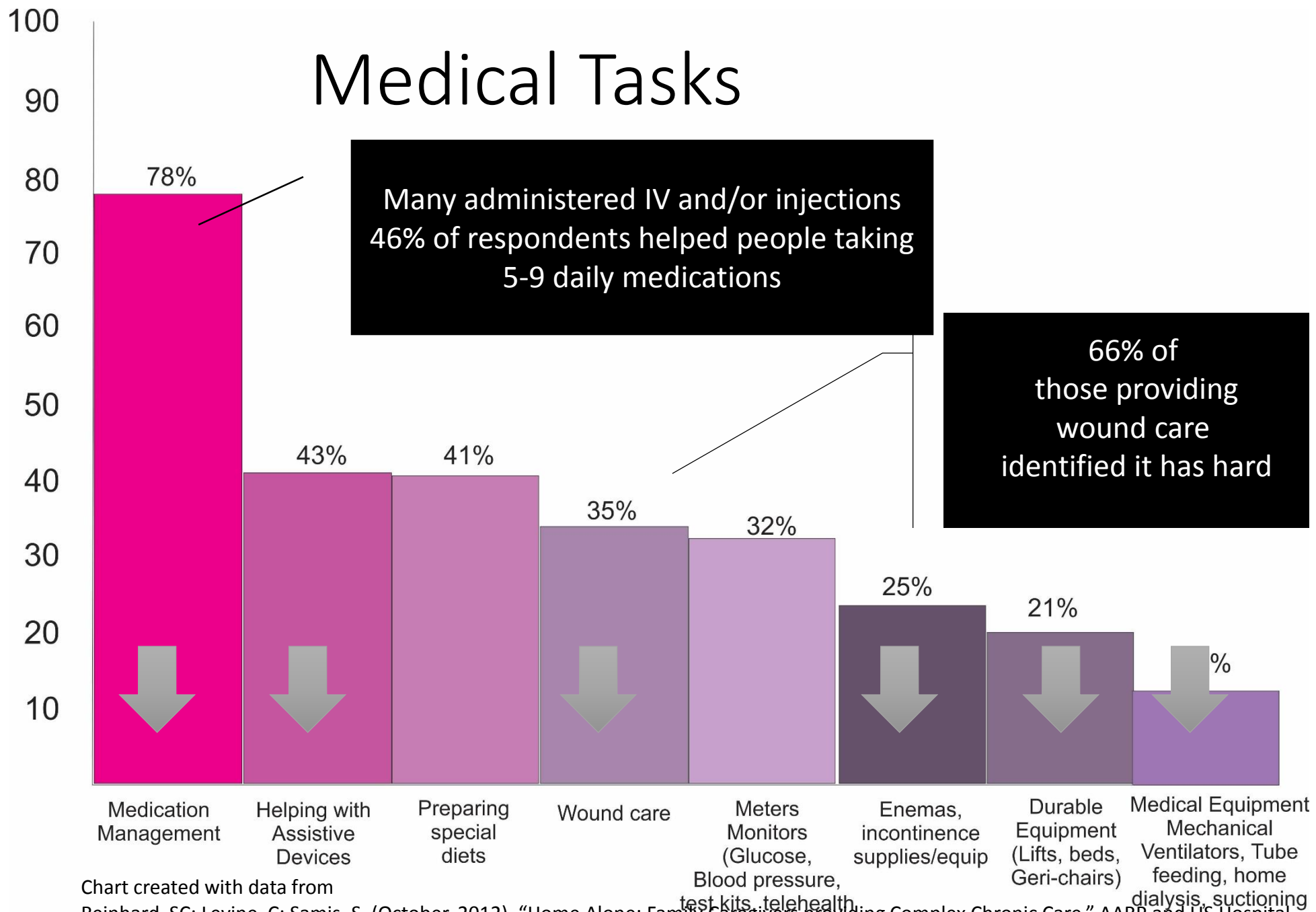


Chart created with data from Reinhard, SC; Levine, C; Samis, S. (October, 2012). "Home Alone: Family Caregivers providing Complex Chronic Care." AARP and US Hospital Fund.

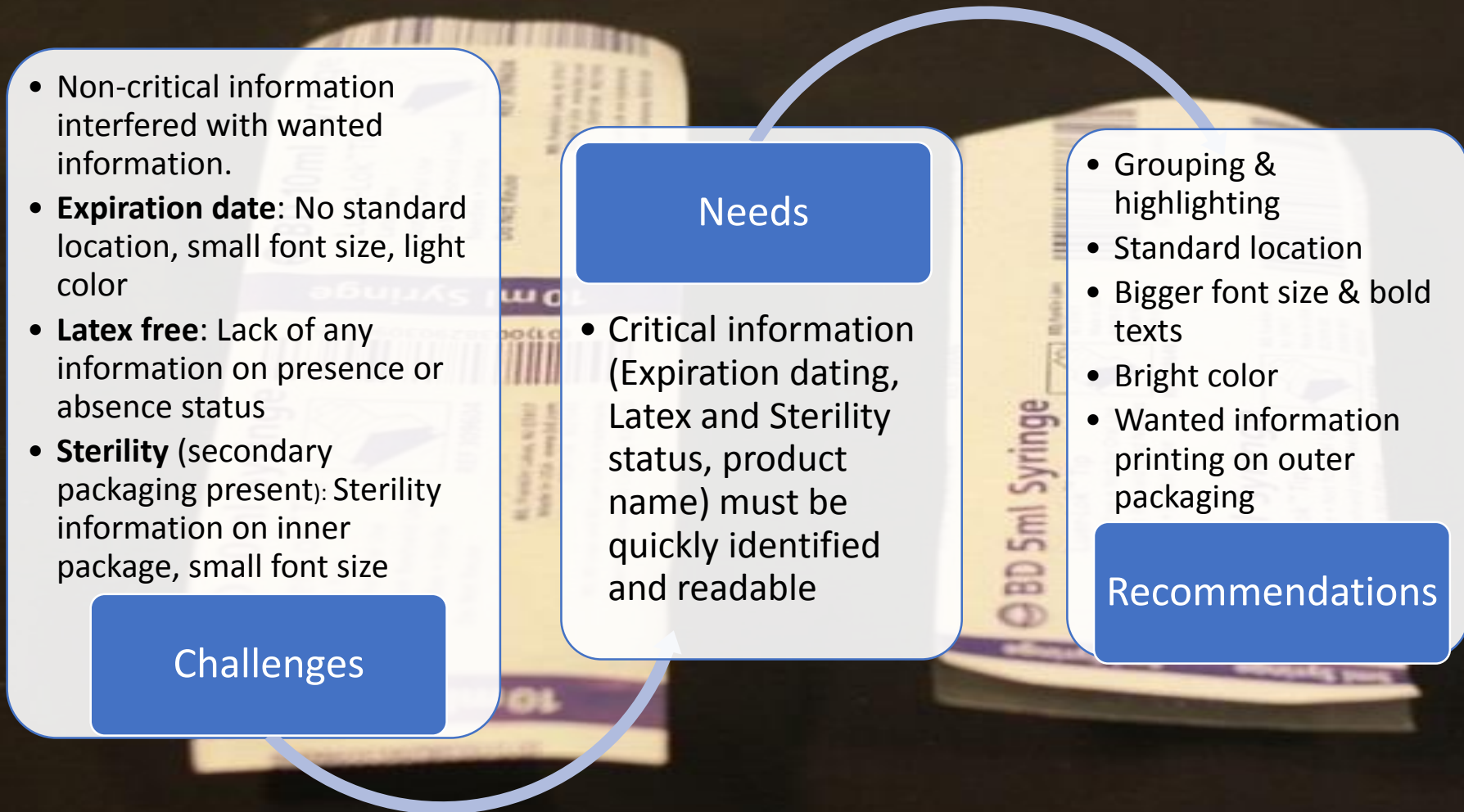


Gaming with Forced Choice Tasks



Seo's Work

Labeling Issues



FDA Rule: Medical Symbols

Summary: Use of Symbols in Labeling (Final Rule)

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The Food and Drug Administration (FDA or the Agency) is issuing this final rule revising its medical device and certain biological product labeling regulations to explicitly allow for the optional inclusion of graphical representations of information, or symbols, in labeling (including labels) without adjacent explanatory text (referred to in this document as “stand-alone symbols”) if certain requirements are met. The final rule also specifies that the use of symbols, accompanied by adjacent explanatory text continues to be permitted. FDA is also revising its prescription device labeling regulations to allow the use of the symbol statement “Rx only” or “R only” in the labeling for prescription devices.

Regulatory Impact Analysis

[Use of Symbols in Labeling \(Final Rule\) \(PDF - 212KB\)](#)

Federal Register: [81 FR 38911, June 15, 2016](#)

Docket: [FDA-2013-N-0125](#)

Packaging Technology and Science

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Do Healthcare Professionals Comprehend Standardized Symbols Present on Medical Device Packaging?: An Important Factor in the Fight Over Label Space

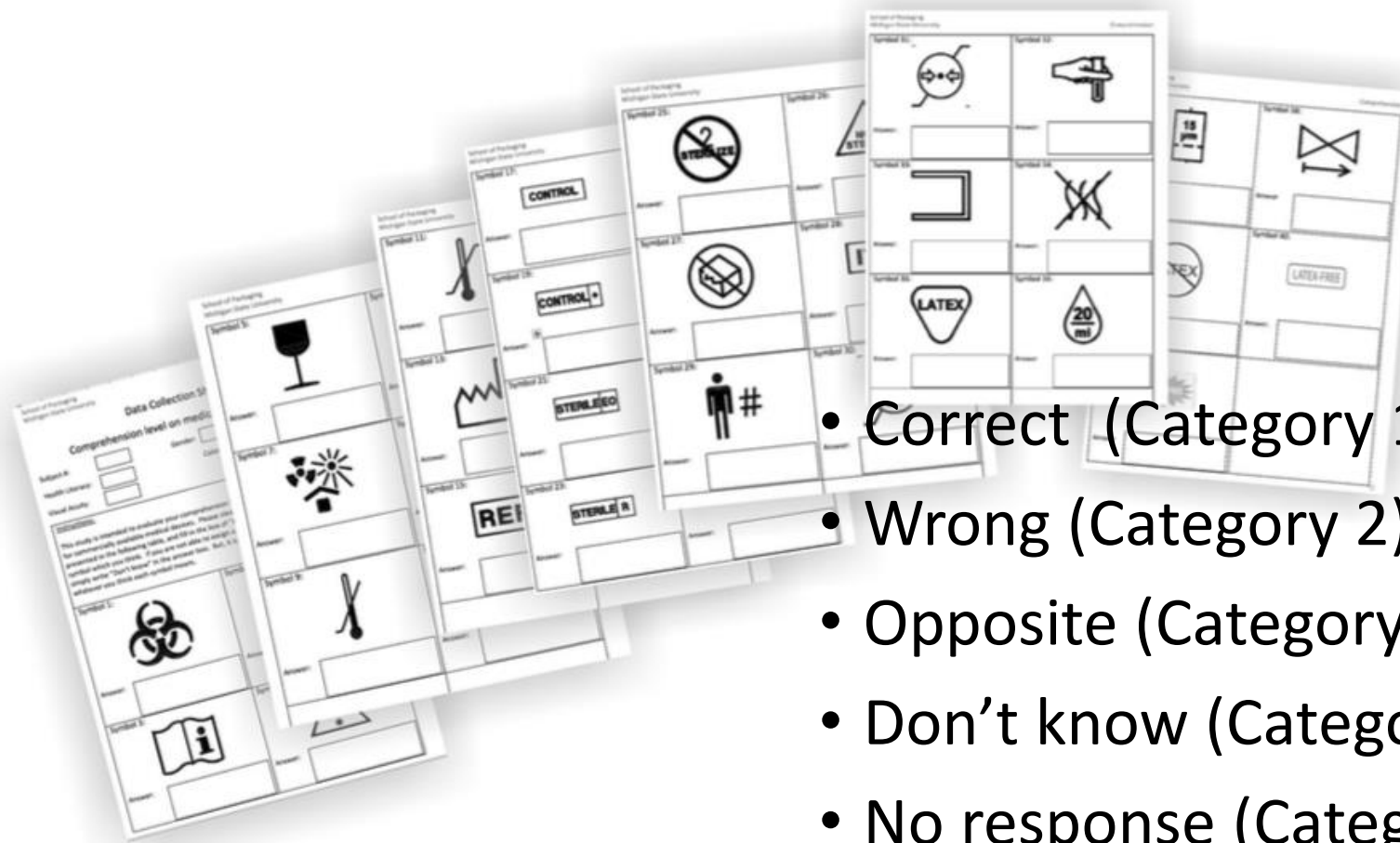
By Do Chan Seo,¹ Moslem Ladoni,² Eric Brunk,¹ Mark W. Becker³ and Laura Bix^{1*}

Standardized Symbols

Table 1. Symbols intended for medical devices identified in international and US standards

No	Symbol description	ISO 15223	EN 980	ANSI/AAMI/ISO 15223	FDA guidance
1	Biological risks	✓	✓	✓	✓
2	Do not re-use	✓	✓	✓	✓
3	Consult instructions for use	✓	✓	✓	✓
4	Caution, consult accompanying documents	✓	✓	✓	✓
5	Fragile, handle with care	✓		✓	
6	Keep away from sunlight	✓	✓	✓	
7	Protect from heat and radioactive sources	✓	✓	✓	
8	Keep away from rain/keep dry	✓	✓	✓	
9	Lower limit of temperature	✓	✓	✓	✓
10	Upper limit of temperature	✓	✓	✓	✓
11	Temperature limitation	✓	✓	✓	✓
12	Use by date	✓	✓	✓	✓
13	Date of manufacture	✓	✓	✓	✓
14	Batch code	✓	✓	✓	✓
15	Catalog number	✓	✓	✓	✓
16	Serial number	✓	✓	✓	✓
17	Control	✓	✓	✓	✓
18	Negative control	✓	✓	✓	✓
19	Positive control	✓	✓	✓	✓
20	Sterile	✓	✓	✓	✓
21	Sterilized using aseptic processing techniques	✓	✓	✓	✓
22	Sterilized using ethylene oxide	✓	✓	✓	✓
23	Sterilized using irradiation	✓	✓	✓	✓
24	Sterilized using steam or dry heat	✓	✓	✓	✓
25	Do not resterilize	✓	✓	✓	✓
26	Non-sterile	✓	✓	✓	
27	Do not use if package is damaged	✓		✓	
28	In vitro diagnostic medical device	✓	✓	✓	✓
29	Patient number	✓		✓	
30	Humidity limitation	✓		✓	
31	Atmosphere pressure limitation	✓		✓	
32	Manufacturer		✓		✓
33	Authorized representative in the European community		✓		✓
34	Sufficient for/Contains sufficient for <n> tests		✓		✓
35	For IVD performance evaluation only		✓		✓
36	Contains or presence of natural rubber latex		✓	✓	
37	Do not use if package is damaged		✓		
38	Fluid path			✓	
39	Sampling site			✓	
40	Non-pyrogenic			✓	
41	Drops per milliliter			✓	
42	Liquid filter with pore size			✓	
43	One-way valve			✓	
Total # of symbols		31	32	38	25

Comprehension Test-ISO 9186-1: 2007



- Correct (Category 1)
- Wrong (Category 2)
- Opposite (Category 3)
- Don't know (Category 4)
- No response (Category 5)

Figure 1. Booklet provided to test participants.

UCL $\geq 85\%$
In
Category 1






































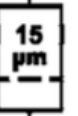
								
Mean Proportion Correct	97.7%	96.5%	95.3%	94.2%	87.2%	76.7%	75.5%	72.1%
								
Mean Proportion Correct	70.9%	70.9%	70.9%	67.4%	61.75	55.8%	47.7%	47.7%
								
Mean Proportion Correct	47.7%	45.4%	44.2%	43.0%	39.6%	39.6%	38.4%	38.4%
								
Mean Proportion Correct	37.2%	34.9%	32.6%	24.4%	18.6%	17.5%	14.0%	5.8%
								
Mean Proportion Correct	2.4%	2.3%	0.0%	0.0%	0.0%	0.0%		
Standardized Symbols Tested								

Figure 2. The 38 Standardized Symbols Tested for Comprehension (Presented from the highest proportion of correct responses in category 1 (correct responses) to the lowest).

4 Symbols didn't receive a single correct response (0% Category 1)





	
	
	
	

Figure 5. Symbols which did not receive a single correct response from study participants

Critically Confusing/Confusing Category







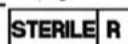

Symbol	Symbol Description	Means	LCL	UCL
	Keep away from rain	15.1%	7.3%	22.6%
	Lower limit of temperature	19.8%	11.0%	28.0%
	Upper limit of temperature	16.3%	8.2%	24.0%
	Keep away from sunlight	2.3%	0.0%	5.6%
	Protect from heat and radioactive sources	4.7%	0.0%	9.2%
	Temperature limitation	2.3%	0.0%	5.6%
	Sterilized using irradiation	2.3%	0.0%	5.6%
	Drops per milliliter	3.5%	0.0%	7.4%

Figure 6. Means and UCL and LCL at 95% CI for Category 2b (Opposite of intended meaning). Orange shading indicates that symbols were found to be confusing (UCL exceeded 5%). Red shading indicates symbols that were found to be critically confusing (LCL exceeded 5%).

- $\geq 5\%$ in category opposite

Summary

- 6/38 (15.8%) Classified as “successful” (UCL \geq 85%)
 - 5 of these had text (English) imbedded within
- 3/38 (7.9%) were found to be critically confusing
 - Interpreted to mean the opposite of what was intended by \geq 5% of the participants

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Packag. Technol. Sci. 2016;

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Do Healthcare Professionals Comprehend Standardized Symbols
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By Do Chan Seo,¹ Moslem Ladoni,² Eric Brunk,¹ Mark W. Becker³ and Laura Bix^{1*}

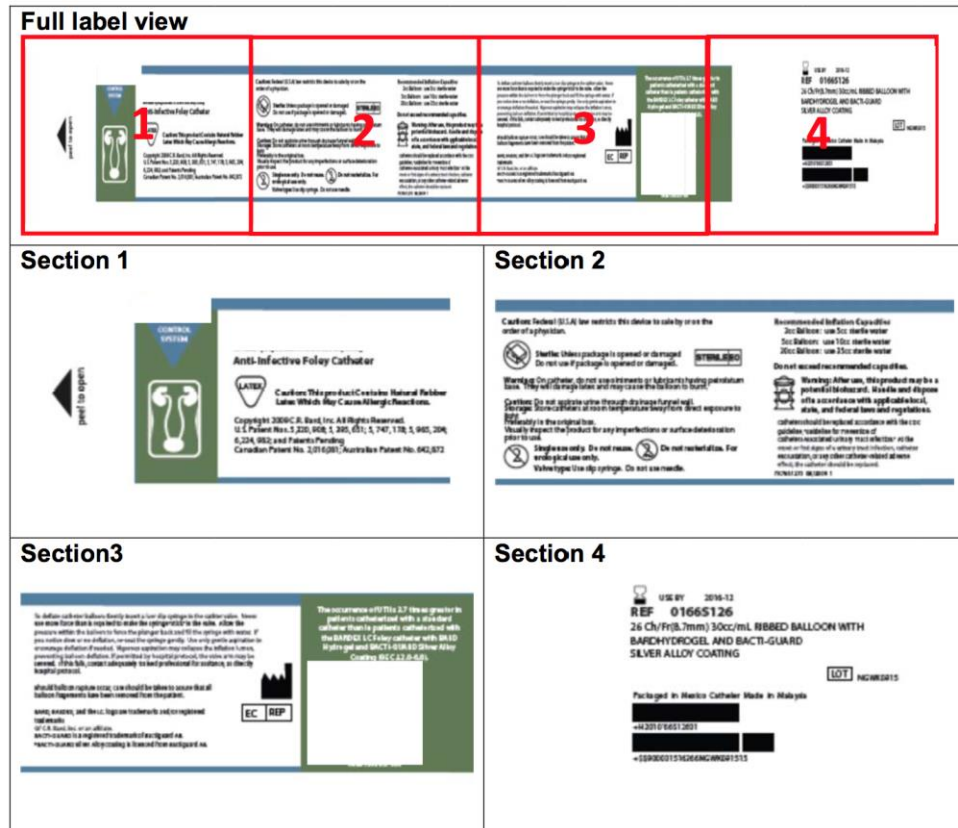


Figure 3. Locations of labeling information

- **6 companies 20 products**
 - **None** of the 20 catheters studied had all four pieces of critical information in one location
 - **40%** of them used **2 locations** and
 - **60 %** used **3 locations** to display the information.

Benchmarking

Commercial label A

CHEMO

CMSure™

Foley Catheter

1 Unit

PEEL TO OPEN

Sterile: Unless package is opened or damaged.

Caution: This product contains natural rubber latex which may cause allergic reactions

Federa (USA) law restricts this device to sale by or on the order of a physician.

CHEMO® and CMSure™ are registered trademarks of CHEMO Inc. International

Warning: On catheter, do not use petroleum-based ointments or lubricants. They will damage the catheter and may cause balloon to burst.

Caution: Do not aspirate urine through drainage funnel wall. For single patient use only. Do not resterilize. For urological use only

Storage: Store catheters at room temperature away from direct exposure to light, preferably in the original box.

Valve type: Use luer slip tip syringe. Do not use needle.

Recommended Inflation Capacities

3cc Balloon: use 5ml sterile water
5cc Balloon: use 10ml sterile water
15cc Balloon: use 20ml sterile water
20cc Balloon: use 25ml sterile water
30cc Balloon: use 35ml sterile water
40cc Balloon: use 45ml sterile water
75cc Balloon: use 80ml sterile water

Warning: After use, this product may be a potential biohazard. Handle and dispose of in accordance with applicable local, state, and federal laws and regulations.

To deflate catheter balloon: Gently insert a luer slip syringe in the catheter valve. Never use more force than is required to make the syringe "stick" in the valve. Allow the pressure within the balloon to force the plunger back and fill the syringe with water. If you notice slow or no deflation, reseal the syringe gently. Use only gentle aspiration to encourage deflation if needed. Vigorous aspiration may collapse the inflation lumen, preventing balloon deflation. If permitted by hospital protocol, the valve arm may be severed. If this fails, contact adequately trained professional for assistance, as directed by hospital protocol.

Should balloon rupture occur, care should be taken to assure that all balloon fragments have been removed from the patient.

Visually inspect the product for any imperfections or surface deterioration prior to use.

Copyright 2002, Chemo International Inc., USA
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Manufactured in Malaysia for
CHEMO International, Inc.,
www.chemo.com

Item #: AS 42022

Type: 2 WAY STANDARD

Size: 22 FR

Balloon: 30 CC

Coating: SILICONISED

Lot #: 12-G-04E

Mfg. Date: 2012/06

Exp. Date: 2017/04

Commercial label B

syco/ Healthcare

CENBALL

SOFTMER*

Foley Catheter

PEEL TO OPEN

21-046-0000

To deflate catheter balloon, fully seat the syringe tip into the catheter valve, twisting slightly. Allow the balloon to deflate passively. Use gentle aspiration to encourage deflation if necessary. Avoid vigorous aspiration which has been known to cause balloon nondeflation. If permitted by hospital protocol, the valve arm may be severed. If this fails, contact qualified personnel for assistance, as directed by hospital protocol.

1 *Trademark of Tyco Healthcare Group LP
**Trademark of Hydromer, Inc.

SYCO HEALTHCARE GROUP LP, LANSING, MI 48823
MADE IN MALAYSIA. 2011 SYCO HEALTHCARE GROUP
ALL RIGHTS RESERVED. 222333
PRODUCT INFORMATION IN U.S. 1-800-222-9999.
www.cenball.com
EC REP SYCO HEALTHCARE U.K. LTD.

Rx
ONLY

STERILE/EO

CE

0120 See Instructions



Single Use

CAUTION: This product contains natural rubber latex which may cause allergic reactions.



Avoid Freezing
And Excessive Heat

WARNING: DO NOT USE OINTMENTS OR LUBRICANTS HAVING A PETROLEUM BASE. WILL DAMAGE THE CATHETER AND MIGHT CAUSE THE BALLOON TO BURST

LOT 8348029Q

REF

2015/12

1614C

14 Fr - 5 cc

Coude Catheter

Sonde Coudee Ch 14 - 5 cm

14 Fr. - 5 cc Cateter Acodado

14 F - 5 cc Sonda Angulada

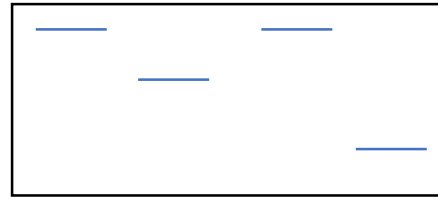
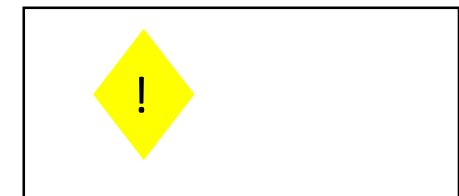
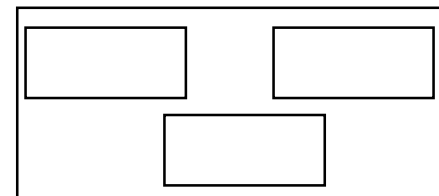
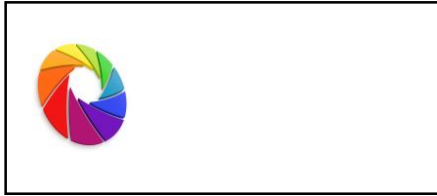
14 F - 5 cc



+3390001516360NGW001515

Critical information difficult to find

Do Chan Seo



Color

Grouping

Boxing

Symbol
Usage

- Location of section images was randomized so as to mitigate location effects.

Anti-Infective Foley Catheter

Copyright 1982 SOP Inc. All Rights Reserved.
U.S. Patent Nos. 1,100,209; 4,200,234; 3,
242,459; 6,344,201;
4,101,244; and Patents Pending
Canadian Patent No. 1,444,921;
Australian Patent No. 457,459



Anti-Infective Foley Catheter

26 Ch/Fr(8.7mm) 36cc/mL Silver Alloy Coating

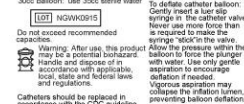


Packaged in Mexico. Catheter Made in Malaysia.

 +559000015163000ACW0001515



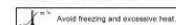
Recommended Inflation Capacities
 3cc Balloon: use 5cc sterile water
 5cc Balloon: use 10cc sterile water



To deflate catheter balloon: Gently insert a luer slip syringe in the catheter valve. Never use more force than is required to make the syringe "stick" in the valve. Allow the pressure within the balloon to force the plunger with water. Use only gentle aspiration to encourage deflation if needed. Vigorous aspiration may collapse the inflation lumen, preventing balloon deflation.



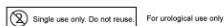
Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.



Warning: On catheter, do not use ointments or lubricants having petroleum base. They will damage the catheter and may cause the balloon to burst.

Caution: Do not aspirate urine through drainage funnel w/o catheter.

Storage: Store catheters at room temperature away from direct exposure to light and preferably in the original box. Visually inspect the product for any imperfections or surface deterioration prior to use.



Anti-Infective Foley Catheter

Copyright 1982 SOP Inc. All Rights Reserved.
U.S. Patent Nos. 1,100,209; 4,200,234; 3,
242,459; 6,344,201;
4,101,244; and Patents Pending
Canadian Patent No. 1,444,921;
Australian Patent No. 457,459



Anti-Infective Foley Catheter

26 Ch/Fr(8.7mm) 36cc/mL Silver Alloy Coating



Packaged in Mono Catheter Made in Malaysia



Recommended Inflation Capacities
 3cc Balloon: use 5cc sterile water
 5cc Balloon: use 10cc sterile water
 10cc Balloon: use 20cc sterile water



To deflate catheter balloon: Gently insert a luer slip syringe in the catheter valve. Never use more force than is required to make the syringe "stick" in the valve. Allow the pressure within the balloon to force the plunger with water. Use only gentle aspiration to encourage deflation if needed. Vigorous aspiration may collapse the inflation lumen, preventing balloon deflation.



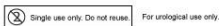
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Warning: Oil catheter, do not use ointments or lubricants having petroleum base. They will damage the catheter and may cause the balloon to burst.

Caution: Do not aspirate urine through drainage funnel wall.

Storage: Store catheters at room temperature away from direct exposure to light and preferably in the original box. Visually inspect the product for any imperfections or surface deterioration prior to use.



Statistical Data Analysis

Binary variable:

- . Proportion of correct choice (Yes/No) prior to timing out at 60 seconds
- . A general liner mixed model was fitted using the Glimmix procedure of SAS.



Terms (significant)	p-value
Boxing	P=0.0101
Symbol	P<0.0001

(There was no evidence of significance for any 2-way , 3-way and 4-way interaction terms)

Continuous variable:

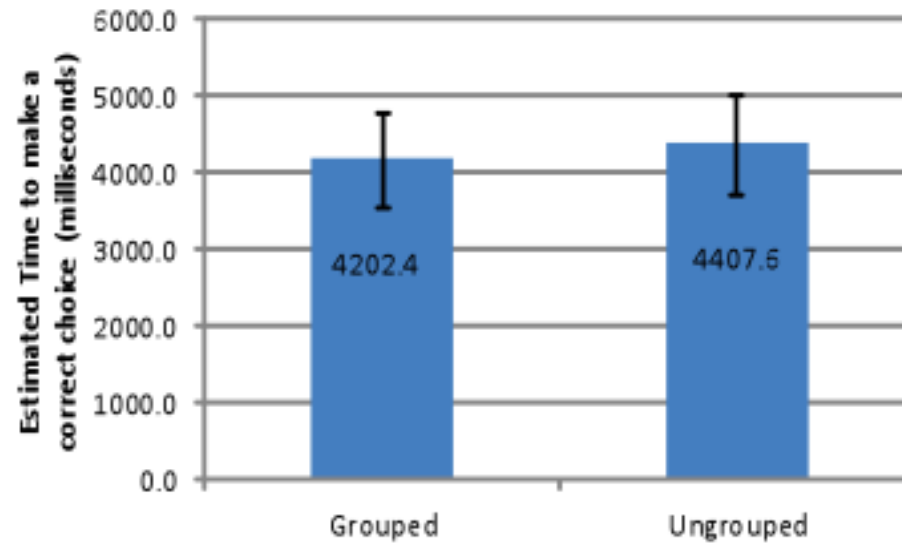
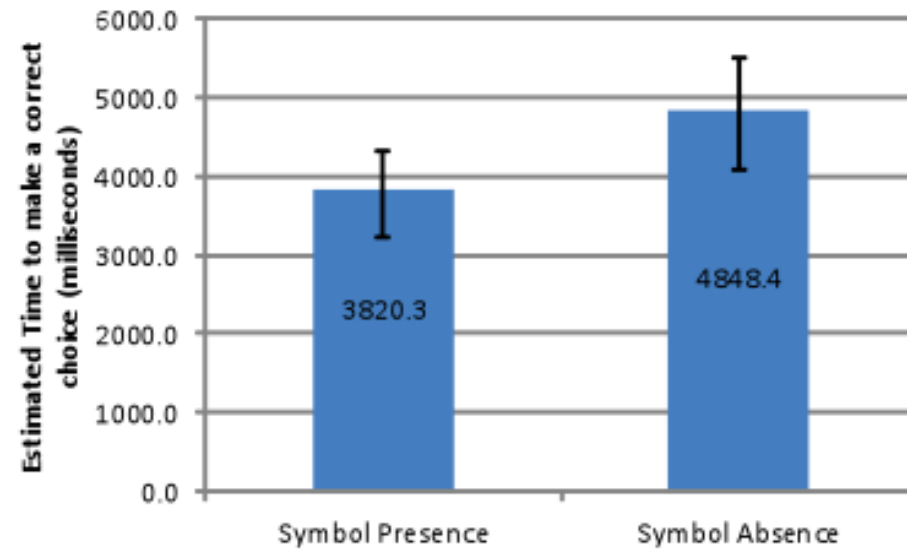
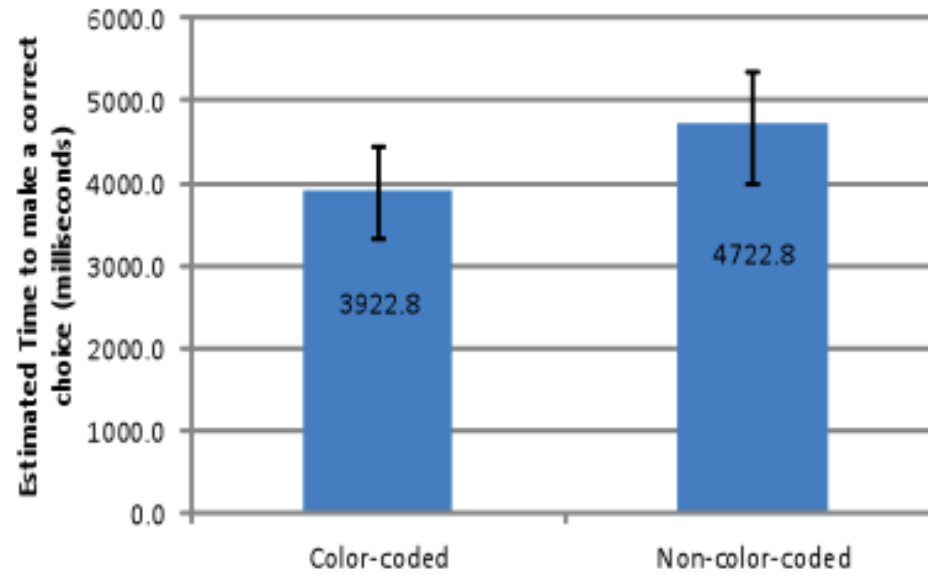
- . Time to correct choice prior to timing out at 60 seconds
- . Log-transformed to meet normal distribution assumption
- . A general linear mixed model was fitted using the Mixed procedure of SAS.



Terms (significant)	p-value
Grouping	P=0.0104
Symbol	P<0.0001
Color	P<0.0001

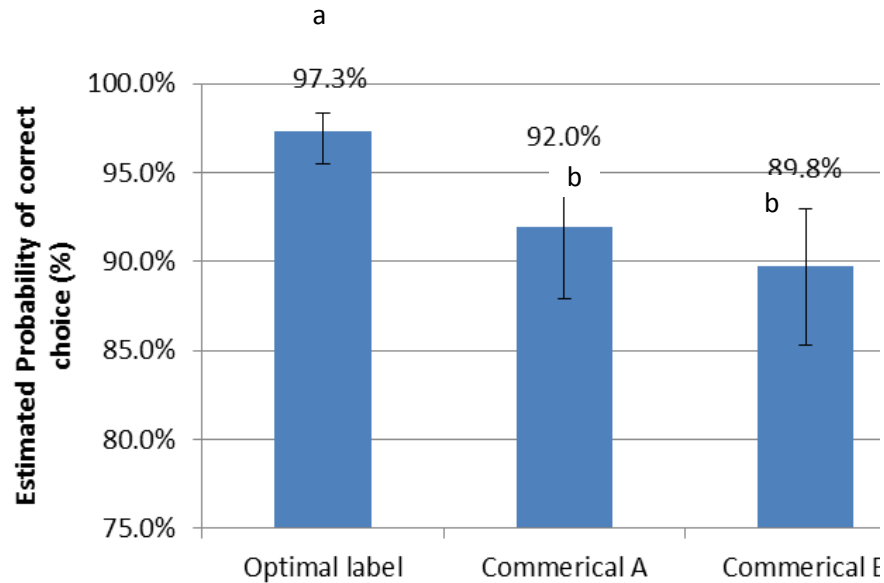
(There was no evidence of significance for any 2-way, 3-way and 4-way interaction terms)

Seo- Results

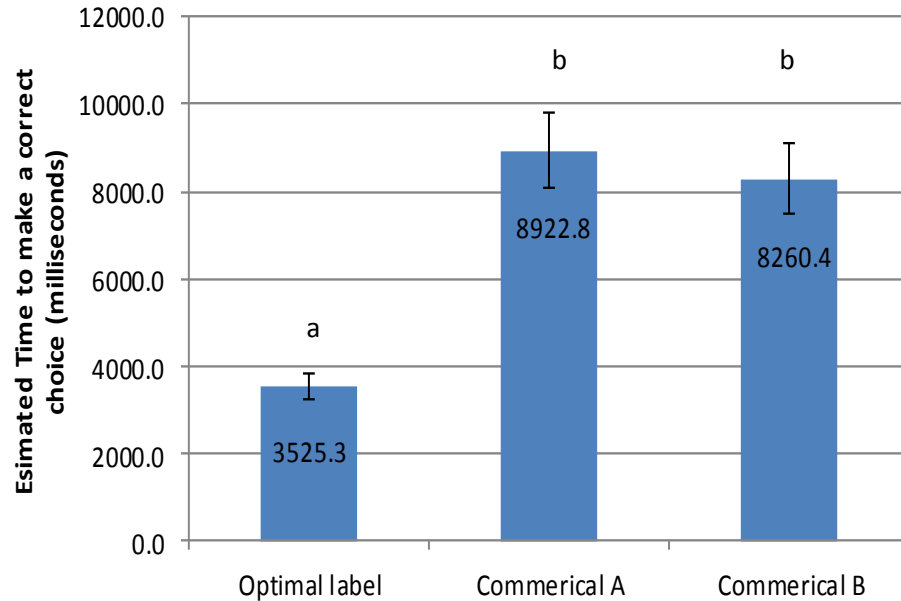


Optimal vs. Commercial labels

- The optimal label (**grouped, symbol presence and color-coded condition**) resulted in a higher proportion and less time to correct choice than the two commercial labels.



Proportion of correct selections

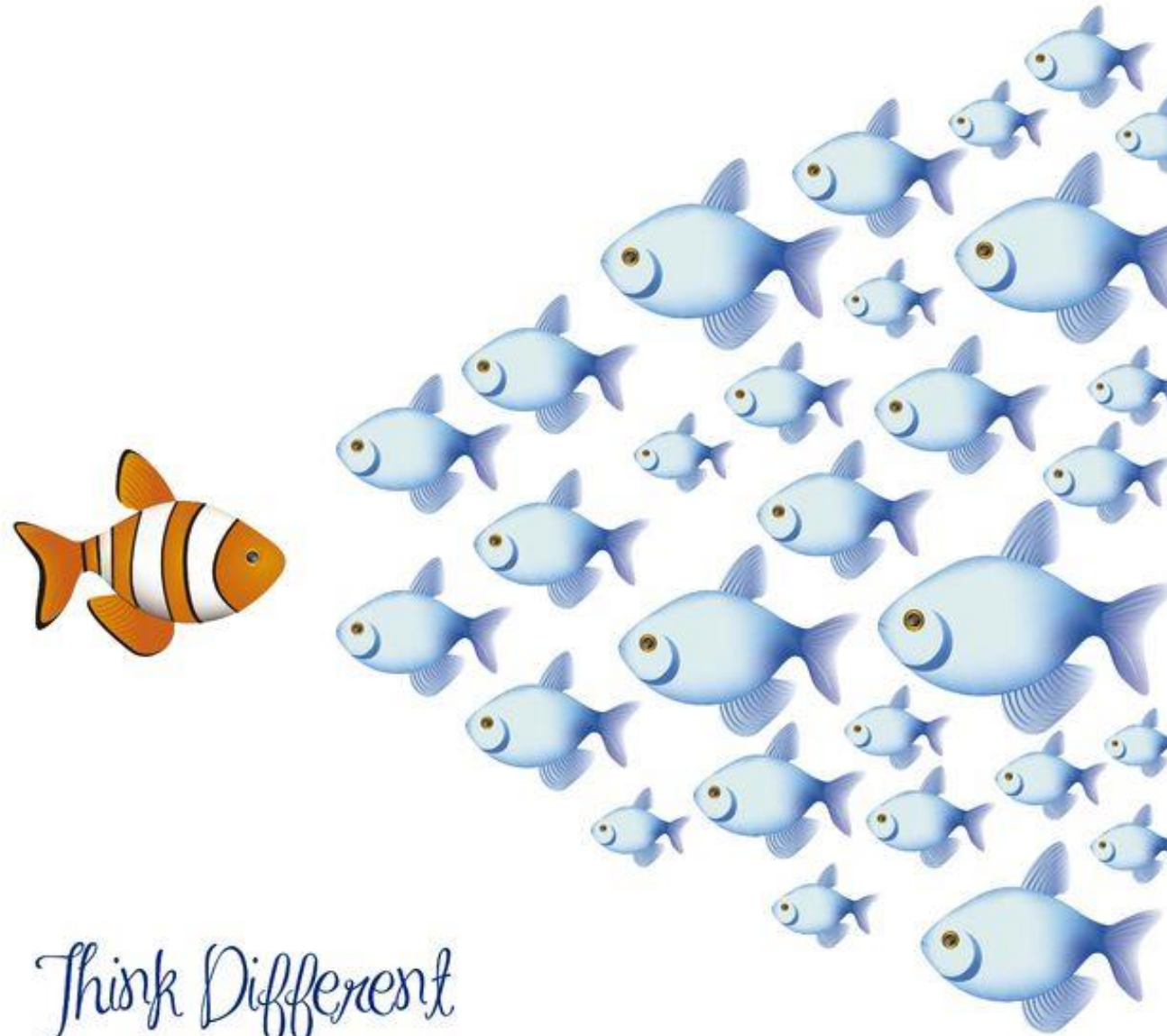


Time to correct selection

Note: Estimated least square means (LSM) with estimated upper and lower limits.

Letters indicate statistical significance at $\alpha=0.05$

- Art + Science = Great things
- Wicked problems require concerted, interdisciplinary “out of the box” approaches
- Thoughtful packaging design backed with careful inquiry can play a part in solving some of the emerging problems of the world
- Its ubiquitous nature provides one avenue to have a substantial impact in unexpected ways.



Think Different
against the current

Questions or Concerns?



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