Arthritis-Friendly Child Resistant Medication Containers

Abstract

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Child resistant prescription medication bottles have been found to be a significant hindrance to the quality of life of arthritis patients. Due to their locking mechanism, these containers are mechanically difficult to manipulate for arthritis patients since they are extremely reliant on strength and dexterity associated with pinching, rotating and pushing with the outer extremities of the hands [1].

Arthritis is the greatest contributor to physical disability in Canada and arthritis prevalence is projected to grow in all age ranges, especially in the elderly [2]. The inability to independently access their medication infringes on the patient's quality of life as defined by Veteran Affairs of Canada which states that persons with disabilities should be ideally be able to carry out the "usual and accustomed activities of independent living, recreational and community activities, and/or personal relationships." [3] It has been further shown that the loss of independence has been linked to deteriorating mental health [4].

Interviews with relevant community members and stakeholders as well as analysis of current prescription vial designs reveal that any candidate solution must be inexpensive so that it can be universally implemented and that the ease of use for arthritis patients of all degrees of severity as well as pharmacists and front-line healthcare workers must be considered [5]. Heavy reliance of force exerted through the extremities of the hands should be avoided A candidate solution which can accommodate the limited physical abilities in the hands of arthritis patients while maintaining the integrity of child resistance would be ideal.

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- [2] Public Health Agency of Canada. (2011, November) Life with Arthritis in Canada : A personal and public health challenge. [Online]. <u>http://www.phac-aspc.gc.ca/cd-mc/arthritis-arthrite/lwaic-vaaac-10/3-eng.php#f110</u>
- [3] Veteran Affairs of Canada. (2012, March) Quality of Life Rating Chapter. [Online]. <u>https://www.veterans.gc.ca/eng/services/disability-benefits/benefits-determined/table-of-disabilities/ch-02-2006#t01</u>
- [4] JE Sale, M Gignac, and G Hawker, "The relationship between disease symptoms, life events, coping and treatment, and depression among older adults with osteoarthritis.," *Journal of Rheumatology*, vol. 35, no. 2, pp. 335-342, January 2008.
- [5] United States Department of Labor. (2011) Pharmacy. [Online]. <u>http://www.osha.gov/SLTC/etools/hospital/pharmacy/pharmacy.html#Ergonomics</u>

Addendum

This is the second edition of the request for proposal "Arthritis-Friendly Child Resistant Medication Containers". This revised document has been modified as a result of editor suggestions and the authors' reconsiderations. This addendum will include details of these revisions, as well as justifications for said changes. These changes will be marked with the "Track Changes" function of Word, and are displayed as colored, underlined text.

In section 2, a major modification is the merge of two subsections, 2.2 and 2.3, into one subsection, "Demographics and Community Definition". Some of the content, including details on the characteristics of a community, have been moved to Appendix 3. The reason for this change is that while some of the definition is needed for the RFP as a whole, the supporting research is more appropriately located in the attached appendices.

In section 3, several sentences have been revised to emphasize the severity of child medication poisoning, and why it serves an important role in the proposed problem. Also, images of the bottles in discussion were added to give the reader a more visual introduction to the problem. Furthermore, a new subsection, "3.3 Accidental Drug Ingestion", has been added to justify the inclusion of child-resistance as a criterion in the requirement section. The subsection on design philosophy has been relocated to section 7, as this subsection, combined with the engineering requirements, would be more effective in guiding a future design team.

In section 7, a subsection from section 3 is added, with the justification provided above. In addition, several criterion have been modified to include specific numbers, in order to provide references for design teams approaching this problem.

Section 8, a concluding statement, was added on the advice of the editors' feedback. The authors agreed that the document ended too abruptly, and this section was needed to make the document whole. Furthermore, the section also presented next steps in the execution of the design process.

Lastly, throughout the document several grammatical and spelling errors have been corrected to maintain professionalism. Transition sentences were added in some places to provide better flow.



Table of Contents

Section 1: Introduction and Overview	4
Section 2: Community & Need	4
2.1 – Medical Definition	4
2.2 – Demographics and Community Definition	5
2.3 – Quality of Life & Need	6
Section 3: Problem Definition	7
3.1 – Qualitative Findings: User Experience	7
3.2 – Quantitative Findings: Severity and Reach	8
3.3 – Accidental Drug Ingestion	9
Section 4: Stakeholders	10
4.1 – Individuals whose Quality of Life is Affected	10
4.2 – Institutions Affecting Requirements	11
Section 5: User to Engineering Problem	11
5.1 – Current Engineering Philosophy behind Child Resistance	11
5.2 - Physiological Factors that Increase the Difficulty of Opening Child Resistant Packaging	11
5.3 Arthritis Friendly Motions and Can Characteristics	12
5.5 – Arunnus-menury Motions and Cap Characteristics	
Section 6: Reference Designs	12
S.5 – Arthinis-Friendry Motions and Cap Characteristics Section 6: Reference Designs 6.1 – Traditional Child Resistant Prescription Containers	12 13
 Section 6: Reference Designs	12 13 13
 S.5 – Arthinis-Friendry Motions and Cap Characteristics Section 6: Reference Designs. 6.1 – Traditional Child Resistant Prescription Containers 6.2 – Recently Improved Child Resistant Containers 6.3 – Third Party Tools 	12 13 13 15
 Section 6: Reference Designs	12 13 13 15 16
 Section 6: Reference Designs	12 13 13 15 16 16
 Section 6: Reference Designs	12 13 13 15 16 16
 Section 6: Reference Designs	12 13 13 15 16 16 16 17
 Section 6: Reference Designs	12 13 13 15 16 16 16 17 17
 Section 6: Reference Designs	12 13 13 15 16 16 16 17 17 18
 Section 6: Reference Designs	12 13 13 15 16 16 16 16 17 17 17 18 19
 Section 6: Reference Designs	12 13 13 15 16 16 16 17 17 17 18 19 23
Section 6: Reference Designs	12 13 13 15 16 16 16 17 17 17 17 18 19 23
Section 6: Reference Designs	12 13 13 15 16 16 16 17 17 17 17 17 18 23 25 26

Section 1: Introduction and Overview

This Request for Proposal (RFP) identifies that child resistant prescription medication vials, due to the nature of their child resistant mechanism, pose a significant dexterity and strength challenge to arthritis patients. Section 2 provides comprehensive definitions for community and quality of life as it pertains to arthritis patients. Section 3 utilizes the definitions defined in the previous section and explores child resistant packaging as a problem for the community from a user experience perspective. Section 4 documents stakeholders either whose quality of life is affected by this RFP or is in a position to affect the quality of life of the community. Section 5 systematically analyzes the user problem in Section 3 and frames the user problem from an engineering perspective. Finally, Section 6 provides reference designs of current vials and the most current candidate solutions while Section 7 outlines the design constraints, goals and evaluation metrics.

Section 2: Community & Need

Arthritis patients have been identified as a community in need in the City of Toronto. This section documents the scope and extent of this community and the common elements that arthritis patients share. Section 2.1 and 2.2 provides foundational medical and demographical information. Sections 2.3 and 2.4 provide working definitions of community and quality of life as they relate to arthritis patients, which will in turn frame the problem definition in Section 3.

2.1 Medical Definition

Arthritis is a broad term used to describe over 100 different conditions characterized by the inflammation of the joints and of the tissues surrounding and connecting the joints. The two most prevalent types are osteoarthritis and rheumatoid arthritis, but every variation under the arthritis umbrella shares the following symptoms: joint pain, stiffness, swelling, and weak ligaments and muscles around the joint [1]. The two latter symptoms tend to reduce mobility in the joint. While both osteoarthritis and rheumatoid arthritis have genetic factors, there are other risk factors associated with the condition; obesity, injury, and occupational hazards are among them [2]. Some patients can effectively manage their symptoms with physiotherapy to strengthen the joint in question, and others with lifestyle changes like diet and exercise. Many use these in combination with pain or anti-inflammatory medications. While treatments can be effective to manage symptoms of the disease, arthritis is a deteriorating chronic condition that has no cure [3].

2.2 Demographics and Community Definition

- The primary purpose of this document is to evaluate a genuine need amongst arthritis patients that would benefit from an engineering design solution. Thus, it is imperative that the community and the associated need be properly defined. A community is usually self-defined in two ways – members identify themselves with the community either by geography or, in the case of arthritis patients, common interest.

Prominent psychology authorities often argue that elective communities are more prevalent today than place communities since modern communication allows us to bypass geographic constraints (refer to A3.1). Since arthritis patients suffer from the same medical condition, they are subjected to similar symptoms and disabilities and often undergo the same medical treatment. Therefore, they share a



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common stake in products and healthcare options that serve to improve their quality of life.

In 2001, arthritis was one of the leading causes of disability in Canada [4] (refer to A2.1). In 2010, 15.8% of people in Canada and 13.5% of people living in Toronto aged 15 and older reported having been diagnosed with arthritis [5] [6]. With Toronto's population of 5 740 700, this amounted to a group of almost 775 000 people diagnosed and living with arthritis [7]. Figure 1 shows that this number is only expected to grow; the prevalence of arthritis in Canada has been projected to increase in the next 20 years especially in the 55+ age demographic [4]. This group represents a substantial portion of Toronto and of Canada's population, and as such, their needs should be treated with an appropriate degree of importance.

2.3 Quality of Life & Need

A genuine need is defined by the lack of solutions to elements that reduce the community's quality of life. Thus, it is necessary to clearly define quality of life as it relates to the arthritis community. Many tools exist on a macroscopic scale to quantify the quality of life in a nation or geographical region, such as the Human Development Index (HDI) which is a composite evaluation of life expectancy, education, and income [8]. These methods of evaluation are not applicable for a community residing in a more economically developed country (MEDC) where most basic needs are well met. Veteran Affairs of Canada provides a more relevant definition of quality of life tailored specifically for those living with disabilities. According to Veteran Affairs, quality of life is infringed upon when a disability "interferes with the ability to carry out the usual and accustomed activities of independent living, recreational and community activities, and/or personal relationships" [9]. While arthritis affects many aspects of a patient's life, "reaching, grasping and/or carrying" was one of the most commonly reported difficulties with 68.5% of arthritis patients responding that it was a significant challenge. This data strongly suggests that factors which require extensive manipulation by the hands are a hindrance to the quality of life of arthritis patients.

Difficulty conducting day-to-day activities has been linked to deteriorating mental health in arthritis patients. There is a strong cause and effect relationship between being diagnosed/living with arthritis and higher rates of mood and anxiety disorders [10]. It has also been documented in a publication by the Canada Health Agency that arthritis patients are more likely to experience depressive symptoms compared to individuals in the general Canadian population of the same sex and age [11]. The same publication also revealed that over 30.4% of men and 29.1% of women living with arthritis identified themselves to be of poor health while only 4.3% and 2.8% of men and woman without chronic medical conditions considered themselves to be of poor health (refer to A2.2). A separate study conducted at the University of Michigan concluded that self-rated health is a reliable and accurate means of assessing individual health and mental state [12]. Depression has been found to "undermine motivation for self-care, such as compliance with medications, eating well and exercising" [11]. Clearly, the loss of motor function associated with arthritis not only contributes to the patient's inability to carry out daily functions but also can significantly impact their mental health.

It can be concluded that an engineering solution that reduces the extent of heavy hand manipulation required by arthritis patients will allow them to better conduct their daily activities independently and thus fulfill the quality of life definition set out by Veteran Affairs Canada and in doing so, also lessen the psychological stresses of living with arthritis.

Section 3: Problem Definition

Patients with arthritis in their hands share a common problem; their condition can make it difficult and even next to impossible for them to open child resistant prescription medication vials, which are prevailing among household containers. Many arthritis patients regularly take prescribed medication to manage the pain of their condition [3], however this pain can be exacerbated by attempting motions such as those required to open a child resistant vial. The following subsections define this problem from a patient experience perspective $\frac{1}{2}$ and identify relevant statistics on the severity of the problem.

3.1 Qualitative Findings: User Experience



involving child resistant packaging by the Ontario government in 1974 [13], pharmacies began to issue prescription bottles equipped with child resistant caps. While the additional barrier in the bottle caps led to a decrease in the number of cases of accidental prescription overdoses [14] [15], it also presented a challenge to patients with diseases such as arthritis. Even though the problem is generally recognized

Since the implementation of regulations

Figure 2: Push-and-turn (far left) and align-and-pop (right) child resistant cap systems. [49]

throughout the patient community, there is yet to be a suitable solution widely implemented.

By default, prescription medications bottles are issued with a child resistant mechanism. Patients have the option of requesting a normal bottle with an easy-open cap. <u>H</u>owever in a personal interview a local pharmacist, Edith Nelson (refer to A1.2) estimated that only about 10% of senior patients request these. Either the patients are unaware that the option is available to them, or they have small children at home and so such an option is not viable. Thus, many patients have to cope with child resistant caps, which are especially difficult to open during an onset of joint pain symptoms [16].

As a result of difficulties presented by the child resistant packaging, users of prescription bottles have developed many unconventional methods to render the task of opening the cap easier. Observations of patient comments on various arthritis organizations' websites suggest that a number of users have converted child resistant bottles to an easy-open alternative by means of disabling the original barrier mechanism [16] [17]. These homemade conversions leave the bottles once again susceptible to children and spillage. While these blog comments cannot reflect the situation absolutely accurately, they do indicate the existence of this kind of practice. Furthermore, pharmacist Edith Nelson revealed that some users simply leave the caps off of the bottle when not in use to avoid having to struggle with the cap more than once. This practice not only has the aforementioned problems of spillage and <u>undesired</u> child access, but also makes the medicinal contents susceptible to deterioration.

These peripheral findings give qualitative insights into the current situation on child resistant medication bottles in the households of arthritis patients. The intended effect of child resistance is nullified by the users' misuse. Thus, a solution that accommodates the polar attributes of being easy-to-open while remaining child resistant is desired to provide a safe and effective way to store medication.

3.2 Quantitative Findings: Severity and Reach

The following table shows the percentage of men and women with arthritis that self-identify to have difficulties with given household tasks:

Difficulty	Age group	Men (%)	Women (%)
Bend over/pick object up from floor	15-44	56.3	47.8
	45-64	60.4	57.0
	65+	49.8	52.4
Reach, grasp and/or carry	15-44	63.9	68.3
	45-64	55.5	73.6
	65+	54.6	75.9
Require use of aid to reach, grasp or carry	15-44	9.8	26.4
	45-64	9.0	15.1
	65+	5.0	12.2

 Table 1: Trouble with Daily Movements for Patents with Arthritis Percentage of Arthritis patients self-reporting to have

 trouble with daily movements
 [4]

A significant portion of arthritis patients reported limitations in mobility-related tasks around the household (See Table 1). Of significant relevance to the problem of medicine bottle caps is the task of "reaching, grasp and/or carry", and "bend over/pick object up from floor". As seen from the table, well over half of arthritis patients have difficulty with reaching, grasping and/or carrying, and 53.9% of individuals face difficulty with bending over and picking up objects from the floor. While some of the categories may not pertain to the act of opening a prescription bottle, these statistics still suggest that a significant number of people living with arthritis, even for younger age groups such as 15-44, face difficulties with these related motions. Furthermore, if the prescription should spill, as could be the case when one is struggling to open the bottle cap, over half of the patients would have trouble recovering the spilt contents.

3.3 Accidental Drug Ingestion

While the previous sections highlighted the difficulties that child-resistant packaging presented to seniors, such measures are still essential in keeping children away from medical bottles in households. According to J.A. Waller, the founder of the science of injury control, children between the age of 18 months and 35 months are most at risk of household poisoning [18]. In this context, poisoning is defined by the National Academy of Sciences as "damaging physiological effects of ingestion ... of a range of pharmaceuticals, illicit drugs ... and common household substances" [19]. While there are regulations regarding the distribution of products in child-resistant packaging, these protections do not guarantee a 100% success rate. In fact, most child-test protocols require that at least 80% of the children being tested be prevented from opening the container during a 10 minute test [18]. This means that a number of toddlers still have the ability to access the contents of the container, even with the current child-resistant packaging in place.

The Ontario Poison Centre indicated that in 2005, 43% of all poisoning cases involved children less than 6 years of age, amounting to almost 40,000 cases [20]. While child poisoning may involve the ingestion of other toxic household substances, however, a major cause is the undesired access to prescription bottles or weekly pill boxes of parents and grandparents in the household [21]. According to Safe Kids, an advocacy group for child safety, reported that in 2012, roughly 165 children in the U.S are taken to emergency rooms each day after finding and taking medications [21]. While this data is taken from US hospitals, it is a valid reference for Toronto, due to the proximity of location and similarity in culture. Furthermore, this trend in child medication poisoning seems to be increasing as well. According to Research by the Cinncinati Children's Hospital Medical Centre, the number of children seeking emergency care due to undesired medication ingestion increased by 28% between 2001 and 2008 [22].

These statistics and trends suggest that current protections against accidental ingestions of medication are not ideal. In this aspect of the problem, a solution is desired to improve the level of protection against undesired access to the contents stored within the prescription bottles.

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Section 4: Stakeholders

There are two main categories of stakeholders: those who have a vested interest in a solution and those who have a considerable effect on the requirements outlined in Section 7.

4.1 Individuals whose quality of life is affected

The following stakeholders are listed in order of decreasing influence on the engineering requirements for the problem.

Arthritis Community: As the community in question, arthritis patients are the primary stakeholder in a solution to the proposed problem. Such a solution will improve the quality of life of patients with arthritis in their hands by reducing the pain and discomfort they experience on a daily basis and thus increasing their independence. As potential consumers of a product solution, the arthritis community has a large stake in the economy of the candidate solution. Patients with arthritis span all socio-economic demographics, but the prevalence is slightly higher in the low to low-middle income ranges in Canada [4]. It is important to make a solution available to the members of the community that fall into these ranges.

Households with Children: Any household with young children has a huge stake in the child resistance of the candidate solution. This stakeholder would prioritize child resistance in the candidate over ensuring the packaging is arthritis-friendly.

Pharmacists and Pharmacy Technicians: As the dispensers of prescription drugs, pharmacists and pharmacy technicians open and close dozens of prescription medication vials a day. If the candidate solution was container-based, pharmacies would have a huge stake in the product. Packaging that is not ergonomic can cause severe harm to pharmacists who open and close them repetitively. Edith Nelson, in a personal interview (refer to A1.2), explained that a pharmacy technician that she worked with developed carpal tunnel syndrome from opening and closing the vials on such a constant basis. Pharmacists and technicians are prone to other conditions such as tendonitis and tenosynovitis from opening the vials as well [23]. A solution to this problem has a high probability of improving the ergonomics of pharmacy work.

Related Medical Communities: There are several medical communities similar to the arthritis community that would benefit to a solution to this problem. While they are not the target community, many other conditions and diseases result in reduced grip strength, pain in the hands, or reduced fine motor skills. In an interview, pharmacist Edith Nelson remarked that those with injuries, stroke victims, those with tendonitis, multiple sclerosis, and muscular dystrophy would be among those who would benefit from a solution (refer to A1.2). Formatted: Font: Bold

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4.2 Institutions affecting requirements

Pharmaceutical Companies: The nature of the pharmaceuticals dictates certain qualities that a prescription medication container must have, such as permeability to light and moisture [24]. In order for a container-based solution to be viable, it must take into account these chemical properties.

Manufacturers: Both the manufacturers of current vials and of any product that is a solution to this problem are stakeholders in this issue. Regardless of what type of solution is proposed, its cost and manufacturability are factors that will affect its implementation which in turn affects its accessibility to the community.

Section 5: User to Engineering Design Problem

In this section the user problem in Section 3 is developed into an engineering problem based on quantitative measurements and mechanics.

5.1 Current engineering philosophy behind child-resistance

The majority of child-resistant medication bottle caps depend on the use of force in conjunction with knowledge of where and how to apply it. Upon examination of three US patents, two require a radially-inward force to be applied at the base of the cap. The other patent, for a child-resistant tamper evident cap, indicates only "torque beyond the ability of a small child" will open it. [25] [26] [27]These generally involve a brute-force approach to child resistance even though various standards attempt to address the issue with senior test panel testing [28].

The introduction of child-resistant containers has certainly reduced the number of accidental ingestion cases of medicinal drugs [29]. However, the next section highlights the drawbacks of these childproofing methods.

5.2 Physiological factors that increase the difficulty of opening child resistant packaging

From an engineering standpoint, arthritis patients find it difficult to open child-resistant medication bottles because of the combination of physical force and fine motor skills required to perform this task. Pharmacist Edith Nelson identified in an interview (refer to A1.2) that the problem arises from the following two sources. Firstly, arthritis patients have reduced grip strengths compared to healthy adults and secondly, the gripping and twisting motions required to open a child-resistant cap cause pain in the finger joints.

These observations are supported by evidence in a 1999 study performed in the UK which measured and compared the grip strengths of rheumatic arthritis patients and healthy adults. The results (refer to A2.3) show the significant reduction in grip strength for the rheumatic arthritis subjects studied. When comparing pinch, tripod, and power grips, rheumatoid arthritis patients exerted as little as 2.5 times less force as opposed to healthy adults. [30]

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In terms of the reduced range of motion experienced by arthritis patients, a 2009 study performed at The University of Birmingham provides corroborating data. For example, healthy adults averaged a range of motion ranging from 100-110° across the four fingers while the average range of motion for rheumatoid arthritis patients was 55-80°. [31] This is a drastic reduction in finger flexibility and dexterity.

Figure 3: 1.Pinch Grip, 2.Tripod Grip, 3.Power Grip [46] [45]

5.3 Arthritis-friendly motions and cap characteristics

The different types of hand grips must be taken into account since the maximum force that can be exerted through them varies drastically. For example, since more power can be exerted with a power grip, motions that integrate this will be preferred over those requiring weaker grips like the pinch grip. Occupational Science & Occupational Therapy professor Catherine Backman (refer to A1.1) recommends motions using larger joints in a stable plane because of the loss of finger dexterity due to arthritis.

Overall, an arthritis friendly child-resistant medication bottle cap will reduce the physical force and dexterity required. These general objectives will be further specified and refined in Section 7.

Section 6: Reference Designs

This section provides information on the functionality, benefits and drawbacks of current designs pertaining to child resistant vials and possible arthritis-friendly solutions. Section 6.1 documents the failures of two of the most commonly used prescription vials currently in circulation while Section 6.2 explores some improved vial patents developed in the past few years. Section 6.3 explores third party tools currently used for opening containers such as jars and bottle caps in the kitchen. These reference designs are intended as a starting point for future innovation.

6.1 Traditional child resistant prescription containers

As mentioned in section 5.3, a cap and lock system should rely primarily on force that does not need to be transmitted through delicate joints such as those in the fingers and at the base of the thumb. Current child resistant packages are overly reliant on the strength and dexterity of the fingers. The analyses of these containers are based on a combination of personal judgment and interviews with arthritis patients. Below are the two most common prescription bottles in circulation as identified by Simon Wong, a pharmacist based on Toronto (refer to A1.3).

Push-and-turn: The push-and-turn mechanism used for many pharmaceutical purposes refers to a locking system which requires the user to twist the cap while simultaneously pushing downwards in the axle perpendicular to the rotating plane. The twisting motion must be accompanied by a significant pinching force against the sides of the cap. The combination of the pinching, twisting and pushing forces put significant stresses on the finger joints and wrist.

Arrow-alignment: The arrow-alignment system requires the user to align an arrow on the cap with another arrow or similar marker on the container's body. Once aligned, the user grips the body of the bottle while exerting an upward force on the cap to pop open the container. This motion can be performed with either one or two hands. Nevertheless, it is always necessary to use the fingers (the thumb, in most cases) as a lever to pry the cap open which, again, puts stress on the fine joints in the hands. Many conventional containers of this type feature a fixed protrusion (a thumb tab) which acts like an extended cantilever to reduce the necessary force exerted by the user. However, this also reduces the child resistance of the packaging [32].

6.2 Recent Improved Child-Resistant Containers



Figure 4: 2009 Child Resistant Packaging Patent [32]

In an attempt to improve child resistance, many containers have ignored the need for elderly friendly designs or mechanisms tailored to those with physical disabilities. In recognition of this design gap, a few designs have evolved where the objective of the inventions are to provide an improved locking mechanism which is child resistant but which can also be easily opened by an adult. These designs however, are not tailored for arthritis patients and have design flaws that make then unsuitable for the arthritis community. The patents provide

detailed analysis of the motions required to open the containers but, in the absence of a prototype, it was necessary to extrapolate these motions as best as possible from 2D schematics and texture descriptions.

Patent 1 [32]: Published in 2009, this patent features an optional child-resistant tab that can be removed or attached as needed depending on circumstance. This provides a possible solution to arthritis patients who do not share living space with young children.

Mechanism (See Figure 3) : The sliding tab (82) is positioned within the cap (86) so that a portion of the tab protrudes in the proximately of the hinge (40). To open, the user must apply a force on the sliding tab in the direction away from the hinge so that the protruding portion retracts into the cap. A clicking sound confirms that the cap is unlocked. The user must then apply a second upward force on the cap on the opposite side of the hinge.

Primary failure: The sliding tab is very thin, fits snugly against the cap and offers minimal contact surface area through which force can be applied thus forcing the user to rely on the finger tips or fingernails to move the tab. Although less total force is required, the container requires that the force be exerted by fingers in a motion associated with fine motor movements which are particularly hard for those with arthritis.

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Formatted: Font: (Default) Times New Roman, Bold, Font color: Custom Color(RGB(34,34,34)) Patent 2 [33]: Published in 2008, this patent features a push-to-unlock system and a large thumb tab to



Figure 5: 2008 Child Resistant Packaging Patent [33]

accommodate easy opening.

Mechanism (See Figure 4): The container remains lock if a force is applied upwards on the thumb tab (30). To open, the upward force must be accompanied by an inward force applied to the cap on the side opposite to the thumb tab (66).

Primary failure: Again, this patent was designed to require less force than traditional vials. However, upon careful examination of Figure A1, it can be seen that the secondary tab that requires the downward force is relatively small thus

requiring a pinpoint force that would be applied by a fingertip. This is unacceptable since the goal of this invention is to reduce or eliminate the need for force to be exerted by the relatively weak and fragile joints in the fingers.

The use of a thumb tab usually attributes to a lower degree of child resistance, however, when used in combination with a secondary locking mechanism such as the opposing overlay used in this invention, the tab provides a significant aid to patients to arthritis without compromising child resistance.

Patent 3 [34]: This patent, published in 1983, is relatively old and is not a good candidate solution. The primary objective of this invention was to simplify child resistant bottles so that less fine-tuned and coordinate motions were necessary.

However, although their design was conceptually easier to open, steps were not taken to reduce the necessary amount of force. The patent explicitly states that "Strength but not manual



Figure 6: 1983 Child Resistant Packaging Patent [34]

dexterity is required." Furthermore, although their 'slide and pivot' system was intuitive for use by the average adult, it required sliding two relatively thin, parallel plates which is especially difficult for arthritis patients, given that this motion is performed by the thumb. This patent was included to draw attention to its unique triangular shape as shown in Figure 5. This not only facilitated easy storage, but was also easier to grip than the traditional round bottles by those with reduced gripping strength.

6.3 Third party tools

There exists a wide variety of tools for those with reduced gripping strength used to aid in opening containers. These tools primarily target food containers commonly found in the kitchen such as jars and beverage caps. These tools have not been designed specifically for opening common child resistant prescription bottles such as the push-and-turn or arrow-alignment caps.

Dycem Non-Slip Jar Opener [35]: Dycem manufactures a dome-shaped cap gripper (see Figure 6) made from a non-slip material intended to aid in opening bottle caps. Although this device does not provide any mechanical



Figure 7: Dycem Non-Slip Jar Opener [35]

advantage, it reduces the necessary pinching force by drastically increasing the frictional force between the user and the cap surface.

Good Grips® Jar Opener [36]: The Oxo jar opener incorporates a handle bar as shown in Figure 7 to

provide leverage and thus reducing the necessary applied force. This design also allows the twisting motion that is usually supplied by the fingers and wrist to be applied by larger muscle groups as the entire arm exerts force in the plane of rotation. The portability and cost of manufacturing a product such as this for medication bottles is a major concern since many patients have to carry multiple medications with them to be administered throughout the day.



Figure 8: Good Grips Jar Opener [36]

Section 7: Engineering Design Requirements

This section entails the design philosophies that should be adopted in approaching the issue. The following set of objectives, constraints and criteria focus on the development of a novel method of child-resistant packaging (CRP). I.e. the constraints and criteria tend to assess the performance of a solution that reengineers child-resistant medication bottles. This focus was chosen over a tool-based candidate solution because a solution intrinsic to the childproofing mechanism was seen to be easier to implement. Based on research on the problem, solutions like third-party bottle opening devices have several difficulties. Firstly, there are several methods of childproofing medication bottles. Bottle caps include continuous thread, lug finish, and snap closure mechanisms [37]. Secondly, pharmacist Simon Wong explains that a solution would have to be portable since seniors carry and administer their medication throughout the day (refer to A1.3). Given the very different motions required to open the different types of bottle caps, and the requirement for portability and cost-effectiveness, a design intrinsic to the medication bottle is probably more feasible. This is not intended to limit teams to only developing child-resistant medication bottle design solutions. Other types of solutions, like effective third-party devices to

aid in the opening of these bottles can be developed as well where appropriate, and where the requirements are still met.

7.13.3 Design Philosophy

Improving of the quality of life of the chosen community requires that the solution be one that universally accessible. The success of such a solution will be determined by two main factors: ease of implementation and ease of use.

Ease of Implementation: The community of arthritis patients in Toronto is large. Ease of implementation refers to how efficiently a suitable solution could be implemented across Toronto, and possibly more widespread arthritis communities such as Ontario and Canada. The main aspects of this efficiency are going to be dictated by manufacturers and pharmacists, as they will determine if and how a solution is distributed.

Ease of Use: Arthritis is a condition that does not discriminate against age or gender. It also varies in severity. A candidate solution must accommodate anyone of any ability (excluding children).

7.2 Objectives

The following objectives are to be achieved, following the guidelines from Section 3.37.1.

- 1. Minimize the degree of fine motor skills required to open CRP.
- 2. Minimize the magnitude of force required to open CRP.
- 3. Design a solution that can be implemented to house a wide range of solid-medications (including those that need to be protected from light and moisture).

7.3 Constraints

The following are absolute restrictions on a candidate design.

- 1. The solution must comply with the Government of Canada's Food and Drug Regulations definition for CRP [38].
- As per the Canadian Standards Association Standard CAN/CSA-Z76.1-M90, Recloseable Child-Resistant Packages, all materials shall ([28], pg. 3):
 - a. Be suitable for storing solid medication
 - b. Be non-toxic; and
 - c. Retain the properties that ensure the child-resistant characteristics of the CRP.
- 3. As per CAN/CSA-Z76.1-M90 ([28], pg. 3), the solution should not resemble toys.
- 4. As per CAN/CSA-Z76.1-M90 ([28], pg. 3), the solution should be well finished and free of irregularities that could present a hazard to a child or the user of the package.

7.4 Criteria

The following are what a candidate solution will be evaluated on, and the candidate's success depends on the combination of all the criteria. If the proposed design solution is a third-party device, it must be tested for all the criteria included below in this section for all the following common types of child-resistant medication bottle caps (refer to A3 for further definitions): continuous thread, lug finish, and snap closure.

<u>Note:</u> The above three child-resistant cap types are to be tested since these are the categories that CAN/CSA-Z76.1-M90 ([28], pg. 1) places the largest focus on.

- 1. Grip-forces. These are listed in ascending order of the mean maximum force exertable by an arthritis patient based on grip-force research [30]. Therefore the following grip-force criteria are ranked in a descending order of importance:
 - a. Pinch grip force required to open bottle [Metric: Force in N, less is better]
 - b. Tripod grip force required to open bottle [Metric: Force in N, less is better]
 - c. Power grip force required to open bottle [Metric: Force in N, less is better]



Figure 9: Range of Motion Measurements [31]

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2. Maximum Range of Motion (ROM) of fingers required to

utilize solution [Metric: flexure of fingers in degrees, less is better]. This is based on experimental procedures used in the ROM research study ([31], pg. 41) aforementioned in this RFP.

- a. Figure 8 displays how measurements of ROM are to be taken.
- b. The maximum flexure is measured in degrees from the black reference line to the yellow reference line (proximal phalange flexure) for all 4 fingers.
- c. The greatest amount of flexure in degrees required from all fingers is the value counted in the criterion.
- e.<u>d. A maximum of 50° in ROM is preferable [based on mean minimum ROM for RA patients</u> in pg. 44, source 26].
- The following time-based criteria are adapted from tests specified in CAN/CSA-Z76.1-M90 ([28]):
 - Mean time required for an arthritis patient to open the child-resistant bottle after having been given print instructions for the solution [Metric: Time in s, less is better]. <u>A time greater than 5 minutes is preferable based on the test period used in CAN/CSA-Z76.1-M90 ([21] pg. 8).</u>
 - b. Mean time required for a child in the 1-4 years age group to open the child-resistant bottle [Metric: Time in s, more is better].

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This criterion is meant to adjudicate the general complexity of implementing proposed solutions in comparison to products made with similar manufacturing processes and materials. This criterion has a significant effect on manufacturers' willingness to invest in proposed solutions.

- 5. Ratio of total available medication storage volume to total volume of the device [Metric: cm³/cm³, larger is better]. Note: This criterion is not applicable to 3rd party devices.
 - a. If the solution is a bottle cap, the total volume of the solution is calculated as the volume of the cap and bottle combination.
 - b. This is included as a criterion since solution portability is important.

Section 8: Conclusion

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The above engineering requirements will be handed to concept design teams to develop candidate solutions to the problem outlined in this RFP. These requirements will also be used to adjudicate the degree to which solutions have solved this problem. Accessing medication in child-resistant packaging is a daily task that is often difficult and painful for arthritis patients. Hence, successful engineering solutions will be expected to improve the quality of life in this community.

APPENDIX 1: Correspondence and Stakeholder Interview Transcripts

A1.1: Catherine Backman, PhD, FCAOT

Professor & Head | Occupational Science & Occupational Therapy

Dear Dr. Backman,

I am an undergraduate student studying Engineering Science at the University of Toronto and I am very interested in your research on the effect of arthritis both at home and at the workplace. As part of my Praxis II course on engineering design, my team and I are researching a community with unique needs and seeking an engineering solution to barriers that exist which hinder their quality of life. This project leads up to a public showcase at the end of the academic year to display solutions and prototypes to various industry members and media.

My team and I have identified that current childproof prescription medication containers (such as squeeze/push to open bottles) are mechanically difficult to open by people with reduced gripping strength or joint pain in their hands. We are currently developing a Request for Proposal (RFP) which is intended to identify the need in the community and frame the problem so that engineering design solutions are possible. It would be immensely helpful to us if you answered a few questions to allow us to better understand the community:

1. What would you say is the most debilitating motion associated with opening containers such as prescription bottles? Is there any particular difficulty that you believe should be addressed or modified to make opening packaging (not limited to childproof containers) easier for those with arthritis?

2. Without modifying the packaging itself, do you believe that a third party tool (such as a cap gripper) is a feasible solution? In other words, would you expect people would be willing to purchase an additional tool to aid in opening packages?

3. The primary purpose of this RFP is to identify need in the community. Are there any other instances in the day to day activities of people suffering from arthritis that would benefit from an engineering modification or design solution?

We greatly appreciate your help. Your input will aid us to better cater our design process to the community.

Yours sincerely,

Max Wei

You've chosen an interesting problem that definitely presents a challenge to many people with arthritis affecting their hands. Containers and packaging in general can be frustrating on a daily basis.

In response to your questions:

1. in general, it is better to use larger joints in a stable anatomical plane, so a large cylindrical grasp would be preferable to relying on fingertips or twisting fingers. If one must turn a lid (or think of the tap on a sink) it is better to turn toward the thumb than toward the little finger as this is less stressful on vulnerable finger joints and ligaments. I think the plastic packages that manufactures have been using so products can hang on display hooks or be less vulnerable to shoplifting are a huge problem for people with limited hand function - you need heavy shears or a saw to get into them! Places like Costco use them for holding all kinds of products.

Have you seen the Tylenol bottle that is endorsed by the Arthritis Society (Canada) and Arthritis Foundation (US)? It's an example of changing the packaging. The large red lid looks like a cogged wheel. This design makes it easier to grasp, plus, you can roll it down your forearm to spin open instead of twisting fingers. It is the only medicine package I've seen used on a widely available over the counter medication.

2. people will purchase a gadget or assistive device such as a cap gripper. There are several available through kitchen stores and medical supply companies. Some work pretty well for jars and bottles, but not for child proof caps. There is also a device for opening soda cans (that I've seen flight attendants use to protect their fingers too). If it is relatively inexpensive and someone needs to use it regularly they will purchase it. Jar openers, extended reachers, and long-handled shoe horns are used regularly; some devices sit in the closet. Because individuals with limited strength and dexterity have different needs, the devices need to meet a variety of user skills as well as a variety of packages/products.

You should also be aware that people can ask the pharmacist to put their prescriptions into non-child proof containers, the old ones that pop off more easily. Pharmacists will also put the medications into blister packs on request, which is easier for some people.

3. there are quite a few problems that would benefit from engineering solutions - lots have been automated over the years, but not everywhere: opening doors (one can adapt their own home but still have to open doors when out in the community and not all are automated and door knobs can be large, awkward, slippery), paying for parking at metered parking lots (getting the coins in the slot that must be pushed/slid into the machine and pulled back), turning taps on/off, opening packages of cheese, boxes of crackers or cereal, water bottles. And seat belts in cars - both one's own and putting kids in car seats; fold/unfold baby strollers. There are consumer groups that can probably tell you lots of everyday issues. If you'd like me to put you in touch with the Consumer Advisory Board here at the Arthritis Research Centre of Canada I'd be happy to pass along your contact info to them.

Catherine Backman, PhD, FCAOT Professor & Head | Occupational Science & Occupational Therapy The University of British Columbia | T325-2211 Wesbrook Mall | Vancouver, BC V6T 2B5 Tel. 604-822-7409 | Fax 604-822-7624

A1.2: Pharmacist: Edith Nelson, Lovell Drugs (Interview)

Interviewer: Grace Cochrane

GC: What are the major issues in opening things like prescription vials or other bottles for patients with arthritis?

EN: A big factor is pain. For many, especially those with rheumatoid arthritis, the pain can be debilitating. In addition to this, the grip strength of most patients with arthritis is severely reduced from that of a healthy person, so they are just incapable of gripping and twisting a cap. The other problem you may not have looked at as much in detail is deformity. Again, especially in those with rheumatoid arthritis, the deformity of their joints may be so severe that that cannot even close their hand around a bottle or a cap.

GC: What do you think of the feasibility of some sort of an opener vs changing the packaging itself to make it easier for arthritic patients to get to their medication?

EN: While an opener would likely give the user more torque, it is often still something that a patient would have to grip, and again if they have deformity in their hands this may still be next to impossible.

GC: Are there any alternatives to child resistant packaging for prescription medication at the pharmacy you work at?

EN: We do offer the "snap-cap" type of vial, but like you say, it's not child-resistant and so not an option for some people. The motion of opening this bottle is also still difficult for many that have reduced strength in their hands. If people are really having trouble, we sometimes put their prescriptions in ointment pots, which are again, not child-resistant. However, these have lids that screw on and off easily, and have much wider lids and are easier to grasp.

GC: Are the alternatives advertised, or are patients required to ask?

EN: The pharmacists don't really advertise them, no. If we notice something, we suggest it though. Only about 10% of seniors probably ask for the alternatives.

GC: What are the issues with this problem (besides the inherent pain with opening the vial)?

EN: Well it's obviously a safety issue. One of the common occurrences I hear of of children getting into prescription medication is when grandparents have their grandchildren visit, or go to visit their grandchildren.

It's also a convenience issue; lots of patients struggle so much with the lid they just open the vial once and leave it open. This is obviously a problem because they are often spilled. The other concern with this is that some medications are sensitive to light, and their vials are designed specifically to deal with that. When they are left open, obviously light can get to the medication.

GC: What other communities would be affected by a solution to the problem we've described?

EN: I know that pharmacists and pharmacy technicians will be hugely affected. One of the technicians that used to work for me developed carpal tunnel syndrome from opening and closing vials day in and day out. Those were the types where you had to line up the arrows to open them.

There are also lots of other conditions that have reduced grip, such as people who have had strokes, multiple sclerosis patients, muscular dystrophy patients, people with tendonitis and tenosynovitis, which are the inflammation of the tendons and the sheath around the tendons, as well as just the elderly and the injured.

GC: What type of vials does your pharmacy use?

E: RIGO, JONES or PREMO vials. For medium size vials, the vial is \$0.18, and the cap is \$0.08.

GC: Can you think of any other points we should follow up on to further our understanding of the problem and how we might develop the requirements for a solution?

EN: I would recommend that you find out what physiotherapists recommend to patients that are faced with this problem. You should also maybe find out exactly which joints are affected by a vial cap specifically, and whether or not the motion of opening the cap causes further damage to the joints.

A1.3: Pharmacist: Simon Wong, Pharmasave, 720 Spadina (Interview excerpt)

Interviewer: Grace Cochrane

GC: What do you think about the feasibility of an opener for prescription vials?

SW: Many seniors have several medications that they have to take through the day, so the opener would have to be something they can carry around with them, but is not easy to lose.

GC: Do you offer any non-child-resistant alternatives at your pharmacy?

SW: Yes, we have the "snap-cap" kind in addition to the kind where you line up the arrows, but patients have to ask for it. They're both the Jones brand.





A2. 1: Top Ten causes of disability among men and woman aged 15 years or older [4]



A2. 2: Proportion of individuals with arthritis and with no chronic conditions who rated their health as fair or poor, by age and sex, household population aged of 15 years and over [4]

	Normal				RA			
	Male		Female		Male		Female	
	Non-dominant	Dominant	Non-dominant	Dominant	Non-dominant	Dominant	Non-dominant	Dominant
F.CIR (cm)	28.50 (2.46)	29.12 (2.65)	25.20 (1.87)	25.61 (2.03)	26.71 (2.15)	27.24 (2.12)	25.22 (2.79)	25.45 (2.65)
F.LEN (cm)	28.88 (1.31)	28.92 (1.22)	26.49 (1.69)	26.87 (1.78)	27.76 (2.22)	27.85 (2.14)	26.10 (1.89)	26.20 (1.78)
H.LEN (cm)	20.35 (0.63)	19.92 (0.04)	18.47 (1.03)	18.41 (0.90)	19.03 (1.42)	18.79 (1.37)	18.07 (1.22)	17.56 (1.37)
H.CIR (cm)	24.31 (1.05)	24.38 (1.29)	20.58 (1.12)	20.67 (1.09)	23.59 (1.79)	23.18(1.98)	21.04 (1.37)	20.84 (1.37)
H.VOL(cm ³)	378.46 (52.69)	395.00 (48.90)	229.39 (53.59)	235.38 (52.97)	374.71 (110.42)	382.35 (99.80)	269.93 (68.87)	267.99 (58.74)
$H_{c} + F_{c}VOL(cm^{3})$	1562.69 (204.58)	1635.38 (241.19)	1063.45 (216.53)	1075.5 (199.25)	1478.24 (275.60)	1507.06 (306.69)	1206.57 (273.19)	1174.25 (267.49)
F.VOL (cm ³)	1183.46 (184.14)	1234.23 (218.28)	841.56 (207.25)	841.29 (163.92)	1106.76 (212.32)	1124.71 (237.46)	938.13 (231.46)	918.96 (233.03)
MAX POW.G. (N)	301.85 (72.08)	322.23 (77.26)	164.59 (56.46)	183.23 (60.20)	82.84 (85.49)	77.35 (85.20)	70.70 (50.23)	66.79 (54.49)
MAX TRLG. (N)	83.69 (24.09)	88.23 (22.53)	59.48 (17.21)	63.88 (20.00)	26.12 (23.35)	26.00 (25.15)	22.91 (17.20)	24.34 (15.45)
MAX PIN.G. (N)	62.85 (12.33)	63.38 (13.15)	41.11 (10.43)	43.30 (9.85)	19.59 (16.79)	20.88 (16.03)	19.31 (12.30)	20.33 (12.79)

A2. 3: Mean results of anthropometric data and grip parameters in normal and RA subjects [30]

APPENDIX 3: Miscellaneous Supporting Research

A3.1: Community Definition in Literature

Dr. E. Bott further argues that members of a community are defined "not as the local area in which they live, but rather as the network of actual social relationships they maintain, regardless of whether these are confined to the local area or run beyond its boundaries" [2].

In addition to the two community definitions in section 2.2, there is a third classification, a communion, that was omitted from the RFP due to its lack of relevance to the arthritis community. For the sake of completeness, the three classifications are shown below.

Place.	<u>Territorial or place community can be seen as where people have something in</u> <u>common, and this shared element is understood geographically. Another way of</u>
	naming this is as locality. This approach to community has spawned a rich
	literature – first in 'community studies' and more recently in locality studies (often
	focusing on spatial divisions of labor).
Interest.	In interest or 'elective' communities people share a common characteristic other than
	place. They are linked together by factors such as religious belief, sexual orientation,
	occupation or ethnic origin. In this way we may talk about the 'gay community', the
	'Catholic community' or the 'Chinese community'. Development in what might be
	called the sociology of identity and selfhood have played an important role in
	'opening out the conceptual space within which non-place forms of community can
	be understood' (Hoggett 1997: 7). 'Elective groups' and 'intentional communities'
	(ranging, according to Hoggett op cit from cyber-communities to car-boot
	enthusiasts) are a key feature of contemporary life.
Communion.	In its weakest form we can approach this as a sense of attachment to a place, group
	or idea (in other words, whether there is a 'spirit of community'). In its strongest
	form 'communion' entails a profound meeting or encounter – not just with other
	people, but also with God and creation. One example here would be the Christian
	communion of saints – the spiritual union between each Christian and Christ (and
	Lange between every Christian). Anothen is Mortin Duber's interact in mosting and
	nence between every Christian). Another is Martin Buber's interest in meeting and
	<u>'the between'.</u>
Source: http://www.i	nfed.org/community/community.htm

APPENDIX 4: Glossary of Terms

Source: <u>http://www.sks-bottle.com/Cap_Glossary.html</u>

<u>Continuous thread closure</u>: (Abbreviated "CT") A non-interrupted spiral design threaded closure. The main purpose of a CT closure is to mate with corresponding bottle threads and provide sealing and resealing of the container.

Lug cap: A closure with raised internal impressions that inter-mesh with identical threads on the finish of container.



Lug cap



Snap closure: The cap is simply snapped on and off

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