**The Mission**

Canada’s healthcare system is a source of national pride and international envy; however, with an aging population, the burden of neurogenerative diseases (NDs) on society is a reality that cannot be ignored. This has led to an increased call for research in neurological diseases such as Alzheimer’s.1 In response to this need, the Canadian Consortium on Neurodegeneration in Aging (CCNA) began the Comprehensive Assessment of Neurodegeneration and Dementia (COMPASS-ND) Study.

There are many components to this study including clinical observation, blood draws, lumbar puncture, brain donation, and autopsy. Unfortunately, there is still a lot of uncertainly around the prognosis and treatment of many NDs and the only way to reach a definitive clinical diagnosis is through a brain tissue analysis acquired via an autopsy at the time of death. This is an important tool to examine different aspects of aging and neurodegeneration. As part of the COMPASS-ND Study, a voluntary National Brain Donation and Autopsy Program has been created to collect brain tissue for banking and to arrive at a definite pathological diagnosis which can then be shared with the deceased patient’s family and be used in future research. This National Brain Donation and Autopsy program is the first of its kind in Canada that invites participants to consider brain donation and autopsy to help provide researchers with a wealth of scientific knowledge with which they can continue to strive towards a better understanding of ND.

This is a national study with over 32 sites across Canada (see Figure 1 in the appendix). Each province has a neuropathology core site at which the autopsy report and tissue diagnosis will take place. The banked autopsy samples will be sent to and stored at the Douglas-Bell Canada Brain Bank (DBCBB) in Montreal – the designated national CCNA Brain Bank. Brain tissue samples collected from participants will be shared with researchers within Canada only. The focus of this communication plan will be on one of the British Columbia (BC) sites located at University of British Columbia Hospital (UBCH) Clinic for Alzheimer Disease and Related Disorders (CARD).

The diagnostic evaluation for all BC sites will be performed by one of the study neuropathologists at Vancouver General Hospital (VGH). The frozen tissue and any formalin fixed tissue that remains after the diagnostic evaluation will sent to Montreal to be stored at the DBCBB. See Figure 2 in the appendix for a flowchart of the logistics involved from the moment someone enters the main COMPASS-ND study, then the Brain Donation and Autopsy program, and finally to the point of brain donation.

*The Data.* The overall COMPASS-ND study recruitment numbers are currently at approximately 1131 participants, with a goal of recruiting at least 2310 participants. In other words, the main COMPASS-ND study is at 49% of its intended recruitment. The Brain Donation and Autopsy program is considered a sub-study of COMPASS-ND and is offered to anyone who is enrolled in the main study. This means that currently, there are 1131 people that could consent to the Brain Donation and Autopsy program; however, the current recruitment numbers for the Brain Donation and Autopsy program lie just over 280 with a total of only two successful brain donations thus far. This low number is not indicative of a lack of interest or people not passing away; it highlights the many logistical processes involved, the sensitive nature of the procedure, and a lack of awareness about the existence of the program. Thus, focus will be placed on increasing awareness about the program in an effort to increase enrolment. This is because study coordinators at the UBCH CARD site have found that once patients learn about the details of the program, a large majority are interested in enrolling right away.

**Audience**

The main audience of this communication plan is patients and their families who visit the UBCH CARD. In other words, the target audience is both patients and their legal next-of-kin (NOK) which is often a member of the family. This is because a successful brain donation and autopsy requires the participation and consent of both parties. Even if participants consent to be part of the Brain Donation and Autopsy program by signing the informed consent form, the final authorization by the legal NOK must be obtained within thirty days of passing via a hospital autopsy authorization form. Therefore, the consent process is two-fold – consent is sought both before, and after, the death of the participant.

*Audience analysis.* When patients decline to participate in any research study, they sometimes provide a reason for their choice. This reason is documented as an encounter note in their file. As a part of the audience analysis, a file review was completed on previous patients who have refused to participate in the Brain Donation and Autopsy program to note the reasons given for refusal. The top two concerns noted by patients were funeral arrangement concerns and burden on loved ones. This communication plan aims to address these two concerns by providing information that directly address these issues.

Looking at research can shed light on important characteristics of the target audience. For example, a study looking at psychosocial outcomes of caregivers to elderly Alzheimer’s patients found that they suffer from an increased level of perceived burden and objective stressors.2 This is understandable given many caregivers have families of their own and must balance a busy schedule. This is important to keep in mind when discussing time-of-death procedures and responsibilities with NOK as they may already feel burdened by their role as a caregiver.

Given the multicultural nature of Vancouver, it is very likely that English is a second language for many patients visiting the clinic. Ideally, we would be able to offer written documents in all the commonly spoken languages but unfortunately this is not something that is possible at this current time due to a lack of allocated funding. That being said, meeting the person where they are at, in terms of language for example, is of utmost importance when communicating with individuals for whom English is not a strength. To ensure the language level is appropriate, the aim will be to avoid using jargon and acronyms to the extent possible. Also, staff will be instructed to adjust the speed with which they speak depending on the individual with whom they are communicating.

Lastly, the nature of ND is that most individuals who visit the clinic will be older than 65 years of age. This knowledge allows us to anticipate certain characteristics such as mobility issues, hearing impairment, and memory problems. The age of the audience effects the amount of time they require to move around the clinic and take-in information. There are often volunteers in the building who can help visitors navigate the clinic; this service is especially valuable for the UBCH CARD patients.

While it is true that initiating conversations about death can be very emotional, patients and their families who learn about the benefits of the program often seek it out themselves and express feelings of gratitude. Finding out the true cause of a loved one’s death, can result in closure for family members and is a step forward in their grieving process. Furthermore, many people feel fulfillment in knowing they are able to help future patients and the field of medicine as a whole.

This is a very difficult situation for patients and their families regardless of the stage of diagnosis. They often face an uncertain future and the potential to leave a legacy behind for their family and society is one that can provide patients with a sense of hope, purpose, and empowerment. An increase in enrollment in a national Brain Donation and Autopsy program would have a lot of benefits for patients diagnosed in the future. This communication plan uses an informational pamphlet to deliver this messaging to the target audience.

**Goals**

*Process Goal.* 90% of patients to receive the Brain Donation and Autopsy program informational pamphlet. This will be assessed by amending the enrollment form to include a question that asks participants how they first learned about the program using multiple choice options. The number of individuals who note the pamphlet as their source of information will be tracked.

*Outcome Goal.* 50% increase in enrolment in the Brain Donation and Autopsy program. All data collected in this study will be uploaded and/or entered into the Longitudinal Online Research and Imaging System (LORIS) database at McGill University in Montreal. The LORIS system allows tracking of the number of completed and signed consent forms; in this way enrolment rates before and after the communication plan deployment can be compared.

Given that so far only two successful brain donations have been accomplished, any increase in this number will indicate some level of improvement; the goal will be a total of four new brain donations over the first year of deployment of the communication plan. The UBCH CARD will be used as a pilot site. If proven successful, the plan can be deployed in other BC sites and then other provinces. This site has been chosen as the pilot because the national coordinator is located at this site and can closely monitor the progress and logistics involved.

*Precaution adoption process model (PAPM).* The hope is for this communication plan to ensure patients as well as their NOK progress from being unaware of the program to being aware of it and making a decision regarding enrolment. An example of PAMP stages for the Brain Donation and Autopsy Program can be displayed below:

Never heard of the Brain Donation and Autopsy program 🡪 Learned about the Brain Donation and Autopsy program via pamphlet but never considered enrolling 🡪 Thinking about enrolling but unsure about whether or not to join the program 🡪 Decided whether or not to enroll in the program 🡪 If decided to enrol, they sign the consent forms.

It is possible for patients to remain in the stage at which they have received the information and are taking their time to come to a decision. This must be respected and even encouraged by research staff. Depending on the family dynamics of the individual, this process may take more time than anticipated. This is because the patient may need to consult their lawyer to find out who their legal NOK is, they may need time to discuss the decision with their religious leader, or they may simply be busy with other aspects of their healthcare. During this time, it is important to strike a fine balance between being available to answer any questions the family may have but also to encourage the patient to proceed with the steps necessary to enrol in the program.

**The Message**

Given the sensitive nature of this topic, it is expected and understandable for patients and their families to have questions, concerns, and reservations. The best way to overcome these potential roadblocks and barriers is to gather as much accurate information as possible to be distributed to patients and their families as they navigate what may be a very distressful moment of their life. The idea of brain donation and end-of-life topics in general, can be outrage provoking. The area of outrage will vary depending on the individual; thus, it is important to identify and address it to be successful.

**Areas of Concern**

*Coercion.* All enrolled participants are expected to make their own decision on whether or not to participate in the program. That being said, in cases where disease progression is in a later phase, it is possible that participants may have cognitively declined to a point where informed consent is no longer feasible. In this case they are no longer capable of providing informed consent at which time they will be invited to assent, and their NOK or legally authorized representative will be invited to consent on their behalf. This is why it is important to have buy-in and involvement from the NOK from the very first stage of this process. After the participant’s death, the legal NOK can withdraw from the program at any time; the tissue as well as all related data will then be destroyed.

Patients may feel pressure to join the program to please their doctor or fear that they may not receive the same level of care if they refuse to participate. It is very important for participants to understand that their participation is optional and does not in any way reduce their ability to have access to any existing medical attention they are receiving. Furthermore, they may continue to participate in the main part of the study even if they refuse to join the brain donation and autopsy portion.

*Confidentiality and Security.* Participants will be assigned a unique study number that will not include any personal information that could directly identify them. No personally identifying information will be allowed to leave the study site. All source data will be safeguarded in locked areas and entered into secure web-based systems on password-protected computers. Data submitted to the database will be de-identified and coded, meaning it will not include any information that might directly identify participants. The LORIS system is a controlled-access database that meets international security and safety standards. Stringent security measures will be in place to prevent unauthorized access or misuse of the stored data. This information will be available to patients in the informed consent form and explained verbally during the consenting process.

*Time of Death Procedures.* Once patients enrol in the program a few things need to happen for the brain donation and autopsy to take place successfully. At the time of death, the family or caretakers need to immediately call the UBCH CARD. Although seemingly simple, this step can be extremely difficult for families who are grieving or in the middle of organizing funeral arrangement. This is why the study staff will be in charge of the logistics and it is important to communicate the availability of this service to participants. Furthermore, participation in this program should not place any financial burden on the family as there is no extra cost to the participant and their family associated with any aspect of the program. Study staff arrange for transport from the place of death to the hospital morgue where tissue removal is carried out. If the hospital morgue is closed, then every effort will be made to perform the autopsy promptly when the morgue reopens on the next business day. Once the brain removal is complete, the funeral home will arrange for the transport of the body from the hospital morgue to their facilities. That being said, this process depends on that initial phone call to the clinic. If there are any issues in the logistics discussed, there can be a delay that may lead to ineligibility that is often quite distressing to the deceased family members who want to proceed with the donation. This is why it is important to identify the NOK, who will be the main line of communication, early to ensure smooth coordination with the study staff.

*Culture and Funeral Arrangements.* The influence of religious or cultural factors can play an important role in end-of-life arrangements. For this reason, it is important to allow for a safe environment in which the patient feels comfortable sharing attitudes toward brain donation. In fact, patients and their NOK must be encouraged to consult with religious leaders in the community regarding this important decision.

*Respectful Handing of Tissue.* Should participants and their NOK have questions or concerns regarding tissue handling, more information can be shared with them both verbally and in written form. If a participant has consented to join the Brain Donation and Autopsy program, any unused remaining samples in storage will be retained for as long as the samples are deemed of scientific value. In the event that the majority of biological samples have been used and the remainder would no longer be of scientific value, any remaining tissue would be destroyed according to local, approved respectful bio sample destruction policies. The DBCBB is committed to retaining all data and samples strictly confidential in accordance with provincial laws and regulations.

**Arouse and Fulfill**

This pamphlet is a great tool with which individuals can feel motivated and educated. Given the emotional and personal nature of this topic, it is natural for people to have strong feelings when engaging with the information provided. This is why the benefits of the program as well as relevant stories can be a great way to capture the audience’s attention.

*The Hero’s Journey.* In an effort to utilize the power of narratives, a short story based on the experiences of previous participants and their family will be outlined. The story will appeal to this audience as they will either relate to the participant or NOK in the narrative. The story is intended to use emotion and empathy to help put the information into perspective for the audience. After consulting with anecdotal notes on patient files, this story has been drafted to be included in the communication plan:

*Sarah Thompson. In 2013, after being diagnosed with Frontal Temporal Dementia, my husband, Kevin, enrolled in the Brain Donation and Autopsy program. He wanted to leave behind a part of himself in a way that could benefit society. This proved to be very important to our family as well because when Kevin passed away, his doctor was able to review his autopsy report with us and provide a definitive diagnosis that gave our family closure and a sense of calm.*

**Pretest**

To make some of the decisions regarding content and sensitive aspects of the pamphlet, a pretest will take place to test different version of the pamphlet on a subset of patients and their NOK. A good candidate would be clinic patients who are not in the COMPASS-ND study and who have indicated on their file that they feel comfortable being approached in the future regarding research. This information can be found on the clinic Electronic Medical Records (EMR). There are several reasons this approach has been chosen. Targeting non-study patients, ensures that they have not yet heard about Brain Donation and Autopsy which allows for first impressions to be analyzed. Individuals who have already signed up to be a part of the study will be able to provide feedback as well but this feedback would not be representative of our target audience as they will have already learned at least some information about the Brain Donation and Autopsy program when they first signed up for the main COMPASS-ND study.

The pretest will take place in-person by the main coordinator of the Brain Donation and Autopsy program. The EMR can generate a list of clinic patients who have indicated interest in being approached for research as well as the date of their next visit to the clinic. The coordinator will approach these individuals after their clinic visit and ask them if they have a few moments to discuss a new initiative. If the patient agrees, they will be led into a private room where they will view the pamphlets and be asked to provide their overall impression of various version of the pamphlet that include or exclude specific content outlined in the table below which require audience testing to gauge appropriateness and effectiveness.

|  |  |  |
| --- | --- | --- |
| **Potential Content to Include** | **Pros** | **Cons** |
| No visible scarring post brain removal | * Families who would like to have open casket funerals can be reassured | * It might be off-putting to read this when first learning about the program |
| Pamphlet to be given via doctor vs. placed on the reception desk | * Doctors are trusted and an existing relationship with patients and their family can be leveraged * Doctors can refer patients to a study coordinator who can provide more detailed information | * Doctors are busy and may not have the time to remember to distribute the pamphlets * Patients may feel pressure to say yes to something provided to them via their doctor |
| Include three ‘hero’s journey’ stories; first one about a spouse, second a child, third a friend vs. only sharing one story | * Given the fact that the NOK can be a spouse, friend, or offspring, it is plausible to presume that reading a story with characters in similar roles will elicit a stronger emotional reaction | * Having too many stories might lose the effect of just the one * Might make those without family feel left out * Might make pamphlet too long |
| Confidentiality information i.e. the fact that data will be de-identified and coded, meaning it will not include any information that might directly identify participants or that all brain bank employees sign a confidentiality agreement | * Patients and families will feel reassured that their confidentiality is respected * Increased sense of professionalism and trust regarding the study and staff | * Too much information may overwhelm the reader * It might be irrelevant and of no importance to the patients and families |

Following these pre-test meetings, the feedback given will be analysed and discussed by the study staff and incorporated in the final version of pamphlet.

**The Medium**

The optimal way for patients and their NOK to learn about the program is through a medium that is reliable, concise, and easy to understand. This can be fulfilled by a pamphlet that can be provided in strategically placed locations in the clinic. This is because we do not want to expose individuals for whom this information may be distressing and/or inapplicable. Each aspect of the pamphlet will consider the emotional wellbeing of the target audience. The aim is for the pamphlet to provide information in an appropriate, sensitive, and accurate way.

*The Aesthetic and Content.* The colours and design of the pamphlet will be simple yet professional. This is to ensure the topic is not trivialized but to also have a tone that is calm and hopeful. Colours will be chosen in a way that complement the already existing colours of the clinic which include blue and white. The reason for this choice is that the clinic as well as UBC are reputable and trusted by the target audience; building on this trust can benefit both the audience as well as the program. The photo on the main page of the pamphlet is to represent the intergenerational nature of this topic. Different photos will be presented during the pre-test phase and the one with the best feedback will get used in the final version. Grade 8 level language will be used, and medical terminology jargon will be avoided to the extent possible. The slogans located on the page also aim to foster hope and awareness that donation is an act of service to society.

**Key Content to Include in the Pamphlet**

*See Figure 3a and 3b in the appendix for an example of what the pamphlet might look like.*

1. Gift to Future Generations - motivational material via words and photos to capture the reader’s attention and emotions
   * It is one of the most important and generous gifts a patient with Alzheimer’s disease and his or her family can make
   * An opportunity for patients and loved ones to provide a gift of hope to future generations in the fight against Alzheimer’s disease
2. Benefits of Brain Donation and why it is important

* The only way to reach a definite diagnosis
* Provides more insight and closure to loved ones.
* Provides valuable information that can be used in developing better treatments for future patients.

1. Making Arrangements - time of death procedures

* No cost to the patient or their loved ones
* At time of death, no matter the time of day, NOK should immediately call one of the following numbers:
  + Weekdays between 08:00 and 16:00 hours: 604-822-7031; Evenings (after 16:00 hours, and before 08:00 hours), weekends, and holidays: 604-822-7121

1. Who We Are - sponsors and organizations

* The UBCH CARD logo and COMPASS-ND logo
* Association with UBC utilizes the university reputation as well as reminds the reader that research is of utmost importance
* Association with COMPASS-ND highlights the national aspect of the program and the fact that it is supported by a team of researchers across the country

**Evaluation Plan**

This communication plan aims to increase awareness of the Brain Donation and Autopsy program among patients and their families leading to an eventual increase in successful enrolment in the program. The main goal of the evaluation plan for this project is to examine the effects of the communication plan on enrolment rates and whether it displays at least a 50% increase. To assess these goals, it is necessary to access the LORIS database as well as patient files. The patient encounter notes will provide the number of patients who received a pamphlet which can let the team know if the goal, of at least 90% of patients receiving this information, has been reached. The LORIS database can provide enrolment numbers which can then be compared to those before the launch of the communication plan.

*Midpoint Review.* Six months after the launch of the communication campaign, a review will take place to evaluate the strengths and gaps in the implementation thus far. This will also provide an opportunity to evaluate the extent to which barriers have been overcome and if there are any new previously unforeseen areas of concern.

*One Year Review.* At the one-year point, a formal in-depth review of enrolment numbers will take place. The LORIS data base and EMR data will get used to evaluate the program both from an enrolment as well as awareness perspective. The data will get compared before and after the implementation of the communication plan.

Enrolment data from LORIS will be combined with EMR statistics over the one-year period and self- report of doctor and coordinator experiences will be gathered via focus group discussions. Focus will be on quantitative and qualitative reports of time saved/lost, especially for the doctors but for other stakeholders as well such as the coordinators who may have been approached about the study.

The qualitative feedback of impact on work- flows and areas of lost or gained efficiencies will be used to adjust the way in which pamphlets will be distributed to the patients and their NOK. The findings of this one-year review will inform the scaleup of this communication plan to other sites. It is important to make sure changes are not due to outside factors; since there are no other efforts currently in place to increase enrollment, any change in rates can be viewed as a step in the right direction.

Feedback on patient experience will be obtained primarily through post-intervention patient focus groups. Patients who have signed the consent form as a result of learning about the program via the pamphlets and indicating an interest in being approached for future research will be contacted and asked to provide their feedback either in-person or over the phone. Although an in-person discussion would be more thorough, given the focus group process, the option of doing this over the phone will respect the patients time as well knowledge of the fact that the UBC is located at a distance from many participants and the commute would place burden on them and their family.

**Implementation Strategy**

*The Team.* There are two primary Investigators at the UBC CARD site. This is Dr. G.Y. Robin Hsiung and Dr. Ian Mackenzie.

Dr. Hsiung is the team leader who ensures optimal use of the data collected for academic research. He is also one of five neurologists who see patients at the UBC CARD. He will be responsible for ensuring all neurologists, who have patients eligible to participate in the Brain Donation and Autopsy program, agree to distribute the pamphlets to their patients. They should also be able to provide brief follow-up information if the patient has questions regarding the program.

Dr. Ian Mackenzie at UBC is the lead neuropathologist of the Brain Donation and Autopsy program and will oversee all aspects of study operations pertaining to brain donation and autopsy. He is also the Neuropathologist at the core site in BC which means that all donated brain tissue in BC will get sent to him for processing and then eventual shipment to the Montreal DBCBB.

The proper functioning of the DBCBB organization is under the direction of Dr. Naguib Mechawar. A good relationship with him is vital in ensuring the final step in the process i.e. the banking of brain tissue for future use. He has many legal and administrative duties such as ensuring Material Transfer Agreements (MTA)s are in place to guarantee legal and safe transfer of brain tissue from the various provinces to Quebec.

*The Delivery of the Pamphlet.* Although the clinic doctors have a great relationship with patients and their family, they are on a very tight schedule and are running behind on certain days. They have been supportive of the Brain Donation and Autopsy program as they recognize the benefits the research has on the medical field, patients, and families. That being said, asking them to carve out time to help with the recruitment process can be difficult.

To facilitate a productive partnership with the clinic doctors, a meeting (with lunch provided) will be organized to introduce the pamphlet to the doctors and brainstorm a few short sentences that can be offered to the patients as the pamphlets are distributed. For instance, the doctor can simply let the patient know that there are some additional programs offered at the clinic such as the Brain Donation and Autopsy program. If this is something of interest to the patient, the doctor can then simply provide them with a pamphlet and inform them that a study coordinator is readily avail­able to discuss the program with them and their loved ones should they choose to learn more.

*The Budget.* The main cost for this implementation plan is the material used to create the pamphlets. There is a budget in the project grant dedicated towards recruitment that has not yet been used. The cost of an 8.5" x 11" Tri-fold Brochure is approximately $22.50 per 25 brochures. A research and university discount will be used to try and reduce this cost.

**APPENDIX**

**References:**

1. Neurotoxicology, ISSN: 1872-9711, Vol: 61, Page: 2-10
2. The American journal of geriatric psychiatry: official journal of the American Association for Geriatric Psychiatry, ISSN: 1545-7214, Vol: 21, Issue: 1, Page: 5-13

**Figures and Images:**

**Figure 1.**

**A picture containing text, map

Description automatically generated**

**Figure 2**



**Figure 3.a**

**![A screenshot of a social media post

Description automatically generated]()**

**Figure 3.b**

**![A screenshot of a cell phone

Description automatically generated]()**