ClereMed: A tool to improve the readability of prescription labels for clients with age-related visual impairment

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"Readability shouldn't be an afterthought when producing materials. It should be the first step in making your merchandise, service, location or information accessible to everyone."

-CNIB Clear Print Guidelines, 2006

Overview

Imagine you are about to take your first dose of insulin. Or maybe a blood thinner. You check the label but the small letters are blurred. How much should you take? When? Should you call a pharmacist? Your spouse? What is the worst that could happen?

For people with visual impairment, the use of prescription medications can be anxiety-causing and degrading, representing a total lack of access to care (American Foundation for the Blind, 2008). Consumer Reports Health even describes the information on prescription medication labels as "confusing, misleading, buried or absent" (Consumer Reports Health, 2011). To improve accessibility, we are proposing to develop a tool to encourage simple actions by pharmacies that promote safer use of medications.

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The purpose of our project is to build a mobile application or "app" called ClereMed to help pharmacists improve the readability of labels. Our primary objective is to demonstrate that ClereMed can help pharmacists reliably identify clients who have difficulty reading labels and make changes to labels to improve readability. Our plan is for ClereMed to serve as a template for app development in other underserved areas of primary care, a template that could prove invaluable to the CNIB as it continues to advocate for access to assistive technologies.

How accessible are prescription labels?

In Canada, prescription label readability is not well regulated. Health Canada describes their current regulations as "flexible" and only suggests that prescription labels use a 10-point font. In contrast, California recently started requiring that all prescription labels use at least 10-point font or 12-point font if requested by the consumer (Board of Pharmacy, 2010). As one Toronto Star reporter put it, when our vision changes with age, "not being able to read a label may seem like a cruel rite of passage [in Canada], but in California, being able to read it is actually a right." (Loxley, 2011).

However, though regulation is lacking in Canada there are guidelines. The 2006 Canadian National Institute for the Blind (CNIB) Clear Print Guidelines recommend that printed material be high contrast and use 12 to 18-point font (Canadian National Institute for the Blind, 2006). In 2011, the United States Pharmacopeia, which is one of the foremost authorities on pharmacy standards of practice in North America, proposed that prescription labels use high contrast print, simple and uncondensed fonts of at least 12-points and adequate white space (Becker, 2011). For people with vision impairment, the American Foundation for the Blind and the American Society of Consultant Pharmacists Foundation recommends pharmacists use large print prescription labels with at least 18-point font (American Society of Consultant Pharmacists Foundation and American Foundation for the Blind, 2008). The Institute for Safe Medication Practices also supports the American Foundation for the Blind's recommendations (Institute for Safe Medication Practices, n.d.).

What does prescription label readability mean for Canadians?

Pharmacy labels are often designed more for the pharmacist than the client. Font size is a central marker of prescription label readability but it is a feature pharmacists overlook. In the US, prescription labels are dominated by pharmacy logos, which use an average font size of over 13-points (Shrank et al., 2007). By comparison, drug names and instructions are around 9-points and warning labels are around 6-points. Features to improve readability such as colour, bolding and highlighting are typically only seen in pharmacy-centric information such as the logo, slogan, phone number or address. In separate study, Drs. Susan Leat and

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Deborah Gold, both members of our research team, are finding similar labels in Ontario.

In Canada, 7% of older Canadians have a self-reported "seeing disability," with eye diseases such as cataracts, glaucoma, diabetic retinopathy and macular degeneration being major contributors to vision loss (Maberley et al., 2006; Statistics Canada, 2006). Many also have difficulties reading if there is glare or dim lighting and struggle with low contrast reading materials (Haegerstrom-Portnoy, 2005).

With normal vision, 3-point font is at the limit of legibility whereas mild to moderate vision loss renders anything smaller than 8- to 14-points illegible (Latham, Waller, & Schaitel, 2011). Seniors have more difficulty recalling and understanding information about their prescription medications when labels use 7-point font compared to 10-point font (Wogalter & Vigilante, 2003). Seniors also read labels with 14-point font more accurately than labels with 9-point or even 12-point font (Smither & Braun, 1994).

Rationale & Significance of a Mobile App to Improve Label Readability

We cannot remedy visual impairment with standard glasses, contact lenses, medicines or surgery. Considering that half of individuals with visual impairment already use large-font reading materials of 16-points or greater (Statistics Canada, 2006), Health Canada's flexible suggestion that prescription labels use 10-point font falls short (as do California's new requirements). Furthermore, pharmacists who are professionally obligated to provide safe drug therapy should already be providing clear and legible prescription labels but that is not currently the case.

Our proposed app, ClereMed, will help pharmacists make prescription labels more accessible to clients living with visual impairment. ClereMed will also build relationships between two underused front-line health professionals: the pharmacist and the optometrist. By doing so, our hope is that ClearMed may even strengthen the clinical relevance of both professions by improving medication safety for people with visual impairment.

Our Study Question, Objectives and Hypothesis

Study Question: Does a pharmacist's use of the ClereMed mobile app improve the readability of prescription labels for people with mild to moderate visual impairment?

Objectives: Our primary objective is to demonstrate that ClereMed reliably identifies clients who have difficulty reading prescription labels and improves label readability. Our secondary objectives are to determine the usability and adoption of ClereMed in pharmacy workflow, to describe the roles of pharmacists

and pharmacy technicians in improving prescription label readability and to determine if the ClereMed mobile app helps pharmacists identify and refer clients with a vision-related drug therapy problem to an optometrist.

Hypothesis: We hypothesize that use of the ClereMed mobile app in 10 pharmacies over a 3-month trial period will identify at least 20 clients who are having difficulty reading prescription labels, will identify a need for improved labeling (e.g., increased font size) and will identify the need for a vision examination by a registered optometrist.

Our Methods

ClereMed will be developed with Communitech, tested at the University of Waterloo, School of Optometry primary care clinic and piloted in 10 pharmacies in Waterloo, Ontario. We will design ClereMed for mobile operating systems such as Android (Google Inc, Mountainview, California) or iOS™ (Apple Inc., Cupertino, California). To guide content, development and usability, we have convened an advisory panel including a representative from the CNIB (Dr. Deborah Gold, Research Director), an optometrist working with low vision patients (Dr. Shamroze Kahn), a community pharmacist (Mr. Bryan Hastie) and a pharmacy student specializing in eHealth technologies (Mr. Calvin Poon). The panel is meeting monthly until the final prototype is developed.

ClereMed will guide pharmacists through 3 steps (Figure 1). A mock-up of the mobile app is provided in the Appendix, Figure A1.

1. Vision Assessment: At the start of a client encounter, the pharmacist will use the ClereMed screening tool to gauge a client's ability to read prescription labels. The tool will ask questions about readability and administer a standardized test of high and low contrast acuity. To measure the accuracy of the screening tool and acuity test, we will validate an electronic prototype at the University of Waterloo, School of Optometry clinic. Our research assistant will screen patients who are waiting for an eye exam and compare screening results to a subsequent vision examination by the optometrist.
2. Pharmacist Assessment: When an individual with vision impairment is identified during screening, ClereMed will produce client-specific recommendations for pharmacy staff to improve prescription label readability. The recommendations will be developed with our advisory panel to ensure they are evidence-based, practical, easily incorporated into the community pharmacy and desirable to the client. In addition, from the client's medication file and with their consent, pharmacists will be asked to identify common medication-related issues that could reduce visual acuity including uncontrolled diabetes or hypertension and chronic use of systemic corticosteroids or anticholinergic medicines.

3. Referral: All pharmacy clients who are identified as having difficulty reading prescription labels will be referred to an optometrist. To refer a client, the app will generate a standardized referral letter (see sample letter in the Appendix, Figure A2). The letter will include any issues identified in the screening test or by the pharmacist. The pharmacist will have the option of printing and faxing the letter or emailing the letter to the client's optometrist. For clients who do not have an optometrist, a list of local optometrists will be provided. Since nearly 66% of vision loss is due to uncorrected refractive error, it is expected that the vision of a high proportion of those who are referred may be improved with spectacle correction. (Cruss, Gordon, Bellan, Mitchell, & Pezzulo, 2011)

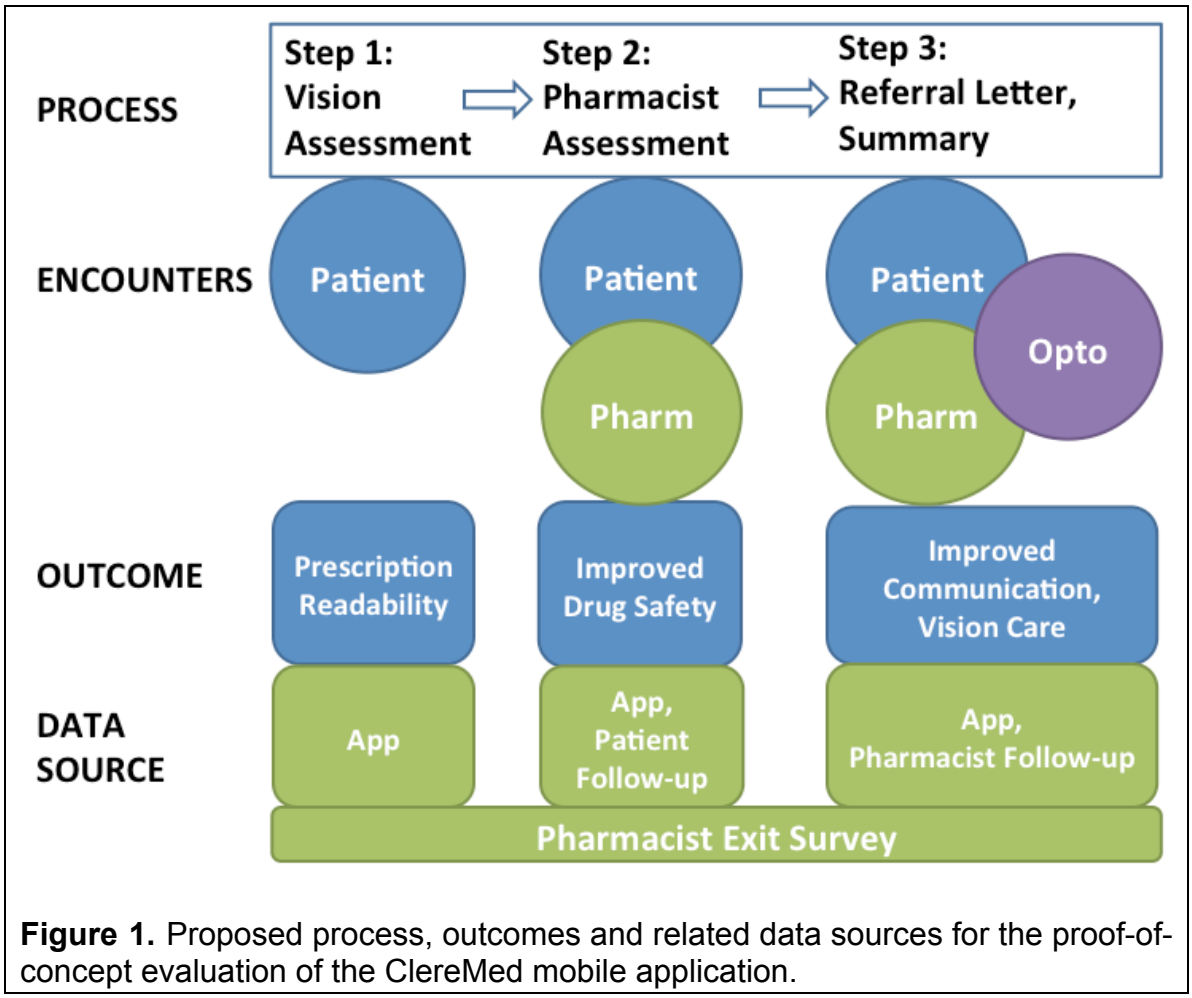

Figure 1. Proposed process, outcomes and related data sources for the proof-of-concept evaluation of the ClereMed mobile application.

Data Collection and Outcomes and Measures of Success

To meet our primary and secondary objectives, ClereMed will collect data on pharmacy staff usage, client responses to the screening questionnaire and any drug therapy issues identified by the pharmacist (Table 1). To protect client confidentiality, pharmacy staff will use a supplementary paper-based form to

collect demographic information (age, gender, income, education) from participating clients. To demonstrate that prescription label readability is improved, a research assistant will follow-up with pharmacy clients 3 months after screening to inquire about changes in prescription labeling, improvements in readability and changes in eye care as a result of referral to the optometrist. To determine usability and adoption of ClereMed in the pharmacy and to describe the roles of pharmacy staff members in improving readability, a research assistant will survey pharmacy staff at 1-month intervals and will perform an exit interview with all participating pharmacy staff.

Table 1. Summary of objectives, data collection, and measures of success for the proof-of-concept evaluation of the ClereMed mobile application.

Objective	**Data Collection**	**Measures/Criteria for Success**
To demonstrate that ClereMed reliably identifies clients who have difficulty reading labels	ClereMed App	% of clients who are identified as having visual impairment Success = 7% (20 out of 300)
To demonstrate that ClereMed helps improve prescription label readability	Client follow-up	% of clients with vision impairment who see a change in labeling Success = 80%
To determine usability and adoption of ClereMed in pharmacy workflow	Pharmacy surveys/exit interview	% adoption by staff at prescription intake, processing and dispensing Success = 50% use in eligible clients
To describe the roles of pharmacists and technicians in improving label readability	Pharmacy surveys/ exit interview	% of recommendations implemented by a pharmacist vs. technician Success = 30-80% by a pharmacist depending on the type of store and technician training levels
To determine if ClereMed helps pharmacists identify clients with vision-related drug therapy problems and refer to an optometrist	ClereMed App, Referral Letter	% of clients with visual impairment who had vision-related drug therapy problems identified on the referral letter and were referred Success = 80%

Sample Size

In terms of sample size, we will pilot ClereMed in 10 pharmacies over a 3-month period. Considering that 7% of individuals over age 55 have visual impairment (Statistics Canada, 2006), if we want to identify at least 20 pharmacy clients who

are having difficulty reading prescription labels, we will need to screen approximately 300 individuals over age 55 (20 ÷ 0.07 = 285). The average Canadian pharmacy fills 150-200 prescriptions per day with independent pharmacies on the low end and franchises on the high end (The Pharmacy Group, 2008). In total, 80% of prescription drug users are over age 50 (Morgan, Cunningham, Hanley, & Mooney, 2009). Considering that 1 in 10 seniors chronically use more than 5 prescription medications, a proportion of pharmacy clients will be filling multiple prescriptions. We estimate that up to half of clients requesting a prescription refill could be eligible for the app meaning that, in a pharmacy filling at least 100 prescriptions per day, up to 50 clients over age 55 could be screened using ClereMed each day.

Data Analysis Procedures

We will summarize demographics, staff member usage, prescription labeling changes, patient experiences and the pharmacy exit survey using descriptive statistics. Because we are proposing a proof-of-concept study, the goal is not to demonstrate efficacy of ClereMed so much as technical feasibility, reliability and validity with the possibility of moving towards a large-scale evaluation (Thabane et al., 2010). Data analysis will focus on describing the function of ClereMed and determining if further evaluation is needed through a large randomized-controlled trial. A large trial would likely examine the effect of mobile apps on health professional behaviors, a major innovation in a sector that has been slow to adopt communication technologies.

Limitations and Proposed Solutions

As we are proposing a novel project with little precedent, we are anticipating some limitations and difficulties. The first limitation is that the project proposed herein is a proof-of-concept study. We will determine the optimal way to collect and interpret data early in the design phase. By collaborating with Communitech, we are gaining a team with extensive experience developing and piloting mobile apps and will learn from their experience throughout the project.

We expect that pharmacists will be reluctant to adopt a new technology into their workflow, especially in busy pharmacies with significant time or software constraints. We are employing a participatory research model wherein pharmacists will be involved throughout the design process to maximize ClereMed's usability. Pharmacist involvement will start with the advisory committee and will continue throughout development and piloting. Pharmacists will be invited to provide feedback for continuous quality improvement for the app throughout the piloting phase. As we analyze our data, pharmacists will be invited to help interpret findings and to guide commercialization and future evaluation.

We also expect that some pharmacy staff members will not know how to change prescription labeling to improve readability. We will encourage pharmacies to

contact their software providers to inquire about enhancement to improve label readability. If pharmacy staff are still unable to change prescription labels we will contact software providers directly.

We are confident that ClereMed can be developed and tested within one year. However, it is our experience that recruitment difficulties can prolong studies. To mitigate this, we will meet regularly with participating pharmacies. After the first month of piloting ClereMed, we will replace any pharmacies that are under recruiting and perform an exit interview to determine the barriers to adoption.

Research Team & Responsibilities

Our research team has representation from the disciplines of health services research, pharmacy, optometry, business and mobile app development. *Dr. Grindrod*, the Principal Investigator, is a licensed pharmacist and researcher with a focus on changing models of practice and eHealth communication technologies. *Dr. Dolovich* is a leader in health services and pharmacy practice research and has extensive experience implementing eHealth technologies in primary care and drug safety. *Dr. Leat* is a licensed practicing optometrist and researcher who is currently funded through the CNIB to investigate prescription label readability. *Dr. Slavcev* is a biotechnology researcher and the Shoppers Drug Mart Professor of Business and Entrepreneurship Chair at the University of Waterloo, School of Pharmacy. As the Lead of the Communitech Apps Factory, collaborator *Dr. Glenn Smith*, brings with him a team of mobile app developers, trainees and marketing specialists. This grant will help train *Mr. Calvin Poon*, a senior pharmacy student, in eHealth technology development and health services research methods and will provide support for *Ms. Allison Gates*, a PhD candidate, who will be employed as a Graduate Research Assistant.

Knowledge Translation and Dissemination

We plan to use our community to build the app, design the evaluation and communicate the results. Our specific activities will include an advisory panel to guide tool development (described above). In addition, we will develop a business case for national promotion and for other mobile health apps for primary care in Canada. Communitech specializes in building technology start-ups. Using the business case developed with the assistance of Communitech, we will commercialize ClereMed to promote it nationally. Commercialization will focus on dissemination rather than profitability.

We will present our findings at 1 national pharmacy conference (Canadian Pharmacists Association Annual General Meeting), 1 international optometry conference (American Academy of Optometry) and 1 international eHealth conference (Medicine 2.0 Annual Conference). We will publish our results in health services research journals, pharmacy journals, optometry journals and/or medical Internet journals.

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Proposed Research Time Line for ClereMed Pilot

We propose to develop and test the ClereMed mobile app over a period of 1 calendar year (April 2012 – March 2013).

Q1 [April-June 2012]: Develop the first ClereMed prototype and validate the screening tool in the University of Waterloo, School of Optometry clinic.

Q2 [Jul-Sep 2012]: Pilot ClereMed prototype; begin monthly follow-up with participating pharmacies; and develop pharmacy staff exit interview. Advisory committee to continue to meet monthly until app development is complete in September.

Q3 [Oct-Dec 2012]: Continue ClereMed pilot and pharmacy follow-up; begin pharmacy client follow-up.

Q4 [Jan-Mar 2013]: Complete pharmacy and client follow-up; perform pharmacy exit interviews; analysis of pharmacy client demographics and usage data collected from ClereMed; begin presenting and publishing ClereMed pilot data.

Budget

The following budget describes how the award funds will be allocated over the proposed 1-year study (Table 2). Each of our respective institutions provides full time annual salaries for Drs. Grindrod, Dolovich, Leat and Slavcev. We will provide CNIB with regular financial statements on how resources are being used.

Table 2. Proposed Budget for the ClereMed proof-of-concept study

Budget item	**Year 1**
Personnel	
a. Graduate Research Assistant - Allison Gates	6,333
b. App development – Programmer salaries	18,415
Material, Supplies & Services	
a. Telephone, fax, mail, office supplies, photocopying, printing	400
b. Data management	1000
c. Publication costs	1,900
Equipment	
a. Tablet computers	5,000
Travel	
a. Conference travel	2,000
Total requested funds	**35,048**

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Personnel:

a. Graduate Research Assistant: Ms. Allison Gates, a PhD candidate at the University of Waterloo will assist with app testing in the School of Optometry clinic and piloting in participating pharmacies. At the University of Waterloo, Graduate Research Assistants are paid $6333/term.
b. App development: We will consult with a senior mobile app developer at the Communitech Apps Factory. The Communitech Apps Factory develops 4 apps per term. The senior developer will supervise 1 co-op student from the computer sciences and will consult with the research team regularly during the development of ClereMed. The co-op student will develop the app prototype. Therefore, app development salaries are based on a 0.25 FTE senior developer and 1.0 FTE co-op computer sciences student, both for a 4-month term.
    - Senior Developer: 0.25 FTE x ($5,692/mo + $1523/mo benefits) x 4 months = $7,215
    - Co-op student: $20/hr x 35hrs/wk x 16 weeks = $11,200

Materials, Supplies & Services

a. Miscellaneous: Telephone, fax, mail, office supplies, photocopy, printing $400
b. Data management: Includes data storage and maintenance of collected data from ClereMed, pharmacy client follow-up and pharmacy staff member exit surveys. The cost of data management for the project is estimated to be $1000.
c. Publication costs: The work will be applicable to specialty journals, such the Journal of Medical Internet Research where the cost of publication is $1,900/publication.

Equipment

a. Tablet Computers: To pilot ClereMed, each of the 10 participating pharmacies will be given a handheld tablet computer.
    - Computer Hardware: $500 x 10 pharmacies = $5000
b. Conference Travel: We are asking for $2000 for travel to an international eHealth conference. We anticipate that the final results of the study could be presented at the Medicine 2.0 annual conference (TBA, 2013), which focuses on eHealth applications and innovations. Registration for this conference is TBA but is approximately $600, transportation is approximately $600, and with the meeting taking 3-4 days and hotel rates at approximately $250.00 per night, the anticipated total cost of attending is over $2000 (CAD).

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Figure A1. A mock-up of the ClereMed mobile application for identifying individuals with age-related vision impairment and for improving prescription label readability.

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Pharmacist
Pharmacy
123 Waterloo Blvd
Waterloo, ON, N1N 1N1

May 1, 2012

Optometrist
Optometry Practice
123 Waterloo Lane
Waterloo ON, N2N 2N2

Dear Dr. Optometrist,

We saw Mrs. Smith at our pharmacy on May 1, 2012. Using a routine screening questionnaire on prescription label readability and a high/low contrast acuity test we identified the following issues with her vision:

- Difficulty reading prescription labels
- Uses large-print materials
- Difficulty reading high glare labels
- Difficulty reading low-contrast labels
- Reduced visual acuity
- Reduced low contrast acuity
- Medication: Mrs. Smith's diabetes is currently managed with metformin but her hemoglobin A1c is 9% (target <7%).

Mrs. Smith has notified us that you are her preferred vision health professional. We have referred her back to your practice for a follow-up appointment to assess her vision.

Sincerely,

Pharmacist

Figure A2. Visual sample of the standardized ClereMed referral letter to help pharmacists communicate with optometrists about visual impairment and prescription label readability.