

Is the test of senior friendly/child resistant packaging ethical?

Laura Bix PhD,* Javier de la Fuente MS,* Kenneth D. Pimple PhD,† and Eric Kou MS,‡

*Assistant Professor and PhD Student, School of Packaging, Michigan State University, East Lansing, MI, USA, †Director of Teaching Research Ethics Programs, Poynter Center, Indiana University, Bloomington, IN, USA and ‡Associate Engineer, Packaging Technology Center – Medical Products Manufacturing, Cardinal Health, McGaw Park, IL, USA

Abstract

Research has documented the drastic reduction of unintentional poisonings of children since the introduction of child resistant (CR) packaging. However, studies also indicate that consumers report difficulty using CR packages, in part because tests which determine the ‘senior friendliness’ of CR designs that are used throughout the world disallow people with ‘overt or obvious’ disabilities from being test subjects. Our review of drug package usability suggests that the current tests of CR packaging can and should be revised to correct this problem. We use US legislation, regulation and data to exemplify these points, but the conclusions are applicable to all protocols that include the exclusionary provision.

Correspondence

Laura Bix
Michigan State University
153 Packaging
East Lansing
MI 48824
USA
E-mail: bixlaura@msu.edu

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Introduction

The testing protocols for senior friendly/child resistant (CR) packaging frequently exclude people with ‘overt or obvious disabilities’ and those who are unable to follow written directions (people with visual impairments and illiterate subjects) as eligible test subjects. These exclusionary practices do not adequately honour the ethical principle of justice.

A review of the evolution of protocol testing for senior friendly/CR packaging is presented. This is followed by a discussion of ethical principles that should undergird research involving human subjects and problems the exclusionary practice presents, when viewed through this standard. Finally, we recommend changes to the protocol that would make it more objective and more inclusive. Although US documents are used to exemplify the ideas proposed, the

implication exists wherever the exclusionary clause is present.

History

The unintentional poisoning of children as a result of the ingestion of household products became a noted problem shortly after the introduction of flavoured aspirin in 1943. By 1953, the first US Poison Control Center had been established to serve as a central source of information and treatment. This was followed by the establishment of a US Clearinghouse for Poison Control Centers in 1957. The Clearinghouse was started to coordinate the efforts of local centers, gather statistical data on poisonings, and provide diagnostic and therapeutic information.

During this same year (1957) the over-the-counter (OTC) drug industry voluntarily

accepted the recommendations of a medical advisory panel^a to reduce the strength of children's aspirin and to limit the number of tablets per package.¹ Efforts to develop 'safety closures' were also recommended by the panel at this time.

Taking the suggestion of the medical advisory group, in 1959, researchers from Durham, NC (US) reiterated the need to use 'safety closures' for aspirin in an article that appeared in the *Journal of the American Medical Association (JAMA)*.² Ten years of hearings, debates, discussion and testing ensued until 1970, when the Congress enacted the Poison Prevention Packaging Act of 1970 (PPPA), the first act of its kind.

The Act required 'special packaging' [child resistant (CR) packaging] on select drugs and household chemicals. The Act defines special packaging as, 'packaging that is designed or constructed to be significantly difficult for children under 5 years of age to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for "normal adults" to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.'³

Administration of the PPPA was the responsibility of the Food and Drug Administration (FDA) until October, 1972, when public law 92-573 transferred administrative responsibility to the Consumer Product Safety Commission (CPSC)⁴ (see Table 1). The CPSC remains responsible for the regulation of the CR packaging of drugs and household chemicals. Additionally, in the years since the creation of CR packaging, the PPPA, and its underlying regulations (16 CFR 1700-1750), have served as a model for many of the other laws, regulations and standards employed throughout the world¹ (See Table 1 for significant historical events associated with CR packaging and Table S1 for a summary of current CR protocols from around the world).

^aThe complete panel name was the 'Medical Advisory Panel on Accidental Ingestion and Misuse of Salicylate Preparations by Children.'

During the first 25 years of US regulation (1970-1995), package designers were so focused on protecting children from poisoning that they frequently forgot to account for the convenience of the person needing the medication. The effect was the exclusion of many seniors and people with disabilities. This was largely because of the fact that the CPSC protocol for testing CR packages for 'senior friendliness' specified that adults aged 18-45 served as subjects for the adult portion of the test.

In actual usage situations, consumers older than 45 had difficulties with CR packages, and frequently circumvented child-resistant features. Many publications from this era, document the difficulties of consumers.⁵⁻¹⁷

By the early 1990s, the CPSC recognized the need to design a new test protocol in order to facilitate CR package designs that could be used more effectively by consumers. As a result, on July 21, 1995 the CPSC published a final rule that revised the senior-friendly portion of the test entitled, 'Requirements for the Special Packaging of Household Substances; Final Rule.'¹⁸ Products packaged on or after July 21, 1998 had to comply with the new adult testing requirements (see Fig. 1).

Because the US protocol was the first of its kind, it has served as the basis for numerous other protocols (see Table S1). This fact is referenced in the commonly adopted global standard, ISO 8317:2004, 'Child-Resistant Packaging - Requirements and Testing Procedures for Reclosable Packages.' The ISO document indicates, 'A number of other countries have introduced standard test methods based on similar principles [to the US protocol]. There are now around the world various types of packaging, which are recognized as child-resistant, based on the test of the nature described.' (ISO 8317, 2004).

The current test protocol for ensuring senior friendly/child resistant packaging

As a result of the 1995 revision, the current protocol employs 100 adults between the ages of 50 and 70 who do not have 'obvious or overt physical or mental disabilities.'¹⁸ Figure 1

Table 1 Historical events in legislation and regulation of child resistant closures for drug packaging

Year	Event
1943	Flavoured aspirin is introduced
Mid-late 40s	Awareness of accidental ingestion builds
1953	First Poison Control Center is established It serves as a central source of information on ingredients, toxicity, expected symptoms and recommendations for treatment
1957	National Clearinghouse for Poison Control Centers established Coordinated efforts of local poison control, gather statistics, and provide diagnostic and therapeutic information
1957	FDA sponsors a meeting of the Medical Advisory Panel Discussed accidental ingestion and misuse of salicylate preparations by children
1957	Efforts to develop safety closures are recommended. The drug industry voluntarily complies with recommendations to reduce the strength of children's aspirin and to limit the number of tablets in containers to 36.
1959	Article published in JAMA recommends the use of safety closures [4]
1961	National Poison Prevention Week established Public Law 87-319 designated the third week of March as Poison Prevention week. (first observation 1962)
1966	US House of Representatives Hearings Established a joint committee of industrial, professional, and governmental people to develop a methodology.
1970	Poison Prevention Packaging Act (PPPA) Congress deems that legislation was necessary to secure the benefits of CR containers to all consumers.
1972	Consumer Product Safety Act Public Law 92-573 transfers the duties of the PPPA and others to the Consumer Products Safety Commission (effective Spring, 1973)
1974	National Research Act Creates the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research, which, in turn, publishes 'The Belmont Report'
1990	Proposed rule to change the protocol methodology
1998	Final rule It applies to products packaged on or after July 21, 1998. At least 90% of 'normal' adults (50-70) must be able to open the package twice within allotted test periods. At least 80% of children unable to open during specified test.

depicts the distribution of gender and age of the adult test panel and the steps involved in the protocol.

As the protocol begins, test participants are screened by testers for 'obvious or overt physical or mental disabilities;' participants determined to have such disabilities are excluded from testing.

Participants who are determined to not have overt or obvious disabilities then test the package, individually, in well-lit, distraction free areas. The presence of other participants or onlookers is not allowed. Each person is provided 5 min to try to open and close the package at test if it is reclosable. If the participant is successful, he/she has to try to open and close a second package during a 1-min-period. If the

person is able to open and close the second package during that period, the package gets a pass; if not, the data is counted as a failure of the CR package for that individual.

If, in the 5-min period, the person is not able to open or close the package, she/he is given a 2-min screening test (1 min for each screening package). This screening determines whether or not the participant is able to open packages that do NOT have CR features. The screening packages are: a plastic snap closure (see Fig. 2a) and continuous thread (CT-see Fig. 2b) plastic closure that have specific dimensions and requirements for preparation. If the person successfully opens and closes both screening packages, the participant continues with the

The current test protocol for ensuring senior friendly/child resistant packaging

 **100 senior adults**
50-70 years old



Normal adult screening
People with overt disabilities can be excluded

Age range	Percentage of the test panel	Percentage by gender	
		Female	Male
50-54	25	68-72	32-28
55-59	25	70	30
60-70	50	70	30

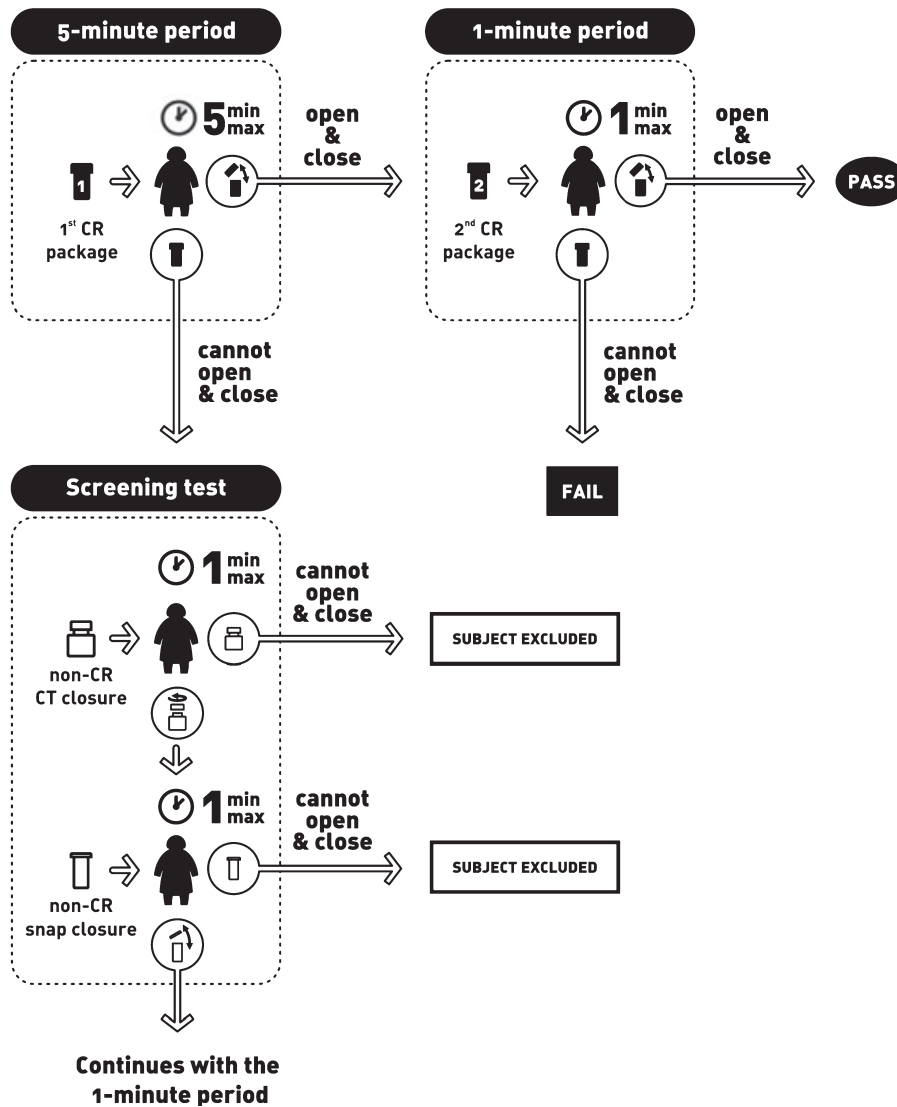


Figure 1 Diagram of the US CPSC senior-adult test – Reprinted with permission from ‘The use of a universal design methodology for developing child resistant drug packaging’.¹⁹



Figure 2 Screening Packages (2A-Snap Closure and 2B Continuous Thread Closure).

1-min-period testing the original CR package, otherwise the person is eliminated from testing and replaced with another participant. See Fig. 1 for a schematic of the current adult test, as dictated by the protocol.

A package passes the senior adult test if the senior adult use effectiveness (SAUE) is at least 90%. The SAUE is the percentage of adults who both opened the package in the first 5-min test period and opened and properly closed the package in the 1-min test period.

Despite the fact that the protocol was changed to test older adults (aged 50–70 as compared with 18–45), studies that have been done since the 1995 revision indicate that seniors continue to have difficulty with CR packages.^{19–24} This problem will continue, and likely grow, as the population ages,^{25,26} lives with increasing levels of chronic conditions (see Fig. 3) and engages in polypharmacy.

Ethical considerations with regard to the current protocol

An ethical analysis of the current protocol is grounded in four broadly accepted fundamental principles of biomedical ethics:²⁷

1. respect for persons,
2. beneficence,
3. non-maleficence, and
4. justice.

Respect for persons requires that the autonomy of individuals be honoured when decisions are made and actions are taken that affect the course of their lives; it also restricts us from forcing our will and values on others. Beneficence enjoins us to do good, while non-maleficence requires the avoidance of harm. Justice requires us to impartially consider the effects of our actions on all persons who will be influenced by them.

The entire process of regulating CR packaging has been driven, in large part, by the ethical principles of beneficence and non-maleficence.

- The inadvertent poisoning of children through toxic doses of medicine is clearly maleficent, and demanded corrective action in the middle of the 20th century.
- Protecting the vulnerable, a population including both children and the ill, is beneficent; children are protected through the use of CR packaging, and the general population of ill persons is protected from undue difficulty in gaining access to medication through the testing process.
- Some of the restrictions on the testing process protect industry from undue burdens (beneficence and non-maleficence) that might result from too-stringent requirements in the regulations. For example, the clause in the PPPA that CR ‘does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time’ makes it clear that packaging does not need be absolutely impervious to children to pass the protocol.
- Likewise, the stipulation that test subjects must be ‘normal adults’ is also intended to

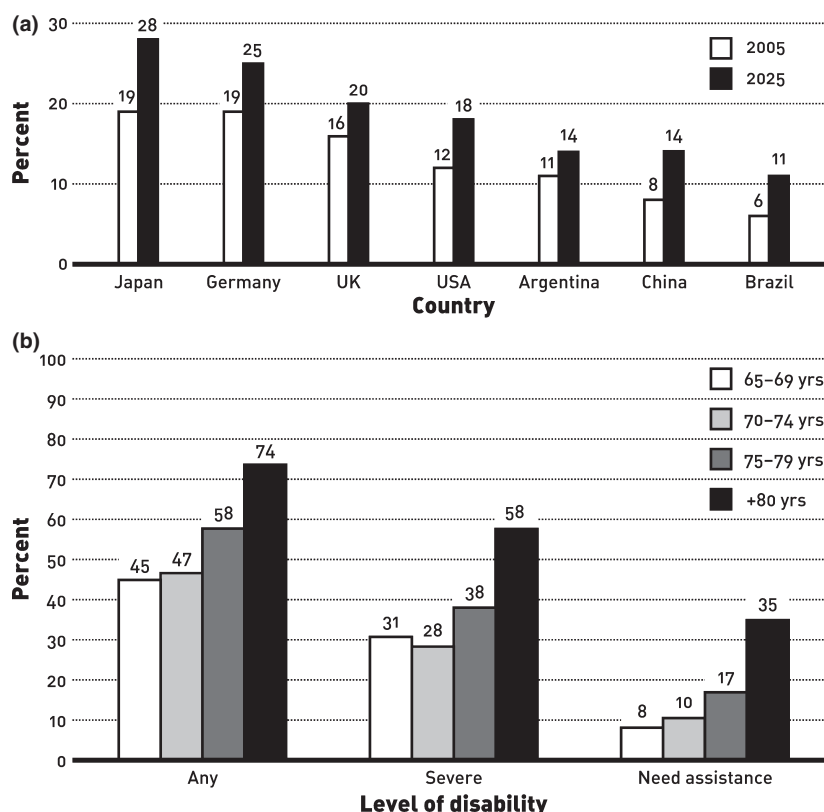


Figure 3 (a) Percentage of people age 65 and over in selected countries for 2005 and projected 2025. Source: US Census Bureau³⁶ (b) Estimated level of disability by age. Source: Agency on Aging³⁷ and US Census Bureau.³⁸

protect industry from an undue burden in designing and manufacturing packaging.

The obvious success^{28,29} of the legislated and regulated design and use of CR packaging is to be celebrated. However, we argue that the ethical principle of justice is inadequately honoured in the current legislation and regulations because the needs of vulnerable populations, people with disabilities and consumers who experience difficulties opening CR packages, are not being met.

We acknowledge that a major step toward serving vulnerable populations was taken with the 1995 revision. Additionally, the law's allowance for the use of non-CR prescription packages upon request for prescription drugs or in a single size for OTCs, aids accessibility. But does the current protocol for evaluating ease of use go far enough? Research continues to indicate difficulties associated with the use of CR packaging,^{19-24,30-34} and consumers who

are forced to choose non-CR systems are not afforded the CR protections that they provide.

It appears to us that the regulations continue to be hampered by the regulatory interpretation of the 'normal adults' clause in the legislation. The vagueness of this stipulation and its necessarily subjective interpretation by test administrators has unintentionally contributed to the continuing difficulties reported by many seniors in opening drug packages.

Proposal

The visual screening for overt or obvious disabilities should be removed from the protocol on several grounds.

1. 'Obvious or overt physical or mental disabilities' is not defined and requires subjective judgment that likely varies from one tester to another. For example, a potential participant using a wheelchair has an obvious physical

disability which will lead some testers to exclude him or her, but other testers might reasonably conclude that this disability is irrelevant to the person's ability to open a medicine package and include him or her.

2. The subjectivity of the visual screening reduces the scientific rigor of the test to the degree that the interpretation can influence test results.
3. The protocol already includes an objective screening test designed to determine whether a potential participant should be excluded, (i.e. the screening packages – see Figs 1 and 2). This makes the subjective visual screening redundant.
4. Removing the subjective visual screening will allow for a greater range of adults, more nearly representative of the population, to test CR packaging; rigorously adhering to the results of the objective screening will protect industry from burdensome testing; and the rigor of the tests will be increased.

This change can be made at the regulatory level by defining 'normal adult' (the language in the legislation) as an individual who can pass the objective screening test. Such an interpretation is within the spirit of the law because the legislation clearly concerns the ability to open medical packages and the objective screening test guarantees that only adults with that ability serve a test subjects.

Conclusion

Although children, 'normal' adults, industry, and society as a whole have benefited from the implementation of this law, a large and growing vulnerable population of seniors and people with disabilities, in particular those who share living space with children, are disserved by the status quo. US Census 2000 enumerated, for the first time, the number of grandparents that were co-residents with grandchildren under the age of 18. The Census statistics indicated that 5.8 million households (or 3.6% of those reporting) reported this living arrangement;³⁵ of these, 2.4 million indicated themselves to be 'caregiv-

ers' for their grandchild. Undoubtedly, even more grandparents are the benefactors of visits from children. For all of these households, the use of non-CR packaging has the potential to put children at risk.

Through this article, we hope to begin a movement to change the test protocols throughout the world, to better serve aging populations, people with disabilities, and the children in their lives.

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Supporting Information

Additional supporting information may be found in the online version of this article:

Table S1. Standards and regulations for senior-friendly child-resistant packaging for pharmaceuticals products.

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