Final Report to the Medical Advisory Secretariat, Ontario Ministry of Health and Long Term Care

Public Engagement Pilot Study on Point-of-Care International Normalized Ratio (INR) Monitoring Devices

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Executive Summary

Increasing health care costs coupled with limited public resources have led to greater public scrutiny of health policy decisions. Involving the public in health policy decisions is meant to ensure that such decisions are informed, transparent and legitimate as, arguably, the public is the most important stakeholder in policy decisions.\(^1\)\(^\text{-3}\)

The Medical Advisory Secretariat (MAS) in conjunction with the Ontario Health Technology Advisory Committee (OHTAC) have developed a public engagement strategy that began with the establishment of a Public Engagement Subcommittee in November 2006. The Subcommittee was created to examine options and make recommendations regarding the ways in which OHTAC could engage the public.

The point-of-care (POC) international normalized ratio (INR) monitoring devices were selected as an appropriate health technology on which to pilot its public engagement process. Public engagement was incorporated at the research question development stage with the objectives of:

1. Gathering input on the research question framing an evidence-based analysis of POC testing for INR monitoring.
2. Ensuring that the research questions incorporated important patient-centred outcomes.

A focus group was conducted in November 2008 with patients and caregivers.\(^5\) Participants were purposively recruited by a nurse practitioner who coordinated the Thrombosis Clinic of the Toronto General Hospital. Variation was sought across the variables of: age, gender, participation in self-testing, and representation of the major indications for INR monitoring.

A total of 12 patients and one caregiver attended to the focus group. On average, the participants were 56 years of age (range: 30-69, SD: 13.9) and were primarily women (67%; \(n=8/12\)) from metropolitan areas (central city: 50%; \(n=6/12\), suburban: 42%; \(n=5/12\) and rural: 8%; \(n=1/12\)), who had at least some university education (67%; \(n=8/12\)) and half were currently employed (50%; \(n=6/12\)).

Participants had been monitoring their INR for an average of 5.4 years (range: 1-15, SD: 4.3), and half were currently self-testing (i.e. the patients measures their own INR and then consult their health practitioner to see if a change in medication dosage is required). The major indications for INR monitoring were represented, including: atrial fibrillation, venous thromboembolism and living with a mechanical heart valve.

In general, focus group participants reported that the POC INR monitoring devices would be ‘very helpful’ in managing their conditions and highlighted several reasons that motivate their desire to use the devices, including: the physical and psychological impacts of long-term venous testing; lack of access to testing facilities; risks of complications; control and empowerment; and work constraints. When taken together, these motivations suggest that the use of POC INR monitoring devices can increase patients’ quality of life.

The level of pain, discomfort, and stress participants experience with the current standard of INR testing were particularly difficult and important motivators of their interest in (or use of) POC devices. Limited access to testing facilities was another reason underlying their interest. They believed that limited access to, and reliance on, testing facilities negatively impacted their life, especially with regard to employment and balancing familial obligations. They also stressed that this lack of access and convenience put them at risk for complications. Conversely, participants felt that self-testing would reduce these unnecessary risks. Further, those that had the device suggested that self-testing was important because it allowed them to better understand and manage their conditions. Finally, there are patient subpopulations, such as children or people with small and/or inaccessible veins, for which the current standard of testing is simply unfeasible.

Few participants raised concerns with POC INR monitoring devices but those that did focused on the potential difficulty of using the device as well as the desire for continued support.

All patients declared that they were ‘very satisfied’ or ‘satisfied’ with the research questions developed for the POC INR monitoring devices.
The focus group offered crucial insights on the physical, psychological, and social impacts associated with the current standard of care, which may not have otherwise been incorporated into the HTA process.

Public engagement within HTA agencies presents numerous implementation challenges, particularly in ensuring that engagement is timely and relevant to the overall HTA process. However, public engagement greatly benefits the development of research questions and the gaining of societal perspectives that are often left out of traditional HTA. Organizational resources, leadership commitment, and expertise are required for its successful implementation.

Subsequent to gathering public input, a systematic review incorporating the outcomes identified by patients is recommended. This is especially important for the transparency and legitimacy of the public engagement, as well as the decision-making processes. An evaluation of the public engagement strategy on the review process and recommendation would be instructive and is thus warranted.
Context

Public Engagement in the context of MAS

Increasing health care costs coupled with limited public resources have led to greater public scrutiny of health policy decisions. Involving the public in health policy decisions is meant to ensure that such decisions are informed, transparent and legitimate as, arguably, the public is the most important stakeholder in policy decisions. 1-3

The Medical Advisory Secretariat (MAS) in conjunction with the Ontario Health Technology Advisory Committee (OHTAC) have developed a public engagement strategy that began with the establishment of a Public Engagement Subcommittee in November 2006. The Subcommittee was charged with the task of examining options to make recommendations regarding ways in which OHTAC could engage with the public. In its Final Report4, the Subcommittee proposed a framework to incorporate social value judgements in its evidence-based process for health technology assessment (HTA).

In an effort to implement this strategy, MAS identified point-of-care (POC) international normalized ratio (INR) monitoring devices, which were under review, as an appropriate health technology on which to test its public engagement approach.

The Health Technology under Review

POC-INR monitoring devices can be used by patients who have an increased risk of thrombosis and thus require long-term oral anticoagulation therapy, particularly, those with mechanical heart valves, chronic atrial fibrillation, and venous thromboembolisms. The technology is being reviewed as it is portable and uses a drop of blood (from a fingertip) to provide INR results almost immediately. In addition, these devices can be used at home, in clinics, in pharmacies and in other patient care settings such as nursing homes.

Patients, their caregivers, and family members are important consumer-stakeholders of this health technology and the resulting OHTAC recommendation.

Public Engagement Methodology

The Subcommittee identified two phases where the public engagement process may fit into MAS’ pre-existing review timelines: (1) before the review period, at the research question development stage and, (2) during its 21-day consultation period; which occurs after OHTAC has made its recommendation (based on an evidence-based review prepared by MAS). Given that the review for the POC-INR devices was at the beginning stage, public engagement was incorporated at Phase 1 - before the review period. By incorporating the public engagement strategy into the research question development stage, patient-centred health and quality of life outcomes that are deemed important by patients may be incorporated into the research question, ahead of the analysis.
Objective

Consistent with the Phase 1 - Public Engagement strategy, a consumer-stakeholder consultation was undertaken by MAS to:

1. Gather input on the research question, framing an evidence-based analysis of POC-INR monitoring devices.

2. Ensure that the research questions (Appendix 1) incorporated important patient-centred outcomes.

Approach

A focus group of patients and caregivers was conducted in November 2008 at the beginning of the review process. Provincial representation in a face-to-face meeting format was sought. In an effort to employ an arms-length approach in its public engagement, MAS initially partnered with a health organization to coordinate the recruitment and administration of the focus group. MAS developed and supplied recruitment and background information materials. Due to competing resource issues and the limited timeframe in which to conduct the public engagement, recruitment efforts through the third-party health organization were halted. MAS subsequently partnered with a local clinic to seek a local, convenience (i.e. unrepresentative) sample of patients and caregivers.

The Research Ethics Board (REB) of the University of Toronto was consulted as to whether REB approval was required for its public engagement activities. Following their review of the public engagement protocol developed for the POC-INR monitoring devices (used as an exemplar), the REB office concluded that such activities fell under the rubric of 'quality improvement,' rather than research, and issued an exemption letter to MAS (Appendix 2).

Recruitment

Participants were purposively recruited by a nurse practitioner that coordinated the Thrombosis Clinic of the Toronto General Hospital. Variation was sought across the variables of: age, gender, participation in self-testing, and representation of the major indications for INR monitoring.

Data Collection

One semi-structured, face-to-face focus group meeting was conducted, which was digitally-recorded and transcribed verbatim. The meeting lasted approximately 65 minutes. Field notes were maintained in order to document what the participants spoke about, their behaviour, intonation, and their emotional responses, as well as to record debriefing discussions with the clinical epidemiologist and student in attendance.

Study Materials

Focus group discussion guide development

A focus group discussion guide was developed to reflect the research questions and objectives of the public engagement. It was based on a review of public engagement literature and included questions adapted from NICE’s public engagement guidelines. The discussion focused on 1) how, if at all, POC INR testing devices may be helpful in managing patients’ conditions, and 2) whether patients had any concerns with the devices. The discussion guide is included in Appendix 3.

Questionnaire development

A follow-up questionnaire was developed based on the focus group discussion guide and included questions typically used to evaluate public engagement procedures. The questionnaire was pilot tested among three members of MAS to test for uniformity in comprehension and comfort with response formats. The final questionnaire is included in Appendix 4.
Analysis

Qualitative

Transcripts were analyzed using descriptive qualitative techniques including constant comparison analysis, noting relevant similarities and differences across participants’ discussions. The analysis began by examining the text and identifying descriptive labels for the data. This process fractured the data into the major concepts brought up by the participants (e.g. ‘access to testing facilities’). These concepts or ‘codes’ were condensed and integrated under core themes. The core themes included:

- Motivations to use POC INR devices
- Concerns about the POC INR testing devices
- Contextual Background and
- Barriers and Facilitators

A description was then developed for each of these major themes. The first two themes are reported as the latter are not directly relevant to the study’s objectives.

Quantitative

Descriptive statistics are reported from the follow-up questionnaire data. Inferential statistics were not reported given the small sample size and lack of representation.

Results

Characteristics of the Participants

Of the 16 patients invited, 12 attended the focus group along with one caregiver. All but one individual completed the questionnaire. The characteristics of the remaining 12 participants are presented in Table 1.

On average, the participants were 56 years of age (range: 30-69, SD: 13.9) and were primarily women (67%; n=8/12) from metropolitan areas (central city: 50%; n=6/12, suburban: 42%; n=5/12 and rural: n=8%; 1/12), who had at least some university education (67%; n=8/12) and half were currently employed (50%; n=6/12).

Participants had been monitoring their INR for an average of 5.4 years (range: 1-15, SD: 4.3), and half were currently self-testing (i.e. patients measure their own INR and then consult their health practitioner to see if a change in medication dosage is required). The major indications for INR monitoring were represented, including: atrial fibrillation, venous thromboembolism, and living with a mechanical heart valve.

Motivations to use POC INR Monitoring Devices: Increasing Quality of Life

Typical of exploratory approaches, few predetermined survey categories adequately captured the range and depth of the issues and experiences that patients spontaneously discussed during the focus group (highlighting the value of adopting such a semi-structured, qualitative approach to public engagement).

In general, all focus group participants reported that POC INR monitoring devices would be ‘very helpful’ in managing their conditions (n=12/12 nominated 1-‘very helpful’ from a scale of 1-5, with 1 being very helpful and 5 being not at all helpful).

Participants highlighted several reasons that motivate their desire to use point-of-care INR monitoring devices, including: the physical and psychological impacts of long-term venous testing; lack of access to testing facilities; reduced risk of complications; control and empowerment; and reduced work constraints. It is important to understand that these issues, even though described separately, interact synergistically to reinforce each other. When taken together, theses motivations suggest that the use of POC INR monitoring devices can increase patients’ quality of life.
Table 1: Characteristics of the Focus Group Participants

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n (Total = 12)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>8</td>
<td>66.7%</td>
</tr>
<tr>
<td>Male</td>
<td>4</td>
<td>33.3%</td>
</tr>
<tr>
<td>Average Age (years)</td>
<td>56.7 ± 13.93</td>
<td></td>
</tr>
<tr>
<td>Education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Some college &amp; higher</td>
<td>8</td>
<td>66.7%</td>
</tr>
<tr>
<td>High school &amp; less</td>
<td>4</td>
<td>33.3%</td>
</tr>
<tr>
<td>Employment</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed</td>
<td>6</td>
<td>50.0%</td>
</tr>
<tr>
<td>Unemployed</td>
<td>6</td>
<td>50.0%</td>
</tr>
<tr>
<td>Setting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metropolitan/central city</td>
<td>6</td>
<td>50.0%</td>
</tr>
<tr>
<td>Metropolitan/suburban</td>
<td>5</td>
<td>41.7%</td>
</tr>
<tr>
<td>Rural</td>
<td>1</td>
<td>8.3%</td>
</tr>
<tr>
<td>Years since monitoring INR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4 years or less</td>
<td>6</td>
<td>50.0%</td>
</tr>
<tr>
<td>5–9 years</td>
<td>3</td>
<td>25.0%</td>
</tr>
<tr>
<td>10–15 years</td>
<td>2</td>
<td>16.7%</td>
</tr>
<tr>
<td>NA</td>
<td>1</td>
<td>8.3%</td>
</tr>
<tr>
<td>Location of INR testing</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Laboratory</td>
<td>1</td>
<td>8.3%</td>
</tr>
<tr>
<td>Doctor’s office</td>
<td>1</td>
<td>8.3%</td>
</tr>
<tr>
<td>Clinic</td>
<td>3</td>
<td>25.0%</td>
</tr>
<tr>
<td>Self-testing</td>
<td>6</td>
<td>50.0%</td>
</tr>
<tr>
<td>NA</td>
<td>1</td>
<td>8.3%</td>
</tr>
</tbody>
</table>

1. Physical and psychological impacts associated with current standard of INR testing

Quantitative findings

The fact that POC devices ‘only require a drop of blood’ was an important aspect for patients (n=12/12), all of whom either ‘strongly agreed’ or ‘agreed’ with this reason (see Table 2). The majority of patients (n=11/12) also ‘strongly agreed’ or ‘agreed’ that the devices may allow them to receive their INR results faster (one patient was ‘neutral’ on this item).

The requirement of a drop of blood and the benefit of faster results determination, however, does not capture the entire importance these devices may have on alleviating the level of pain, discomfort, and stress patients experience with standard INR testing. The qualitative findings offer further insight.
Table 2: Motivations to use Point-of-care INR Monitoring Devices

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I might not need to go to the lab to get a blood test</td>
<td>12</td>
<td>100.0%</td>
</tr>
<tr>
<td>I might not need to visit my doctor to get a blood test</td>
<td>10</td>
<td>83.3%</td>
</tr>
<tr>
<td>My International Normalized Ratio (INR) may be better controlled (n=11)</td>
<td>11</td>
<td>100.0%</td>
</tr>
<tr>
<td>My medication may be better controlled</td>
<td>11</td>
<td>91.7%</td>
</tr>
<tr>
<td>I may receive my results quicker</td>
<td>11</td>
<td>91.7%</td>
</tr>
<tr>
<td>I may be tested more frequently</td>
<td>10</td>
<td>83.3%</td>
</tr>
<tr>
<td>I may not need the help of others</td>
<td>12</td>
<td>100.0%</td>
</tr>
<tr>
<td>It only requires a drop of blood</td>
<td>12</td>
<td>100.0%</td>
</tr>
<tr>
<td>I may adjust my own medication (e.g. Warfarin or Coumadin)</td>
<td>6</td>
<td>50.0%</td>
</tr>
</tbody>
</table>

*Participants who answered ‘strongly agree’ or ‘agree’ to the following question: “In what ways might Point-of-Care Monitoring Devices be helpful in managing your condition?”

Qualitative findings

Laboratory monitoring of INR levels requires frequent (often weekly or bi-weekly) venous testing. For participants, this has resulted in bruising, the formation of scar tissue, and permanent disfigurement of arms and other body parts. Although not overly conscious about their appearance, some participants were disturbed by the lasting effects of long-term blood draws. The prospect of a finger prick was a welcomed improvement, as one participant asserted: “having scar tissue on the ends of my fingers is a little more exciting than scar tissue on my arms”.

If scar tissue can be problematic from an aesthetic perspective, it also results in more painful sessions when blood is drawn. Overly scarred tissue or inaccessible veins forced some technicians to use other areas, such as the back of the hand, which also resulted in more painful interventions. One patient illustrated how painful it is to have blood drawn regularly: “they had intravenous stuck in whatever place they could get in that would work and then they’d come to this arm, which is very poor for allowing them to get blood. At six o’clock every morning, I’d be begging and I’d be squinting saying: “Please! No!” Participants added that the pain they experience is not limited to their laboratory visits and suggested that long-term blood draws increase the risk of developing chronic pain, such as joint ache.

Stress was another factor often mentioned by patients, which motivated their interest in (or the use of) the POC devices. Delays of up to 3 days to receive INR results left some guessing at their INR levels and wondering whether they were reaching dangerous thresholds. Reflecting on the resultant stress, one participant explained: “The stress is phenomenal. It just ruins your life… the stress alone does.” Participants conceded that it was not only their medical condition that is chronic, but their anxiety as well: “It’s always a worry… I think [the worry]’s always there.” For participants who acquired the device, they felt that POC INR monitoring circumvented the protracted delays and stress they experienced while waiting for their INR results from laboratories. It allowed them to choose a “calm place” and time to self-test. Patients who used to “dread going to the doctor’s office” were now integrating INR monitoring into their daily routine and the monitoring process had ceased to be a source of pain or anxiety.
2. Limited Access to Testing Facilities

Quantitative findings

Patients suggested that POC INR monitoring devices would be helpful in eliminating the need to travel to the lab to get a blood test (n=12/12 for ‘strongly agreed’ and ‘agreed’) or to a doctor for testing (n=11/12 who ‘strongly agreed’; one patient classified this benefit as ‘neutral’). Further, these devices would alleviate the need for other’s help (n=12/12 who ‘strongly agreed or agreed’; see Table 2).

Qualitative findings

The issue of patients’ limited access to testing facilities was one of the most critical reasons underlying the interest in POC-INR monitoring devices, in part because they felt it exposed them to unnecessary risks. Access to INR testing facilities was limited by a wide range of factors including: familial commitments, having to depend on others for transportation, co-morbidity, taking time off work, road conditions and weather, distance from testing facilities, the need to travel abroad, rarity or distrust of foreign testing facilities, and the facilities’ limited hours of operation.

Despite their varied lifestyles, all patients believed that the inconvenience of having to go to a testing facility on a regular basis negatively impacted their life. A third of the patients highlighted the difficulty of monitoring their INR levels while traveling. Patients generally acknowledged the "logistical nightmare" that restricted access to INR testing facilities imposed on them. In contrast, POC-INR monitoring devices alleviated these constraints for those using them, and provided a highly-valued convenience factor. As one patient described, “It's been a life saver to just realize that it's ten o'clock at night and that I can get a reading on the spot.” Patients agreed that using the POC monitoring device is “much easier than running to a lab and having to get the right technician who can find the right spot [to draw blood from].”

Notably, the current standard for INR testing was impossible to perform for certain patient subpopulations including children or people with small or inaccessible veins. Rather than having access or convenience issues, one patient emphatically described their monitor as a lifesaving machine: “For me, it's life and death; it's not a convenience issue”. This patient claimed to be refused entry to laboratories after numerous unsuccessful attempts at venous blood draws.

Access to testing facilities was especially difficult for those who needed to negotiate between tending to their health and familial responsibilities. On some occasions, patients prioritized family over making the trip to the laboratory. Others described the burden they felt they imposed on their caregivers, which was difficult for them to accept. They suggest that caregivers are also likely to benefit from POC devices as they are often charged with tasks such as transportation and childcare.

For some patients, the lack of access resulted in lower compliance in monitoring their INR levels and receiving appropriate care. One participant explained that before getting the monitoring device, she went to a clinic only after she had “been chased enough [by the nurse]” because of the challenge of making arrangements to get to her appointments. A variety of factors limited participants’ access to regular INR monitoring, which put them at risk of developing complications.

3. Risk of Complications

Quantitative findings

Controlling INR levels and medications were strong motivators for using POC-INR monitoring devices. All patients either ‘strongly agreed’ or ‘agreed’ that the devices may ‘better control their INR’ and 11/12 patients ‘strongly agreed’ or ‘agreed’ that the devices may help ‘better control their medication’ (one patient was ‘neutral’ on this item). Self-management, however, was not a strong reason for using the devices as only half of the participants endorsed adjusting their own medication as a reason to use the device (n=6/12 ‘strongly agreed’ or ‘agreed’).

Qualitative findings

Patients stressed that lack of convenience and access put them at risk for poor health outcomes. The idea of having a stroke was frightening for patients, but small hemorrhages were also causes of embarrassment. A
patient described her visits to the dentist, which often resulted in uncontrollable amounts of blood spilling from her mouth. The constant anxiety that mundane situations could pose a risk to one’s health was described as taking serious tolls on the mental wellbeing of patients.

Others also felt that having to travel to testing facilities on a frequent basis jeopardized their health. For some, delays in receiving INR results made them feel as though some portion of their treatment was left to chance. Some speculated that access to a POC device would reduce the need for uninformed self-medication: “When you do have [an INR] reading that's off, you can deal with it right away instead [of thinking: ‘Well, I guess I'm going to have to wait… but… Oh! My gums are red! Oh! Maybe I'll self-medicate’”]. Participants felt that self-testing would eliminate guesswork and exposure to possible complications.

4. Control and Empowerment

Quantitative findings

The prospect of more frequent testing was seen as a benefit of the POC devices by a majority of patients (n=10/12 patients ‘strongly agreed’ or ‘agreed’, one patient was ‘neutral’ on this item).

Qualitative findings

Patients’ need to feel a sense of control over their health and treatment was made very clear. They emphasized how the ability to self-test would give them “a little bit of control” that “helped [them] a lot” in feeling empowered over their own health. After acquiring a POC device, some participants even felt that their previous condition was graver than they had considered. “I didn't know any better. I was told that Warfarin was a little pill you took every day and had your blood tested every month or so. That was what I expected and that's how much respect I gave to a drug like Warfarin”. Indeed the device was helpful in helping patients to better understand their condition: “Now, you've got your monitor, you know what Warfarin mismanagement can do to you. All the red flags are up – I have to know what I'm doing here. I want to find out everything”.

Participants suggested that POC-INR was also beneficial in enabling them to have a degree of self-management over their condition. Participants wished to take control of their care and have “freedom from the lab”. Patients affirmed their vested interest in keeping their health in check: “It’s your health, you’re going to take care of it, you’re going to learn everything you can”. Others suggested that self-testing would bring about better nutritional balance: “If I could monitor myself, I would know for my own personal body what things would be better for me to eat or not.” Participants were especially gratified by the sense of ownership for keeping themselves healthy.

Participants also drew comparisons with those suffering from other health conditions to compare the level of control and empowerment the POC-INR testing device may bring. For example, diabetics were seen as living under similar circumstances, requiring frequent glucose monitoring and treatment adjustments. They questioned why their conditions warranted different treatment since glucometers are available for diabetics1.

5. Work Constraints

Qualitative findings

The final set of motivations to use POC-INR monitoring devices involved constraints on employment due to the reliance on testing facilities. A few patients insisted that they were unable to resume full-time employment because of their inability to commit to a regular schedule. As one participant asserted: “There’s no way I can go back to work if I don’t have a device like that”. Even for those who had “a very understanding boss”, some participants lost paid work time because of the time required to visit a lab: “…when I was working, I always had to take some time off”. One participant admitted to feeling ‘stuck’ in their job: “With the hospital and all the visits that I have to go to, I’ve actually changed my career. No, I can’t keep doing what I was”.

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1 The Assistive Devices Program provides partial funding towards the cost of glucometers, testing strips and lancets for Ontario residents with diabetes, who require insulin or who have gestational diabetes.
Even if their position was not directly threatened, some participants felt that frequent absences from work may affect their chances for promotion or that they may receive less recognition than their peers. Participants linked their job insecurity with several psychosocial effects including: lower quality of life, financial burdens, psychological impacts (e.g. depression), and marital problems. The current standard of INR testing was thus seen by the focus group as an immense constraining factor in their employment that further affected other domains in their lives.

**Concerns with POC INR Monitoring Devices**

A few participants raised concerns with POC-INR monitoring devices, but those that did focused on the potential difficulty of using the device and the desire for continued support.

The following are the qualitative themes that arose from discussions on participants’ concerns with the POC devices, along with the survey results, which attempt to quantify these sentiments (see Table 3).

**Quantitative findings**

While the majority of patients did not have concerns over the use of POC-INR monitoring, a few individuals who expressed apprehension with the potential difficulty of using the devices (n=2/12), discomfort with the prospect of being responsible for checking their own INR (n= 1/12), interpreting their own INR (n=1/12) and adjusting their own medication (n= 1/12). Another person was concerned with the fact that their INR might not be monitored by a lab.

Upon further exploration, individuals with these concerns included a balance of older and younger patients (age range: 30-68) who had been monitoring their INR for a range of 2-15 years through laboratories and clinics. No trends were apparent among those with these concerns (though such results cannot be generalized from this small sample).

**Qualitative findings**

**Need for Education and Continued Support**

Participants who possessed a POC device were quick to admit that well-trained health professionals remained important to their care and that they could not, as some participants seemed to hope, rely only on the device. One of the roles clinicians played for self-testing participants was that of trainer and teacher. First time users emphasized the importance of finding someone to teach them how to use the device: “I was trained here by Dr. X a couple of times and nervously went and did it myself at home the first two times but, since then, the last three or four times felt much more relaxed.” The learning process was found by participants to not be instantaneous: “I got the machine and then came [to the clinic] two or three weeks in a row. Dr. X taught me and my wife to go through the steps to take my blood”. As such, health professionals became a trusted source of information and training.

A caveat raised by one participant about the widespread use of POC devices was the fear that using the unit will "make everybody even more individualistic" and reduce their interaction with other patients and health professionals.
Table 3: Concerns with Point-of-care INR Monitoring Devices

<table>
<thead>
<tr>
<th>Characteristic*</th>
<th>n (Total = 12)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>My International Normalized Ratio (INR) might not be monitored by the lab</td>
<td>1</td>
<td>8.3%</td>
</tr>
<tr>
<td>My International Normalized Ratio (INR) might not be monitored by my doctor</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>I may not feel comfortable using the device</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>I may have difficulty using the device</td>
<td>2</td>
<td>16.7%</td>
</tr>
<tr>
<td>I may still need the help of others</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>I might not understand how to use the device</td>
<td>0</td>
<td>0.0%</td>
</tr>
<tr>
<td>I might have to be responsible for checking my own INR</td>
<td>1</td>
<td>8.3%</td>
</tr>
<tr>
<td>I might have to interpret my INR</td>
<td>1</td>
<td>8.3%</td>
</tr>
<tr>
<td>I may not feel comfortable adjusting my own medication (e.g. Warfarin)</td>
<td>1</td>
<td>8.3%</td>
</tr>
</tbody>
</table>

*Participants who answered ‘strongly agree’ or ‘agree’ to the following question: “Are there factors that might concern you about Point-of-care Monitoring Devices for INR testing?” “I am concerned because…”

Feedback from Participants

On the public engagement

All patients were comfortable with the way they were approached to participate in the focus group (n=12/12 reporting being ‘very comfortable’ or ‘comfortable’).

Reasons to participate in this focus group were unanimously to have their voices heard by the Government of Ontario, as well as the desire to have the POC-INR monitoring devices funded (n=12/12 patients ‘strongly agreed’ or ‘agreed’ to these items). Roughly half of the participants attended to learn about the POC devices (n=7/12) or to participate in a focus group (n=6/12).

Half of the participants came prepared to the focus group meeting (n=6/12 did ‘some preparations’), largely by reflecting on their experience with, and the benefits of, POC-INR monitoring devices.

With regards to the conduct of the meeting, most participants found the purpose of the meeting and the discussion to be ‘very clear’ or ‘clear’ (n=12/12 and n=11/12, respectively). The majority also felt sufficiently involved in the focus group (n=11/12 rating their involvement as ‘very involved’ or ‘involved’) suggesting their opinions and concerns were heard.

On the research questions developed for analysis

All patients declared that they were ‘very satisfied’ or ‘satisfied’ with the research questions developed for the POC-INR monitoring devices (n=12/12).

Taken together, these finding indicate that public engagement appears to rank highly on; representation, procedures, and information – dimensions typically used to evaluate deliberative methods. An outstanding dimension – outcomes – could be evaluated given that the HTA was not complete as of the writing of this report.
Reflections on the public engagement process

Public engagement within HTA agencies forms a critical part of research question development and gaining societal perspectives. There is no doubt that engaging the patients who are likely to be affected by OHTAC’s recommendations provides a significant amount of added value to the HTA process. However, sufficient organizational resources, leadership commitment, and expertise are all required for its successful implementation in HTA process.

The experiences gained during this pilot study present insights for future public engagement initiatives within HTA agencies. First, it is important to appreciate that exercise of engaging the public is, in effect, a research endeavour, grounded in health research. Positioning public engagement within an HTA agency requires an acknowledgement that, in addition to an evidence-review capacity, the agency will be serving an evidence-generating role, similar to MAS’ field evaluations. Negotiating between these roles will require both distance and objectivity to its systematic reviews, as well as an active involvement in generating research. Likewise, the role of the public/patients should be separated from the subsequent review of the relevant qualitative, social science literature. This is especially important to achieve an objective, impartial review. Thus two individuals would fulfill the respective roles of evidence-generation and evidence-review, respectively. Qualitative and quantitative research expertise is required for both these roles: reviewing qualitative research and developing public engagement approaches for the particular topic and stage of the review.

Subsequent to gathering public input, a systematic review incorporating the outcomes identified by patients/public is recommended. This is especially important for the transparency and legitimacy of the public engagement and the health policy decision-making processes. Themes that warrant further exploration and possible inclusion in the research question include: the pain and discomfort related to venous testing; the impact of venous testing for patient subpopulations (i.e. children and those with small or inaccessible veins); the stress related to limited access to standard testing facilities; and the levels of compliance and complications associated with POC-INR devices.

While an arms length approach is ideal, this experience proved that a proactive approach was required to meet the demands of keeping the public involvement timely and relevant to the overall HTA process. As a first attempt, partnering with an advocacy or disease-centred organization is recommended. After a predetermined period of time, however, efforts need to be made to proactively work through clinics or other relevant organizations to reach the target stakeholders.

Ultimately, the effectiveness of any public engagement process should be judged by some measure of the outcomes achieved. An evaluation of the public engagement strategy on the HTA process and agency is critical for public accountability as well as for the objective of ensuring that health policy decisions are informed, transparent, and legitimate. Thus a follow-up of how, if at all, the results of this public engagement are incorporated into the review and recommendations is warranted. Further, understanding the impact of such exercises on the HTA agency would be helpful toward any future endeavour aimed at the long-term development of public engagement within an HTA agency.

Conclusions

The focus group offered crucial insights on the physical, psychological, and social impacts associated with the current standard of care, which may not have otherwise been incorporated into the HTA process.

Public engagement within HTA agencies presents numerous implementation challenges, particularly in ensuring that it is timely and relevant to the overall HTA process. However, public engagement forms a critical part of developing research questions and gaining societal perspectives that are often left out of traditional HTA. Organizational resources, leadership commitment and expertise are required for its successful implementation.

Subsequent to gathering public input, a systematic review incorporating the outcomes identified by the patients/public is recommended. This is especially important for the transparency and legitimacy of the public engagement and the decision-making processes. An evaluation of the public engagement strategy on the HTA process and agency would be instructive and is thus warranted.
References


Appendices

Appendix 1: Research Questions

Effectiveness:
- Does POC INR testing improve clinical outcomes in setting X\(^2\) compared to standard lab-based testing?
- Does POC INR testing in any setting impact patient satisfaction, quality of life and convenience compared to standard lab-based testing?

Cost-effectiveness:
- Examine the cost-effectiveness of POC INR testing in all settings compared to usual care.

Appendix 2: Research Ethics Board Exemption Letter

UNIVERSITY OF TORONTO
Office of the Vice-President, Research and Associate Provost

Office of Research Ethics
3rd Floor, McMurrich Building
12 Queen’s Park Crescent West
Toronto, Ontario M5S 1A1

Dr. Les Levin
10 York University Avenue
Toronto, Ontario M5S 1A1

Dr. Levin,

Thank you for contacting the Office of Research Ethics (ORE) at the University of Toronto with regard to the Public Engagement Strategy: Point of Care INR Monitoring Devices.

This is to notify you that the process which you have described does not require Research Ethics Board (REB) review according to the University of Toronto’s Principles to Determine Exemption from Research Ethics Review. These principles were approved in 2007 by the University of Toronto’s Research Ethics Policy and Advisory Committee (then the Committee on Human Subjects Research). For this reason, you will not be required to submit your project for review by the University of Toronto’s REB.

We would like to acknowledge that any kind of engagement of the public may still subject to certain ethical and legal considerations such as the process of free and informed consent, respect for privacy and confidentiality, as well as the duty to report the intent to harm oneself or someone else, even though the project is beyond the jurisdiction of the REB.

We wish you the best of luck with your undertaking and thank you for your evident commitment to the Research Ethics Review process.

Sincerely,

Jill Parsons
Research Ethics Officer – Health Sciences

September 3, 2008

3/9/2008
Appendix 3: Focus Group Discussion Guide

POC Focus Group Discussion Guide

Introduction

Thank you for coming today to discuss point-of-care monitoring devices for INR. My name is Yvonne Bombard and I am leading the group discussions today. The Ontario Government is interested in hearing your opinion on how this new technology might affect you. This may help us to expand the research questions we have developed for our evidence-based review of this technology.

This is XXXX, a clinical epidemiologist with the Ontario Government, who will introduce the technology. If, after hearing about the details of the project again, you decide you do not wish to participate, please feel free to leave. You can always call me later on if you wish to share your thoughts. Our discussion here today will also be tape-recorded. We are going to start by introducing ourselves; as a courtesy to fellow participants, please do not discuss what we talk about today with others outside of this room. We want to stress that we will keep all of these discussions confidential.

Does anyone have any questions before we get started?

Introductions: Let’s go around and introduce ourselves – please tell us your only first name and why you have decided to participate today. Again, my name is Yvonne, and this is XXX (introduce other members who may be present).

Thoughts on POC Monitoring Devices:

1. How might Point-of-Care Monitoring Devices be helpful in managing your condition?
   
   Prompts:
   
   ➔ No need to go to the lab to get a blood test?
   ➔ No need to visit doctor to get a blood test?
   ➔ Better control of INR?
   ➔ Better control of medication?
   ➔ Adjust medication on your own (e.g. Warfarin or Coumadin)?
   ➔ Quicker receipt of results?
   ➔ Frequent testing?
   ➔ Only requires drop of blood?
   ➔ Travel costs?
   ➔ Lost wages?
   ➔ Caregiver costs?
   ➔ Going for less doctor visits?
   ➔ Are there other ways that Point-of-Care Monitoring Devices might be helpful in managing your condition?

2. How might Point-of-Care Monitoring Devices impact your caregiver or family?
   
   Prompts:
   
   ➔ Others’ help may be unnecessary?
   ➔ Spend less time away to monitor INR?
   ➔ Are there other ways that Point-of-Care Monitoring Devices might impact your family or caregiver?
3. **How might Point-of-Care Monitoring Devices impact your quality of life?**

_Prompts:_
- Change physical health?
- Change mental health?
- Reduce pain or disability?
- Contribute to carrying out your daily activities?

4. **Are there factors that might concern you about Point-of-Care Monitoring Devices for INR Testing?**

_Prompts:_
- INR may be monitored less closely by the lab?
- INR may be monitored less closely by your doctor?
- Discomfort using the device?
- Difficulty using the device?
- Difficulty understanding how to use the device?
- Still need others’ help?
- Increased responsibility for checking your own INR?
- Difficulty in interpreting your own INR?
- Discomfort adjusting your own medication?
- Are there other factors that concern you about Point-of-Care Monitoring Devices for INR testing?

**Closing**

**Questions**
1. Do you have any suggestions on how we might improve our research questions we have developed for our review?
2. Do you have any other comments about how Point-of-Care Monitoring Devices for INR Testing might affect the management of your condition?

**Comments**
Thank you very much for your participation. Before you go, we will be circulating an evaluation form. Can you please complete the short form about your thoughts of the discussion we had today? It will also ask whether you will be willing to participate in a follow-up telephone interview and questionnaire; we hope that you will consider this request. Please return the form to us on your way out.

Thank you again.
Appendix 4: Follow-up Questionnaire

Follow-up Evaluation Form:
Point-of-Care Monitoring Devices for INR Testing

Section A: Your Thoughts about the Focus Group

We would like to know your thoughts about participating in this focus group today.

BEFORE THE FOCUS GROUP:

A1  How comfortable are you with the way you were approached to participate in this focus group?  
(Please check only one box)

Very comfortable  Comfortable  Neutral  Not comfortable  Not at all comfortable

A2  What are the reasons that you have chosen to participate in this focus group?  
(Please rate how strongly you agree or disagree with EACH of the following statements by placing one check for each row)

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>I was interested in learning more about Point-of-Care Monitoring Devices for INR Testing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b</td>
<td>I was interested in participating in a focus group</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>c</td>
<td>I wanted my voice to be heard by the Government of Ontario</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>d</td>
<td>I wanted Point-of-Care Monitoring Devices to be funded by the Government of Ontario</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

A3  How much preparation did you do before coming to the focus group? Some examples are: thinking, reading or talking with others about Point-of-Care Monitoring Devices for INR Testing  
(Please check only one box)

A lot of preparation  Some  Neutral  Little  No preparation

Please specify the type of preparation done:


DURING THE FOCUS GROUP:

A4  How clear did you find the purpose of this focus group?  
(Please check only one box)

Very clear  Clear  Neutral  Not clear  Not at all clear
A5  How clear did you find the issues that were discussed during the focus group? (Please check only one box)

Very clear  □  Clear  □  Neutral  □  Not clear  □  Not at all clear

□1  □2  □3  □4  □5

A6  How would you rate your level of involvement in this focus group? (Please check only one box)

Very involved  □  Involved  □  Neutral  □  Not involved  □  Not at all involved

□1  □2  □3  □4  □5

A7  How clear did you find the background information SHEET on Point-of-Care Monitoring Devices for INR Testing? (Please check only one box)

Very clear  □  Clear  □  Neutral  □  Not clear  □  Not at all clear

□1  □2  □3  □4  □5

A8  How clear did you find the background information PRESENTATION on Point-of-Care Monitoring Devices for INR Testing? (Please check only one box)

Very clear  □  Clear  □  Neutral  □  Not clear  □  Not at all clear

□1  □2  □3  □4  □5

A9  How satisfied are you with the research questions developed for the analysis of Point-of-Care Monitoring Devices for INR Testing? (Please check only one box)

Very satisfied  □  Satisfied  □  Neutral  □  Not satisfied  □  Not at all satisfied

□1  □2  □3  □4  □5
Section B: Your Thoughts on Point-of-Care Monitoring Devices for INR Testing

We would like to know your thoughts about Point-of-Care Monitoring Devices for INR Testing.

B1 How helpful might Point-of-Care Monitoring Devices be in managing your condition?

<table>
<thead>
<tr>
<th>Very helpful</th>
<th>Helpful</th>
<th>Neutral</th>
<th>Not helpful</th>
<th>Not at all helpful</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
<td>☐ 5</td>
</tr>
</tbody>
</table>

B2 In what ways might Point-of-Care Monitoring Devices be helpful in managing your condition?

(Please rate how strongly you agree or disagree with EACH of the following statements by placing one check for each row)

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>a</td>
<td>I might not need to go to the lab to get a blood test</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>b</td>
<td>I might not need to visit my doctor to get a blood test</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>c</td>
<td>My International Normalized Ratio (INR) may be better controlled</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>d</td>
<td>My medication may be better controlled</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>e</td>
<td>I may receive my results quicker</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>f</td>
<td>I may be tested more frequently</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>g</td>
<td>I may not need the help of others</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>h</td>
<td>It only requires a drop of blood</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
<tr>
<td>i</td>
<td>I may adjust my own medication (e.g. Warfarin or Coumadin)</td>
<td>☐ 1</td>
<td>☐ 2</td>
<td>☐ 3</td>
<td>☐ 4</td>
</tr>
</tbody>
</table>
B2 Are there factors that might concern you about Point-of-Care Monitoring Devices for INR Testing?
(Please rate how strongly you agree or disagree with EACH of the following statements by placing one check for each row)

<table>
<thead>
<tr>
<th>“I am concerned because…”</th>
<th>Strongly agree</th>
<th>Agree</th>
<th>Neutral</th>
<th>Disagree</th>
<th>Strongly disagree</th>
</tr>
</thead>
<tbody>
<tr>
<td>a …my International Normalized Ratio (INR) might not be monitored by the lab</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>b …my International INR might not be monitored by my doctor</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>c …I may not feel comfortable using the device</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>d …I may have difficulty using the device</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>e …I may still need the help of others</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>f …I might not understand how to use the device</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>g …I might have to be responsible for checking my own INR</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>h …I might have to interpret my INR</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
<tr>
<td>i …I may not feel comfortable adjusting my own medication (e.g. Warfarin)</td>
<td>□ 1</td>
<td>□ 2</td>
<td>□ 3</td>
<td>□ 4</td>
<td>□ 5</td>
</tr>
</tbody>
</table>

Section C: About You

We would like to know more about you in order to describe the people that have participated in this focus group.

C1 Are you…? (Please check only one box)
□ 1 Male
□ 2 Female

C2 In what year were you born? (Please complete the blanks)
19 [__] [__]

C3 Which of the following best describes where you live? (Please check only one box)
□ 1 Metropolitan / central city
□ 2 Metropolitan / suburban
□ 3 Small city / town
□ 4 Rural area

C4 What is the highest grade or level of education you have attained? (Please check only one box)
□ 1 No schooling
□ 2 Some elementary
□ 3 Completed elementary
□ 4 Some Secondary
□ 5 Completed Secondary
□ 6 Some community college, technical college, CEGEP or Nursing training
□ 7 Completed community college, technical college, CEGEP or Nursing training
□ 8 Some university or teacher’s college
□ 9 Completed university or teacher’s college
□ 99 Other (please specify): ________________________________
C5 What is your current employment status? (Please check only one box)

☐ 1 Full-time
☐ 2 Part-time
☐ 3 Unemployed and seeking work
☐ 4 Unemployed and NOT seeking work

C6 Please indicate how long you have been monitoring your International Normalized Ratio (INR)? (Please complete the blanks)

☐ ☐ Years
☐ ☐ less than a year

C7 Where do you currently receive your INR monitoring? (Please check all that apply)

☐ 1 Laboratory
☐ 2 Doctor’s office
☐ 3 Community Care Nurse
☐ 4 Self-test with Point-of-care INR Monitoring Device
☐ 99 Other (please specify): ___________________________________________

C8 Do you have insurance coverage from an extended health insurer? (Please check only one box)

☐ 1 Yes
☐ 2 No
☐ 3 Not applicable (I do not use the Point-of-care Device)

C9 Do you have insurance coverage FOR YOUR POINT-OF-CARE DEVICE from an extended health insurer? (Please check only one box)

☐ 1 Yes
☐ 2 No
☐ 98 Not applicable (I do not use the Point-of-care Device)

C10 Would you be willing to participate in a brief telephone interview to discuss your views and concerns with Point-of-Care Monitoring INR Monitoring devices? (Please check only one box)

☐ 1 Yes; here is my name & telephone number:
   Name: ________________________________________________________
   Telephone number: (______) ________________________________
☐ 2 No thanks

C11 Would you be willing to receive a follow up questionnaire about your views and concerns with Point-of-Care Monitoring INR Monitoring devices? (Please check only one box)

☐ 1 Yes; here is my name & address:
   Name: ________________________________________________________
   Street & Number: ________________________________ Apt:__________
   City: ________________________________ Province: ________________
   Postal Code: ________________________________
☐ 2 No thanks
Do you have any comments, questions or concerns?

___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________
___________________________________________________________________________________

Thank you for participating today. Please return this to the facilitator.