

## AN INVESTIGATION INTO CHILD-RESISTANT CLOSURES

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An ever higher occurrence of accidental poisoning in children caused by drugs and other poisonous substances have lately brought about much activity towards developing adequate packing of drugs and other dangerous substances so as not to allow opening by children. In this connection a bill was put before the United States Senate in 1968 concerning the packing of drugs and similar substances dangerous to children.

This paper gives data on author's own efforts towards solving this problem in the UK; author's observations on some of the closures available at present, and the characteristics which he considers constitute a successful child-proof closure.

The paper I am presenting is a summary of the work I have carried out in the UK on various types of child-resistant closures. In examining these closures I have used the following points as a guide as to what constitutes a child-proof closure:

1. The safety feature should not appear to be a toy that would stimulate an enthusiastic child's interest.
2. The closure should be such that all consumers can be easily educated to accept how to use and re-use the safety feature.
3. Unusual strength, dexterity or perfect eyesight should not be needed to either remove or re-apply the closure.
4. Closures should be easily re-applied in such a manner as to re-establish the original safety feature.
5. Design of the closure should not be so involved that consumers would be likely to discard their safety features at the time of the original use.
6. Safety closures should not be expensive.
7. To ensure acceptance by adults the closures must have continuous appeal for the adults.
8. Closures should seal properly to retain the strength and purity of the product i. e. effectively preventing contamination and loss of potency of the medicine.

9. Closures should be capable of being handled on medicine packing and filling equipment.
10. The design of the closure should permit the use of necessary packing such as cotton inserts.
11. Multiple components in the safety feature should be avoided if at all possible.
12. Closure and container design should be executed to avoid any possibility of fracture of any component during assembly or capping operation.
13. The closure should be suitable for all products – liquids, powders and tablets, and all forms of packaging – plastic vials and glass bottles.

#### UK CONSUMER TESTS

During 1969 the manufacturers of 'PALM 'n' TURN' in Great Britain had carried out a limited child study with the Royal Society for the Prevention of Accidents (ROSPA), and the London Borough of Hammersmith Health and Education Services. They obtained encouraging results but failed to go further i. e. adult tests, arthritic tests etc.

We then carried out similar tests at the London Borough of Hammersmith Health and Education Service's Mulgrave Day Nursery. But in our tests we used screw top glass bottles with plastic caps applied at the following torques: 7 in/lbs (.09 kg/m), 10 in/lbs (.115 kg/m) and 15 in/lbs (.180 kg/m). The children were of varying ages and the results showed that (with one exception only) providing the caps are correctly placed on the bottles the ordinary screw cap is child-proof. This was also borne out in the 'PALM 'n' TURN' tests which showed that the closure had to be *correctly applied to the container* to be child-proof.

It was fortunate that almost all children at the Day Nursery were able to take part in the complete trials.

Permission was very readily granted by all Parents/Guardians for the children to participate.

#### *Container details:*

For the Mulgrave Day Nursery Tests the Metal Box Co Ltd Plastics Group supplied glass bottles, rectangular in shape, with measurements – height: 3½", width: 2"×1", 22 mm. wadded plastic screw cap.

The caps were applied at the following torques: 7 inch/pounds, 10 inch pounds and 15 inch pounds.

A torquemeter was available to ensure correct check prior to tests. The method of measuring torques in inch/pounds simply implies that, for example, 10 inch/pounds means a pressure of 10 pounds at one inch diameter or 1 pound at 10 inches.

Torques were selected because other tests had indicated parents could readily apply screw caps at 7 inch/pounds and 10 inch/pounds, and with a little effort could also apply them at 15 inch/pounds.

TESTS HELD AT MULGRAVE DAY NURSERY ON 31st MARCH, 1969

It was considered advisable in the pilot scheme to concentrate primarily on children in the 1-5 years group in order to try and ascertain:

1. Could a child under 5 years open the containers?
2. Measurement of delay occasioned if containers might be opened.
3. To observe reactions of children - and containers! - to stress conditions.

*Test procedures*

1. Groups of children (Boys and Girls) aged under 5 years tested at Mulgrave Day Nursery, Fulham, the children having followed their normal programme routine of the day.
2. Random selection of participants, from lists supplied by the Matron (Miss P Autie). No prior information given to the Testers as to intelligence, behaviour, habits, etc. or any mental or physical factors of any of the children listed.
3. Children to sit or stand in groups of not more than 5 at each playroom table. Children timed (stop watch) from start, with individual reactions observed.
4. Each container would include a coloured toy block fitment - from familiar interlock kit.

First instruction would be by Matron inviting participants to »Play a Game - see if you can open these!« Four container sizes utilised.

(Appreciated that in a home situation most children might attempt to open a container in the absence of parent or minder and that this would be a lone enterprise or by a limited number of other young participants; it was thought incentive might be provided by the element of playing a game).

Further Groups tested without any incentive motivation. In the event of mass failure further encouragement be offered by the Matron and/or Testers demonstrating containers could be opened, and further attempts then permitted.

Each container double-checked to ensure cap was correctly tightened before individual attempts.

Where a child »gave up« at any point he or she need not be required to persevere but could retire from the tests.

Table 1  
*Comparative test results*  
 Venue: Mulgrave Day Nursery  
*Glass screw-cap containers (Metal Box Co Ltd., Plastics Group)*

	T o r q u e		
	**15inch/lbs.	**10 inch/lbs.	**7 inch/lbs.
Total of test participants	11	16	15
Average age	3y 11m	4y 0m	3y 8m
Sex distribution			
Male	54%	53%	40%
Female	46%	47%	60%
% success in opening container	*One	31%	53%
Average age of successful	3y 9m (Actual)	4y 3m	3y 10m
Sex distribution of successful			
Male	—	25%	37.5%
Female	1	75%	62.5%
Average time to open container	*6 sec. (Actual)	1m 48secs.	43.5secs.
Average time for each test	3m 6secs	2m 30secs	2m 4secs

Remarks:

\* The one female opening container in 6 seconds could not repeat test.

\*\* These closing torque figures were determined after asking a large number of females what they considered to be containers closed very loosely, loose and tight enough to resist children, that is if the container held a harmful product. Women were asked to screw the closure onto a container and then the unscrewing torque was determined. The application torque was then determined by screwing on closures at known torques and determining the opening torque. This was then related back to the previous results and the figures of 7 inch/pounds, 10 inch/pounds and 15 inch/pounds were determined.

On the basis of these limited tests discussions were held with our own Market Research Division and the Psychological Research Institute and it was decided that we must have a closure that: (a) has considerable appeal to adults, that is satisfies a desire when they close the container, and (b) offers a high degree of child resistance.

These points (a) and (b) and points '1-13' were put to our Product Design Division to investigate what designs were available on a world-

-wide basis. It was decided to do this because on examination of the patent situation, which was extremely complex, it was thought that a lot of time and money could be spent in avoiding contravening these patents, and the net result would have been unsatisfactory.

#### FINDINGS OF PRODUCT DESIGN DIVISION

As one might expect there are numerous patents filed on this subject in the world but few have been exploited commercially. The most significant patents are:

Palm 'n' Turn	Reflex Corporation, USA
Makap (version of Palm 'n' Turn)	E J Treanor, UK
Staytight	Armstrong Cork, USA
Push-on'	
Pop-Lok'	Safety Packaging Corporation, USA

#### *Palm 'n' Turn/Makap*

Both of these closures work on the well-known principle of the light bulb bayonet, the only difference being that the 'PALM 'n' TURN' closure has one ratchet to retain the closure, whereas the Makap involves a double ratchet. It could be argued that the 'PALM 'n' TURN' is not sufficiently child-proof with only a single ratchet, but on the other hand it could also be argued that the Makap with its double ratchet would cause confusion with arthritic and aged people. Both of these types of closure are suspect when compared against the British Standard Specification for dispensing containers, and to date they have only been applied to plastic vials.

#### *Twistlok*

This closure has been developed in Canada for both plastic vials and glass bottles. However, the basic design does suffer when subjected to low temperature conditions. The polypropylene becomes more rigid and it is virtually impossible to open the closure. This is particularly so on the 28 mm diameter closure which has been developed for glass bottles. This diameter closure would be almost impossible to remove even under warm conditions for an arthritic patient.

#### *Push-on*

This design is a basic push-on cap but the transfer ring on the neck of the bottle is interrupted in two places to enable the patient to remove the closure. At the same time it is an ideal leverage for young childrens' teeth etc.

### *Pop-lok*

This closure is marketed in the USA by Lermer Packaging for the Safety Packaging Corporation. The action of the closure is simple. The centre tab is lifted and when in the vertical position is large enough to give the patient a purchase from which to then pull the cap from the container. On closing the container the cap is snapped onto the container and then the tab is pushed down. Both snapping actions have a satisfying effect.

### *Conclusions*

Our Design Division decided that only one closure met the points required in the brief and that was 'POP-LOK', and the main features of 'POP-LOK' are:

1. Simple construction.
2. Ease of manufacture and low cost – comparable with existing screw cap.
3. It can be used on injection moulded containers, blow moulded containers and glass bottles.
4. The functional aspects are simple and easily understood by all.
5. The design is with the accepted tolerances in the manufacture of closures.

The closure meets the BSI Specification 1679 Appendix G for dispensing containers. (This test is for moisture vapour transmission.)

### *Stage 1: Pop-lok Safety Container Study*

(Children under 5 years of age)

This preliminary study conducted with children aged between two and five is the first stage in our programme to evaluate the performance of 'POP-LOK' safety containers. Later studies will include:

1. *The general public*  
A comparative test of 'POP-LOK' and 'PALM 'n' TURN' carried out through practising pharmacists, involving about 1000 respondents.
2. *The Aged*  
A study of individuals over 60 years of age to establish the level of acceptance for 'POP-LOK'.
3. *Children under five years*  
An extension of the test carried out in stage one with children in different locations to validate our own findings and the research conducted in the United States on 'POP-LOK'.

### *The Results – Stage 1*

This first study involved 18 children between 2 years and 5 years of age. The results may be tabulated as follows:

Age (Months)	No of Children	Success in opening Pop-Lok	
		Before demonstration	After demonstration
24-36	2	Nil	Nil
36-48	10	Nil	2
48-60	6	Nil	2
Total	18	Nil	4

No child opened Pop-Lok before demonstration, although three children succeeded. Four children representing 22% of the sample opened Pop-Lok after demonstration.

The figures above should not be considered in isolation without some thought for the notes below.

### *Results in perspective*

It is only when we compare the above results with the general picture on child poisoning that we are in a position to interpret these results and draw meaningful conclusions.

The sample of children used in our test was heavily biased to the older child. No child under two years old was included and this factor alone helps explain the relatively high success rate on opening Pop-Lok after demonstration.

There are 4.75 million children under 5 years of age in the UK at the present time fairly evenly distributed as follows:

Age (Months)	0-12	12-24	24-36	36-48	48-60
Number (000's)	929	940	950	982	996
Percentage	19.4	19.6	19.8	20.4	20.8

If we had included children from all age groups, thus eliminating the bias, we could expect the success rate with Pop-Lok to fall to about 10% after demonstration.

One factor which does help to put the rate of success in opening Pop-Lok more into perspective concerns the data we already have on child poisoning generally. About 16,000 children are admitted to hospital each year suffering from poisoning and these cases may be broken down as follows:

Age (Months)	0-12	12-24	24-36	36-48	48-60	5-16 years
Percentage	4	34	40	17	3	2

The real period of danger seems to lie between the ages of one and four years with 90% of all poison cases. Only the top group succeeded in opening Pop-Lok after demonstration, and the conclusion we may draw from this regarding Pop-Lok's performance as a safety container is that only one group (36-48 months) is both capable of opening Pop-Lok and represents a danger group in the overall context of child poisoning.

This theory clearly needs to be tested in future tests, but if it is correct the overall success of opening Pop-Lok after demonstration can be shown to drop to 4% - a very good performance indeed.

7. The tests have shown that children below the age of five cannot open the closure and that the aged have little difficulty in understanding its principles. This is borne out by a consumer study survey carried out in the USA by Booz, Allen and Hamilton.

It is interesting to note here that this is the only child-resistant closure which has such a study covering all aspects of its development, and tests with both children and the aged.

#### FURTHER STUDIES

Based on our findings we have decided to carry out further work on 'POP-LOK'.

1. A limited study at a London Day Nursery. This study has already taken place and the results show identical findings to those of Booz, Allen and Hamilton.
2. A study to take place through eight pharmacists in the UK using some eight-thousand containers. Two types of container are to be used - 'PALM 'n' TURN' and 'POP-LOK'. This study is in hand and the results will be available by early August.
3. Further long-term studies will be carried out on children. The time of this study depends on the results in 2.
4. A study at either an arthritic rehabilitation centre or with geriatrics. This study again depends upon 2 and 3.
5. A long-term study at one of the large London hospitals through their pharmacy department.



*Sažetak*

## ISPITIVANJE DJECI NEPRISTUPAČNIH ZAPORA

Sve češća akcidentalna otrovanja djece lijekovima i drugim otrovnim supstancama pobudila su u posljednje vrijeme velik interes za pronalaženje takvog načina pakiranja lijekova i opasnih supstancija koje djeca neće moći otvoriti. S tim u vezi podnesen je 1968. god. Senatu Sjedinjenih Država prijedlog Zakona o pakiranju lijekova i sličnih supstancija opasnih za djecu.

U ovom članku izneseni su podaci o mojim naporima da se taj problem riješi u Ujedinjenom Kraljevstvu, moja opažanja o nekim ambalažama u upotrebi te karakteristike ambalaže za koju smatram da predstavlja uspješno rješenje jer je djeca neće moći otvoriti.

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