Product Design Specifications

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Project title: Medication Delivery

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Function

A device that improves the ability of people with impaired grip strength and vision to open their hospital provided medication and safely self-administer it. The device will allow for straightforward and simple instruction and can be implicated into a patient's ADL's (Activity of Daily Living). It will be lightweight, require minimal force to open, and will reach the regulatory compliance rules for the packaging of medication.

Client requirements

- Develop a device to open pharmaceutical packaging for patients who can self-administer their medication that is both portable and reusable.
- Include a feature to help visually impaired patients read the labels on the medication packaging.

Design requirements

1. **Physical and Operational Characteristics**
    a. **Performance requirements:**
        i. The device will cater to an adult population with a majority aged 60 and up that have reduced grip strength and low vision. Control surfaces must accommodate power grips instead of requiring pinch strength [1].

ii. The tool must accommodate different pill packaging and shapes. It will be able to pierce through tough foil backings without crushing the medication and have a grip feature to pull foil edges.
iii. This tool must feature tactile cues or contrast coloring to assist users with impaired vision and ensure identifying correct pills is made easy.
iv. The device must be compact and lightweight for daily use and continuous transport in a pocket or bag. This includes the durability to withstand everyday living.

b. **Safety**
   i. The device must limit sharp elements and incorporate a protective cover to prevent injuries to the patient.
   ii. Precautions must be integrated to avoid access to children and pets while still reaching performance requirements.
   iii. All external edges on the device must be smooth and rounded to prevent injury or discomfort when in use [1].
   iv. A non-toxic food grade material will be used so contact with medication does not cause chemical contamination [2].

c. **Accuracy and Reliability**
   i. The tool must align with the targeted opening of medication packaging to avoid crushing the medication.
   ii. The device must achieve a successful extraction rate for all testable medication packaging without difficulty, mechanism failure, or device degradation.

d. **Life in Service**
   i. This tool should be able to withstand daily use for the duration of the patient's time in home based hospital care.
   ii. The device will be used for 1-10 medications daily.

e. **Shelf Life**
   i. The device should be stored at reasonable temperatures ranging from 20-25°C to avoid material destruction, specifically in hinges and in any blades [3].
   ii. Will need to withstand nonactivity for extended periods of time even after principal use.
   iii. Will require long-term storage at the patient's residence.

f. **Operating Environment**
   i. The device will be used by patients in the home based hospital care program of UW Health so it must be able to withstand typical housing conditions. The device should be functional within the average housing temperature range from 18°C to 35°C [4]. While in storage the device should be able to endure extreme temperatures ranging from -20°C to 40°C if necessary.
   ii. The device needs to be easy to clean so it must not experience degradation from exposure to water or any other fluids. The functionality of the device should not change after exposure to any common household cleaning products or chemicals as well.
   iii. The device must be able to withstand daily use. It should be resistant to daily wear including minor scratches and any sharp components must also minimize wear from use.

g. **Ergonomics**
   i. The device should allow the user to operate it with a power grip rather than a precision or

pinch grip, reducing the amount of fine finger control required. This is especially important for patients with reduced grip strength, arthritis, or muscle atrophy [5].

ii. The grip diameter of the hand held gripping surface should be approximately 30-50 mm, with a preferred diameter near 40 mm, to support a power grip. The usable handle length of the device should be at least 100 mm so that the force is distributed across the palm rather than concentrated in a small area [6].

iii. The device should minimize wrist flexion, extension, and deviation during use so that the patient can operate it with the wrist in a relatively neutral position [7].

h. **Size**

i. The device must accommodate the range of medication packages provided by the client. The opening area should be large enough to fit the largest package while still securely holding smaller packages during use.

ii. The device should be compact enough for daily transport in a pocket, purse, or small bag. A maximum overall size of approximately 150 mm x 100 mm x 50 mm is proposed to maintain portability while providing enough space for the medication package and gripping features.

iii. The medication loading area should provide enough clearance for the user to insert and remove the package without requiring precise finger placement or fine motor control [8].

i. **Weight**

i. The product should be lightweight and easily portable for use within and outside the home.

ii. The weight should not significantly limit a patient's ability to hold, operate, or transport the device.

iii. The product should be designed to minimize unnecessary weight while maintaining sufficient structural durability.

j. **Materials**

i. Materials should provide sufficient durability to withstand repeated use and transportation.

ii. Materials should be lightweight and comfortable for patients to handle.

iii. Materials should not have sharp edges or surfaces that could pose a safety risk during use or transportation.

k. **Aesthetics, Appearance, and Finish**

i. The final product should have a clean, simple, and intuitive appearance appropriate for use by patients, caregivers, and healthcare professionals.

ii. The exterior surfaces should have a texture or grip pattern that facilitates secure handling, particularly for users with reduced grip strength.

iii. The product should be aesthetically pleasing while maintaining a straightforward and functional design.

2. **Production Characteristics**

a. **Quantity**

i. One functional prototype will be built for testing and evaluation. It should be designed so that more units can easily be made later as the device is meant to be used by many HBHC patients with reduced grip strength and/or low vision, not just one specific individual.
ii. Since the device should be portable and reusable, each patient would need only one unit at a given time. This keeps the number of units per patient low compared to a disposable product.

b. **Target Product Cost**
i. A per-unit production cost target of less than $20 is proposed so that HBHC could hand the device out to many patients in a wide variety of socio-economic situations.
ii. The device should be made from inexpensive, accessible materials, like 3D-printed PLA/PETG or molded plastic, with few moving parts. This keeps both prototyping and future production costs low, which benefits both the manufacturer and the consumer.
iii. A reduced-price device is justified by the much larger cost of patients not taking medications as prescribed. A systematic review of 79 studies found that the yearly disease-specific cost of non-adherence per person was between $949 and $44,190 USD in 2015 [9]. If difficulty opening packaging leads patients to skip or delay doses, even a small improvement in adherence would make up for the cost of the device.

3. **Miscellaneous**
a. **Standards and Specifications**
i. DHS 132.65
- This is an administrative code in Wisconsin that defines the pharmaceutical services of residential care facilities. Medications are not allowed to be transferred between containers and the original package labeling with dosing, drug strength, expiration date, and lot number must be maintained [10].

ii. 82 FR 4578
- This is a federal regulation that defines the conditions for home health agencies to participate in Medicare and Medicaid. Patients must have an individualized plan of care that includes a statement of medication and treatments. Patient medication information must be included in written instruction and any training or education related to medication administration must be provided by the home health agency [11].

iii. 21 CFR Part 201
- This is an FDA regulation that defines standards for drug labeling. A standard format is established including names, sufficient directions for use, ingredients, warnings, and the manufacturer name [12].

b. **Customer**
i. The customer would like the device to be reusable and easily transportable.
ii. The customer dislikes potential exposure to sharp components of the device. They would prefer to limit the amount of sharp areas of the device and these areas must be covered when the device is not in use. The cover must also be secure for transporting the device.

c. **Patient-related concerns**
i. Patients with arthritis, post-stroke contracture, or muscle atrophy can feel pain in their joints during use if the device requires too much force or an awkward hand position.

Opening blister packs can already be painful for older adults. One usability study measured pain as a main outcome [13]. The device should not be painful to use.

ii. Any sharp part used to pierce foil could cut or puncture the patient's skin, especially if they have poor vision or limited hand control. Older patients may have fragile skin that heals slowly, which makes even the most minor cuts a concern. Sharp parts must never be exposed when the device is carried or stored.

iii. Older adults often drop pills while opening blister packs [14], and patients with poor eyesight, limited mobility, or impaired hands can have trouble finding them afterward [14]. Bending down or reaching to look for a pill could lead to a fall, which could cause serious complications to their health and wellbeing.

iv. Patients with low vision who can't read the packaging may take the wrong pill or dosage as they have reduced accuracy when reading prescription labels [15]. The specified medication delivery device should not make it harder to identify medication information.

v. In one population study, fewer than half of the elderly people who could not open at least one container received help with their medication [16]. Therefore, the device should reduce stress and let patients take their medications on their own with ease, not add another difficult step to their routine.

vi. A reusable device that comes into contact with medication could carry germs if it isn't cleaned properly. It could also crush or chip tablets, which may change the dose the patient receives. The device should be easy to clean with soap and water or alcohol wipes, and it should not damage the pills.

d. Competition:

i. Medacube is a dispensing mechanism that automatically sorts a bulk amount of medication in a lockable vault and disperses it to the patient at set times throughout the day. This management of medication lasts for up to 90 days and eliminates manual sorting by dispensing prescribed doses from a dedicated bin. Every delivery is logged and has built in alerts for when the prescription is delivered and when it is taken [17].

ii. Hero Health, similar to medacube, is a multi-medication management at home. The machine has an internal carousel that can store and organize up to ten different oral medications [18].

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