

**THE DEVELOPMENT OF A PLAN FOR A COMPREHENSIVE REVIEW OF
THE VACCINE STORAGE AND HANDLING PRACTICES IN THE GENERAL
PRACTICE SETTING**

by

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Abstract

Background: To protect their immunogenicity, vaccines need to be maintained within the stable conditions of a cold chain, as per published vaccine storage and handling recommendations. In Newfoundland, Public Health Nurses are well monitored in their cold chain activities, however no methods are currently in place to assess these activities in general practice.

Methods: 1) A literature review was conducted to identify potential concerns and interventions related to the cold chain in general practice; 2) information was obtained from Peel Public Health about their mandated cold chain monitoring procedures; 3) key local staff were consulted to gain feedback and input into the development of processes; 4) a proposal for a comprehensive review of the vaccine storage and handling practices in the general practice setting was developed; and 5) the proposed methods were pilot-tested to assess for usability.

Results: The findings from the literature review and consultations guided the development of the proposed review, which involves interviewing clinic staff, observing storage conditions, and providing feedback. The pilot test was successful in identifying some cold chain maintenance concerns in a small sample of general practice clinics and confirmed the feasibility and usability of the proposed methods.

Conclusion: The proposed review is ready for implementation as planned for the summer of 2015. If successful, it should aid in identifying specific concerns and guide the development of targeted resources.

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Background

Vaccines are sensitive biological products that are vulnerable to a variety of environmental conditions, including exposure to extreme temperatures and light.

Vaccines need to be maintained within a cold chain in order to ensure the maintenance of vaccine integrity. The term cold chain refers to the maintenance of optimal conditions through a series of links in a chain that begins with the manufacture of vaccines, and continues through the distribution, storage, and finally administration of the vaccine to an individual. Exposure to temperatures outside of the recommended range, typically 2°C-8°C, can cause permanent damage to the immunogenicity of the vaccine product. Three studies conducted lab experiments to assess the potency of various vaccines after exposure to freezing temperatures (Adu, Adedeji, Esan, & Oducanya, 1996; Boros, Hanlon, Gold, & Robertson, 2001; Chen et al., 2009). The results of each of these studies indicated a statistically significant drop in potency after exposure to freezing conditions in many of the tested vaccines. Where non-statistically significant results were noted, the titers still trended towards a decrease in potency. Exposure to conditions above the recommended temperature range does not appear to be as detrimental to vaccine potency as exposure to freezing temperatures; however heat exposure can still result in damage to the vaccine (Arya & Agarwal, 2004).

Maintaining the quality of vaccines is crucial in ensuring that they offer adequate protection. The Public Health Agency of Canada (PHAC) (2007) have published national guidelines that are intended to guide health care workers within Canada to adequately maintain the cold chain. These guidelines provide recommendations in the use of proper

equipment, well-trained and educated personnel, and the maintenance of formal monitoring procedures.

In Newfoundland, the delivery of the publically funded vaccine program is a shared responsibility between Public Health Nurses (PHNs) and General Practitioners (GPs). The vaccine storage and handling practices of PHNs are well monitored within the regional health authorities, and are guided by specific policies and procedures. There are currently no methods in place to evaluate the cold chain practices in the general practice setting. There is some anecdotal evidence that suggests some concerns exist regarding the vaccine storage and handling practices within the general practice setting; however there is no concrete data available to support this. The rotating power outages that occurred in January of 2014 resulted in significant cold chain failures and large amounts of vaccine loss in the general practice population. This highlighted the need for some increased attention to cold chain practices.

The following report will include an overview of the practicum objectives as well as the methods used to achieve these objectives. Summaries will also be included of the completed literature review and consultations; the developed proposal for a review of the vaccine storage and handling practices in general practice; and the findings from a small pilot test . A discussion of the various competencies of Advanced Nursing Practice (Canadian Nurses Association [CNA], 2008) that were demonstrated throughout the practicum project will follow these sections.

Objectives

The original objectives of the practicum project were:

- 1) Gather information to identify possible areas of concern related to cold chain practices in the general practice setting.
- 2) Identify potential solutions for issues in cold chain management.
- 3) Develop a comprehensive system to monitor the cold chain practices of general practitioners.
- 4) Identify potential resources to educate and support best practices in regards to cold chain maintenance.
- 5) Demonstrate the competencies of Advanced Nursing Practice.

These objectives were formed after an informal assessment of the needs identified within the Communicable Disease Control (CDC) department with Eastern Health. Objectives three and four did change part way through the practicum project based on findings from the consultations. Rather than developing a monitoring program and identifying resources, the revised objective was to develop an assessment protocol that would allow for the collection of valuable data related to the cold chain management practices within the general practice setting.

Methods

An integrated literature review was completed and a copy can be found in Appendix A. Consultations were undertaken with a key informant from the Peel Public Health Vaccine Management team and with several colleagues working within the Communicable Disease Control department at Eastern Health. A copy of the consultation report can be found in Appendix B. The Health Research Ethics Authority (HREA)

screening tool was completed and is included as a part of the consultation report. The interpretation of this tool indicated that review by an ethics board was unnecessary prior to completion of the consultations. The consultations were not completed for purposes of research; rather, the purpose was for quality and evaluation, and the gathering of information specific to a particular program and a local population. A proposal for a review of the cold chain management practices in the general practice setting was developed based on the findings from the literature review and the consultations, and a copy of this can be found in Appendix C. The methods proposed in the review of practice were piloted to assess for any issues of feasibility and a full report of this pilot is included in Appendix D. Summaries of these reports are provided in the next few sections.

Summary of Literature Review

An integrated literature review of pertinent research was completed. The CINAHL and PubMed databases were searched using terms including: cold chain; cold chain maintenance; vaccine freezing; vaccine heating; cold chain break solutions; and vaccine audit. A search of the Google search engine was also completed to access any relevant grey literature. Inclusion criteria were: English articles; full text availability; and from a community setting. All abstracts were scanned. If they appeared relevant, and met the inclusion criteria, then the full texts were retrieved. Some older data was referenced from the 1990s and early 2000s. In many cases these articles were considered to be still valid because newer studies had found similar results; in other cases it is because this was the most current data available on the situation.

Concerns in temperature maintenance

Much of the research noted difficulties in maintaining the optimal storage

temperature range of 2°C-8°C. The strongest predictor for whether or not an appropriate temperature range was maintained was the type of refrigerator being used (Carr, Byles, & Durrheim, 2010; Gopal-Krishnan et al., 2014; Yuan, Damiels, Naus, & Brcic, 1995). A bar-style refrigerator is not recommended for vaccine storage; however it is the most popular choice in many general practice clinics due to the compact size and low price point. The concern is that this style of refrigerator typically experiences highly fluctuating temperatures. One study that monitored temperatures in 256 bar-style fridges over a 72-hour period found that only 58% of these refrigerators were adequately maintaining the accepted temperature range (Carr et al.). Domestic frost-free refrigerators are occasionally found in general practice clinics (Carr et al.). These fridges are considered acceptable as they are capable of maintaining consistent temperatures (PHAC, 2007). Drawers need to be removed from these fridges and water bottles should be stored on the door shelves and in any empty spaces inside. Vaccine should not be stored near vents, on the bottom, or on the door, as these areas are prone to highly fluctuating temperatures. The purpose-built vaccine fridge is the gold standard in vaccine storage due to minimal temperature fluctuation. These models are typically significantly more expensive than any other refrigerator type, and are rarely found in the general practice area (Lewis, Reimer, & Dixon, 2001; Page, Earnest, Birden, Deaker, & Clark, 2008; Turner, Laws, & Roberts, 2011).

Concerns in temperature monitoring

Many researchers found that regular monitoring of vaccine refrigerator temperatures was inadequate or non-existent (Haworth, Booy, Stirzaker, Wilkes, & Battersby, 1993; Weltermann, Markic, Thielamm, Gesentives, Hermann, 2014). Thermometer use in

general was noted to be limited. Two studies found similar results in that only approximately 50% of refrigerators had any type of thermometer installed (Lewis et al., 2001; Weltermann et al.). The majority of clinics that did have a thermometer installed in their fridge did not use the recommended min/max type (Haworth et al.; Weltermann et al.). Taking daily readings was the rarest behavior. The results of one study noted that only 14% of clinics were meeting this recommendation (Haworth et al.).

Concerns in storage and handling

Several authors described concerns related to how vaccine products were being stored in general practice vaccine fridges, and how it was being handled once removed from storage. Vaccine products were often noted to be poorly organized (Carr et al., 2010; Gopal-Krishnan et al., 2014; Yuan et al., 1995). Like-product was not always stored together and expired items were noted in some fridges, increasing the likelihood that an individual would receive an incorrect or expired product (Carr et al.; Yuan et al.). A Toronto study of 135 general practice clinics found that 89% of the clinics were storing vaccine along side extraneous items including food, beverages, specimens, and other drugs (Yuan et al, 1995). This is a concern because some of these products can destabilize the internal temperature of the fridge, and it also typically results in the refrigerator door being opened more frequently, exposing the contents to warmer temperatures. The fridge door was also noted to be a common vaccine storage area. A cross-sectional study found that a range of 44% to 63% of general practice clinics had vaccines stored on the refrigerator door (Yuan et al.). This study also found that in multiple general practice sites vaccine products were left at room temperature for up to eight hours at a time. As well, in many cases, vaccine was being transported away from

these facilities in paper bags, rather than in insulated containers as per the recommendations (Yuan et al.).

Miscellaneous concerns

Assigning a single individual to vaccine-related responsibilities is an important guideline (PHAC, 2007). The majority of studies found that only 50% of general practice clinics actually met this recommendation (Haworth et al., 1993; Lewis et al., 2001). One Canadian study noted that 90% of clinics reported assigning a single individual (Yuan et al., 1995); however this individual was often a clinic secretary, or other clinic staff member with limited medical knowledge. The limited availability of an emergency power source or another contingency plan to protect vaccine products in the event of power loss or inclement weather was another identified concern (Haworth et al., 1993). As well, very few practices reported having a hard copy of the vaccine storage and handling guidelines on hand (Yuan et al.).

Several authors found that poor knowledge of cold chain management procedures likely contributed to low compliance with storage and handling recommendations (Page et al., 2008; Yuan et al., 1995). One study in particular found that for every unit increase in knowledge score, the odds ratio associated with maintaining optimal storage conditions increased by 1.69 (95%CI: 1.15-2.49) (Page et al.).

The impact of general practitioners' attitudes regarding the importance of the cold chain on actual compliance with the recommendations was examined in one study (Azira, Norhayati, & Norwati, 2013). The findings from this research noted that while 78% of participating physicians scored well on knowledge related questions related to the recommendations, they performed poorly in actual compliance. Only 20% of participants

actually felt it was important to follow the recommendations and maintain acceptable storage conditions. The authors concluded that a good attitude and a commitment to quality were very important in ensuring the maintenance of the cold chain.

Local research

Almost 15 years ago, O’Keefe (2000), a Master of Science student at Memorial University, completed a thesis study within this population of interest. The study targeted family physicians within the jurisdiction of St. John’s Health and Community Services on the Avalon Peninsula of Newfoundland. This thesis research investigated some of the vaccine storage and handling procedures as well as the vaccine related knowledge of these general practitioners (O’Keefe). The results indicated that no practice was meeting all aspects of the expected national guidelines; very few practices used proper storage equipment; and the vast majority used no temperature-monitoring device (O’Keefe). A discussion was held with each physician where guidelines were imparted and a second, unannounced clinic visit was held to assess any changes in behavior (O’Keefe). Several practices had invested in a proper thermometer but very few other factors had changed (O’Keefe). This study is the most recent research available on this particular population.

Potential solutions

Multiple solutions to deal with the concerns surrounding vaccine storage and handling practices can be noted in the literature. Several authors make recommendations for the provision of resources to upgrade existing equipment (Carr et al., 2010; Page et al., 2008; Turner et al., 2011). Even with perfect compliance with all of the cold chain recommendations, an inadequate storage device can limit the maintenance of optimal storage conditions. Turner et al. described the impact of multiple national policy changes

that occurred over a six-year period in New Zealand. One of the changes involved supplying all vaccinators with a purpose-built refrigerator. Statistically significant decreases in vaccine wastage were noted at study completion. Due to the study methods, it was impossible for the authors to pinpoint exactly what changes were most effective in reducing wastage; however shortly after the purpose-built refrigerator intervention, the largest decrease in vaccine wastage occurred.

A number of authors made recommendations for providing staff training and education, and completing routine audits of compliance (Gopal-Krishnan et al., 2014; Lewis et al., 2001; Turner et al., 2011). The methods from two separate studies involved the implementation of education and training initiatives, in addition to the completion of regular fridge inspections, in order to assess the impact on vaccine storage and handling practices in the general practice area (Gopal-Krishnan et al.; Lewis et al.). In both studies, statistically significant increases in the compliance with recommendations were noted from baseline measurement to study completion.

Several Canadian provinces have already made a commitment to improving vaccine storage and handling practices. British Columbia provides regular training to vaccine professionals via multiple informative videos that are easily accessible via the Internet, in order to promote acceptable vaccine management (ImmunizeBC, 2012). The Alberta Health region in the province of Alberta incurred a large vaccine loss at their local vaccine depot due to a serious break in the cold chain (Henneigh, 2014). Alberta Health staff responded to this wastage by improving their vaccine monitoring procedures. Some of these procedures included: the use regular data logging of temperatures; staff training sessions; banning the use of bar style fridges; and implementing an annual audit

of all vaccine fridges utilized by their Public Health department. This intervention led to a long-term solution that improved the overall maintenance of the cold chain within this region (Henneigh). These procedures are very similar to those currently utilized by the Public Health Nurses in Newfoundland to monitor the vaccine cold chain.

The Ministry of Health in Ontario has mandated a process that requires each Public Health Authority to complete an annual inspection of the storage and handling practices in all general practice clinics across the province of Ontario. These inspections are guided using a standardized, province-wide electronic checklist (Ontario, 2013). Peel Public Health (2014) uses this checklist to complete these regular audits, and in addition have created a comprehensive education and monitoring program that provides detailed information on vaccine management expectations, and ensures compliance with the expected guidelines outside of the yearly audit process. Ontario is the only province in Canada with a mandated inspection program. The comprehensive program offered through Peel Public Health was identified as likely being an excellent source of information for program development within the province of Newfoundland. They were consulted to gather more detailed information on their vaccine storage and handling education and monitoring procedures.

Summary of Consultations with Peel Public Health Key Informant

The contact information for the Vaccine Management Team was obtained from the Peel Public Health website. An individual who identified herself as a Public Health Nurse working with direct involvement with the vaccine storage and handling audit process provided verbal agreement to participate in a short interview. The interview questions were administered via a telephone conversation. Email addresses were

exchanged and electronic resources were received in this manner. Some follow up questions were administered via email. Notes were taken throughout the interview processes and organized narratively.

Findings

Peel Public Health employs four full time Public Health Nurses that are responsible for completing annual audits of vaccine storage and handling practices in approximately 600 clinics. These nurses are also responsible for providing education sessions on proper cold chain management practices as necessary. Each audit is guided by a standardized checklist, as per the mandate of the Ministry of Health and Long Term Care in the province of Ontario. Based on the results of the audit, clinics are assigned a score of pass, fail, or conditional. When clinics receive a fail or conditional result, their vaccine may be removed from the facility and future vaccine orders will be placed on hold. These clinics are then required to submit a temperature log containing at least 72-hours of appropriate refrigerator temperatures before the hold is lifted from vaccine orders. They may also be required to participate in education sessions and undergo another inspection.

In addition to these annual audits, Peel Public Health also has methods in place to ensure continuous monitoring of cold chain management. Each immunization clinic is required to regularly monitor and log temperatures electronically. A copy of this temperature log is required to be submitted with each monthly vaccine order. Each log is reviewed and if inappropriate temperatures are noted, then a hold is placed on the order until any issues are addressed and resolved. Clinics are also required to submit occurrence reports when any cold chain failure occurs. Each month, the clinics with the

most failure reports must undergo additional inspections and participate in mandatory education sessions.

There have been no formal evaluations completed thus far on the audit and education programs offered by Peel Public Health; therefore it is impossible to make conclusions related to any strengths and weaknesses. However, the Vaccine Management Team does track all cold chain failures on a spreadsheet. This spreadsheet revealed that regular cold chain failures do continue to occur, however human error is rarely the cause. Equipment failure, primarily related to the use of bar-style fridges and malfunctioning thermometers, is the most common source of cold chain concerns.

Summary of Consultations with Communicable Disease Control Colleagues

Interviews were completed with four Communicable Disease Control (CDC) staff members with knowledge of vaccination practices in the general practice setting. Verbal agreement to participate in a short interview was obtained from each individual. Notes were taken during each interview and were analyzed for content.

Findings

Several common concerns were noted through the analysis of interview data. Several CDC staff members completed follow-up with general practice clinics after the period of rolling blackouts that occurred in January 2014. This follow-up was completed to assess if power was lost at various clinics, how long power was lost, and whether or not the vaccine products stored within each clinic were exposed to temperatures outside of the recommended range. The CDC staff noted a significant concern that there was limited, and sometimes non-existent temperature monitoring; most clinics were not able

to provide details about whether or not their inventory was exposed to a cold chain failure.

The use of bar-style fridges, and the storage of vaccine products along side extraneous items, was also considered to be a concern. Due to the small size of many clinics, they often lack the storage capacity to house large refrigerators; as well, purpose built refrigerators are often expensive to purchase. Therefore, the majority of fridges found in local general practice clinics are expected to be bar-style. As well, due to the lack of space in these clinics, it was felt that it would be unlikely that a clinic would have multiple refrigerators, therefore vaccine products could also be stored alongside specimens, food, and beverage products, potentially destabilizing the storage temperature.

Several participants expressed concerns related to difficulties in engaging general practice staff to participate in vaccine management activities. Some voluntary vaccine inventory programs have been introduced to this population in the past, and there has been minimal, if any, participation.

The information collected from the Peel Public Health key informant was shared with CDC staff. The programs provided through Peel Public Health were seen as an ideal long-term goal. At this time, there is no concrete data available to support a need for comprehensive education and regular audits of compliance in the general practice population. Therefore it would be impossible to implement such an extensive program. Of greater importance at this time is a method for collecting quality data related to the cold chain management practices in general practice. The tool used for the completion of audits in Ontario received positive feedback due to the ability to be used for both the

collection of data, and the provision of immediate feedback that could be used to help correct significant errors in cold chain management.

Summary of Proposed Practice Review

A proposal was developed describing a review of practices that would allow for an opportunity to collect valuable data related to the vaccine storage and handling practices in the general practice setting. This practice review was proposed based on the results of the consultations with CDC staff that revealed the great need for data on these practices. The objectives for this practice review are:

- 1) Identify specific areas of concern.
- 2) Provide immediate feedback on any areas of concern.
- 3) Identify potential resources to aid the general practice vaccinators in achieving best practice.
- 4) Gather input from physicians on appropriate resources and acceptable interventions.

This practice review is set to be completed over the spring and summer of 2015 and will target physicians and other staff with vaccine related responsibilities working within the general practice clinics in the Eastern Health region. To recruit clinics, Eastern Health CDC staff will mail a cover letter and information sheet to each general practice clinic in the Eastern Health region. Each clinic will then be contacted via telephone to request permission to visit, and an appointment time will be arranged if agreeable. All data collection will be completed through a single clinic visit.

Each clinic visit will involve a confirmation of agreement to participate; a structured interview with one physician employed in the clinic; an inspection of the cold chain management practices, guided by a checklist; and a review of the overall results

with the provision of applicable feedback. The structured interview has been designed to gather input from physicians related to their specific concerns regarding maintaining the cold chain in general practice, as well as the types of resources and interventions that they would accept from outside sources. The checklist tool was designed based on the national recommendations published by PHAC (2007), and the tool used to complete storage and handling audits across Ontario. It allows for both the collection of data pertaining to which cold chain maintenance guidelines are and are not being met, and the provision of important feedback and education. Once the inspection process is complete, the checklist is reviewed with a staff member, and a copy is provided for their records and future reference.

Any data collected via the interviews with physicians will be typed and analyzed for content; any data collected from the checklist will be entered into an Excel database and analyzed with descriptive statistics. Results will be used to create a picture of the overall state of the vaccine storage and handling practices in the general practice population of interest, and to inform the development of future resources to aid in appropriate cold chain management practices.

The Health Research Ethics Authority (HREA) Screening Tool has been completed for this project and it indicates that review by an ethics board should not be necessary prior to implementation. The overall goal of this practice review is related to quality and evaluation, rather than research. A copy of the HREA tool is included as a part of the proposal found in Appendix C. The privacy and confidentiality of each participating clinic will be protected throughout the process. Codes will be used as identifiers on each checklist form to protect participants' identities. The review is being

completed in partnership with Eastern Health's CDC division and therefore individual level results will be made available to officials working within this department; only reviewers and CDC authorities will have access to the code identifiers. The sharing of any data beyond the CDC authorities will be at the aggregate level only to protect the privacy of each participant.

There may not be any immediate benefits for participating in this project; however, individual feedback will be provided to each participant that could potentially lead to immediate improvement in practices if participants take action related to the feedback provided. Participants may also benefit in the long term if the information collected leads to the establishment of future resources. The risks associated with participation in this project are primarily to do with the reporting of results to CDC officials. If significant concerns are noted during any clinic visit that could be compromising the vaccine being supplied, the CDC authorities may decide to follow up. However, the purpose of following up would be to work with participants to address issues and find acceptable solutions; punitive action would not be taken.

Pilot of Proposed Methods

A small pilot test was designed and implemented to test the methods proposed for the full review plan, and to identify any issues of feasibility. The methods used in this pilot test were as per the methods described in the previous section, with the addition of follow up questions for participants and self-reflection questions for the reviewer. The questions were designed to gauge whether or not changes needed to be made to the process. Physicians were asked to comment on the overall process, from recruitment to

the completion of feedback, and to provide opinions on the types of questions asked throughout the inspection.

A Public Health colleague conducted one clinic visit, accompanied by the author. Two checklists were completed independently and compared in order to assess for any usability issues for different users. The colleague also used the self-reflection questions to reflect on the methods used.

Findings from interviews

Six general practice clinics were contacted to request participation in the pilot test, and a total of five agreed to participate. All participants were able to provide details of formal cold chain monitoring procedures, however these varied in intensity. All participants reported using a refrigerator, with a thermometer installed inside, to house vaccine. All participating clinics had issues regarding a lack of space for a large refrigerator, and a lack of space inside of their existing refrigerators. Three clinics used bar-style refrigerators and two clinics used under counter purpose built models.

No clinic had a hard copy of the vaccine storage and handling guidelines on site, however all participants were able to identify a reputable source of information. Some physicians identified using the guidelines as published by PHAC (2007), while others noted using the Newfoundland and Labrador Immunization Manual. Each participant voiced that they felt there was low communication between general practice and Eastern Health related to practice changes, new recommendations, and resources. The participants reported that they would appreciate access to some Eastern Health resources that could be used to train their staff and increase their own knowledge on appropriate

vaccine storage recommendations; the commonly requested formats included posters, webinars, and online modules.

The processes used in the province of Ontario for the completion of yearly audits were discussed with each participating physician. All participants gave positive feedback and reported feeling that an inspection process would be a positive experience that would aid in increasing quality and safety. All participants reported they would agree to participate if similar voluntary processes are ever implemented in Newfoundland.

Findings from checklist

All participating clinics used a refrigerator to store vaccines; each refrigerator was in excellent condition and was being used exclusively for vaccine products. All refrigerators were noted to be very cluttered with vaccine product, and there was little space available. In one refrigerator a large amount of vaccine products were being stored on the door; other clinics were utilizing the floor of the refrigerator for storing vaccines. All clinics had a contingency plan in place to protect vaccine in the event of power loss.

All clinics had appropriate fridge temperatures at the time of each inspection, as measured by the reviewer's calibrated thermometer. Only two inspected refrigerators had a min/max thermometer installed. The two clinics that used purpose built models relied on the attached thermometer and alarm for the identification of cold chain failures; however this thermometer had no alarm memory or min/max capabilities and so could not reliably monitor temperatures after-hours. One clinic used a glass basal thermometer, installed on the fridge door, to monitor temperatures. This particular thermometer was also noted to be inaccurate when tested against the calibrated thermometer. Only one of the five participating clinics was actually formally monitoring temperatures twice daily.

Findings from follow up discussions

Each clinic visit ran smoothly and was concluded in an acceptable timeframe. There were no changes suggested to the process. All feedback received from participants was positive. The Public Health colleague had no issues in implementing the methods as proposed and suggested no changes; the completed checklist form matched the responses recorded by the author. The only small change that came about as a result of this pilot test was to change how a copy of the completed checklist form is provided. A copy of this form will now be provided via mail immediately following a clinic visit, rather than during a clinic visit. This change was made early in the process because it was not always possible to use all participants' photocopiers at the time of the visits.

Advanced Nursing Practice Competencies

Advanced Nursing Practice (ANP) is described by the Canadian Nurses Association (CNA) (2008) as "...an advanced level of clinical nursing practice that maximizes the use of graduate educational preparation, in-depth nursing knowledge and expertise in meeting the health needs of individuals, families, groups, communities and populations" (p. 10). The competencies are divided into four categories: clinical, research, leadership, and consultation and collaboration. This practicum project focused primarily on the research competencies, in addition to some aspects of the leadership and consultation and collaboration competencies. It did not focus on the clinical category.

ANP values evidence-based practice and encourages the creation and use of sound nursing research to guide the various aspects of nursing practice (CNA, 2008). While a research project was not completed, research methodologies were utilized throughout this practicum project. Through the completion of an integrated literature review and

consultations with various key informants, data were collected to assess what is currently known regarding the concerns and potential solutions related to the storage and handling of vaccine products in the general practice setting. These data was utilized in the development of a proposal for a review of the cold chain management practices in general practice; this proposed practice review, once implemented, has the potential to aid in the collection of important data. Knowledge of research methodologies was used in the creation of a data collection tool, the conduction of various interviews, and the collection, management, and analysis of data. A small pilot project was developed and implemented which helped to establish the usability of the checklist tool and feasibility of the methods proposed in the practice review. This pilot test also aided in creating a picture of the various cold chain maintenance issues in a small population of general practices.

Nurses in positions of ANP must be leaders in the workplace by working as advocates and acting as agents for change (CNA, 2008). Methods used within the pilot project focused on creating change through the identification of specific concerns related to cold chain management practices in a small number of general practice clinics. Immediate feedback and education were provided in these cases to initiate change within these clinics to better protect the quality of the vaccine products.

The competency of consultation and collaboration involves a nurse's ability to effectively communicate and collaborate on an interdisciplinary level across organizational and geographical boundaries (CNA, 2008). To meet this competency, consultations were undertaken with multiple health care professionals both within the region and outside of the province. As well, the development of this project was achieved through ongoing collaboration with the CDC nurse manager.

Next Steps

The implementation of the proposed practice review is set to begin in the spring of 2015 by a group of Master of Public Health students. These students will receive an education session related to the methods and tools to be used in the review. Data collected via the review process will be analyzed and then compiled into a report by the end of summer 2015; full details regarding the timeline proposed for this practice review are included within the appendix of the proposal. This report will be presented to both the regional and the provincial Communicable Disease Control divisions. The data will be valuable in identifying specific areas of concerns and in the creation of effective interventions to reduce the issues. Evaluation of the success of the practice review will be ongoing throughout the data collection process. It will be determined based on how useful the results are in meeting the overall goals of the review, and based on any feasibility issues that may arise in the processes.

Conclusion

Publically funded vaccination programs are a major Public Health success story; vaccines have saved countless lives since their introduction (PHAC, 2007). Maintaining the immunogenicity of vaccine products is imperative in ensuring their continued success. The thorough review of the literature that was conducted in this practicum project has allowed for the identification of a multitude of concerns that appear to exist regarding improper storage and handling of vaccines in the general practice setting. This same literature review also revealed some potential solutions to combat some of these issues. Staff working in Public Health in the province of Newfoundland are concerned that significant cold chain failures are occurring in the general practice setting related to a lack

of compliance with the set guidelines; however there is currently no evidence to back up these concerns. Through the utilization of the data available in the literature, and consultations with several key informants, a proposal was developed to aid in the collection of important data regarding the cold chain management practices within the general practice population. The proposed methods were implemented in a pilot project, and though the sample size was small, already some issues have been uncovered that are comparable to some of those identified in the literature.

The developed checklist and procedures have been identified as useful in the collection of good data from the population of interest. If implemented as proposed, the review of the vaccine storage and handling practices in the general practice setting has the potential to create an accurate picture of concerns that exist in this specific population. Health care professionals have a responsibility to protect the health of the population; the provision of safe and quality vaccinations is a reliable way to accomplish this. The utilization of any data collected via the proposed review will allow for the creation of targeted and appropriate interventions to combat any identified issues. This can ultimately lead to the improvement of the quality of vaccines offered to the public, and in turn, prevent the reemergence of communicable diseases.

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Appendix A – Literature Review and Summary Tables

Literature Review: The importance of and compliance with cold chain maintenance in the
general practice setting

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Appendix

Vaccination is the most successful and cost effective public health program to date, and has saved countless lives since its introduction by reducing the spread of many serious communicable diseases. Ensuring the quality of vaccine products is important in maintaining this success. Vaccines are sensitive biological products that need to be maintained within a stable temperature range, known as the cold chain, in order to preserve their immunogenicity. The literature reveals that there is some concern related to errors occurring at several links in the cold chain (Matthias, Robertson, Garrison, Newland, & Nelson, 2007). Vaccine manufacturers and distributors have specific protocols and systems in place to ensure the quality control of their vaccines. While comprehensive guidelines exist within Canada to inform vaccine storage and handling by all health care workers, evidence has shown that significant concerns continue to exist regarding the condition of the cold chain in the general practice setting.

For the purposes of this literature review, the focus on the cold chain will be narrowed to examine vaccine storage and handling in general practice. Cold chain will be discussed in relation to its meaning, importance, and how it can be maintained. Specific concerns regarding the storage and handling of vaccine in the general practice area will be described from a global perspective and within Newfoundland. Possible solutions for tackling the problem will also be revealed based on recommendations identified within the literature. Within this paper, vaccine storage deals with the equipment used to hold vaccine, how vaccine is organized within the storage device, and how it is monitored while in the clinic area. Vaccine handling refers to the procedures involved when vaccine is outside of its storage refrigerator: from the receipt of the vaccine until it is stored in the

refrigerator; removal of the vaccine in preparation for administration; and preparing the vaccine in preparation for transport away from the clinic.

Methods

This literature review began with a search of both the CINAHL and PubMed databases. Search terms used included: vaccine storage and handling; general practice; cold chain; cold chain maintenance; vaccine freezing; vaccine heating; cold chain break solutions; and vaccine audit. A search was also completed via the Google search engine in order to identify any pertinent grey literature. Inclusion criteria included English language articles with full text availability. Selected articles were based in a community setting and were primarily from developed countries. Abstracts were scanned and if they appeared pertinent to the topic and met the inclusion criteria, then full texts were retrieved. Critical appraisal of the research was completed and literature summary tables containing detailed information can be found in the Appendix. When a literature summary table can be found for a particular study, the lead authors name will appear in bold print.

What is the Cold Chain?

The term cold chain is used to describe the maintenance of optimal conditions through a series of links that start with the manufacture of vaccines, and continue through the distribution, storage, and finally administration to the individual. Vaccines are sensitive to a variety of environmental conditions, including heat, freezing, and light. The majority of publically funded vaccine products available within Canada are required to be maintained between the temperatures of 2°C and 8°C across the entire cold chain (Public Health Agency of Canada [PHAC], 2007). Vaccines that require storage at freezing

temperatures should be maintained below -15°C (PHAC). The most common temperature related error at each link in the cold chain involves the exposure of vaccine to freezing temperatures (**Boros**, Hanlon, Gold, & Robertson, 2001; **Chen** et al., 2009). A systematic review of the literature found that anywhere from 14-35% of vaccines were exposed to freezing conditions while stored due to unstable temperature control within a refrigerator (Matthias et al., 2007); studies that examined temperatures across all steps of vaccine storage and transport found that a staggering 75-100% of vaccines were exposed to freezing temperatures, either from an unstable refrigerator, or improper packing within an insulated container (Matthias et al.).

Many vaccines will also degrade if exposed to UV radiation and artificial light for a significant period of time (PHAC). Maintaining the cold chain is a critically important component in ensuring the safety and quality of the vaccines provided to the public and national guidelines exist within Canada to guide the practices of health care workers in maintaining optimal conditions.

Importance of the Cold Chain

Maintaining the quality of vaccines is crucial in ensuring they offer adequate protection to the public. If vaccine is administered that has been compromised in some way, it may limit seroconversion, decreasing immunity and increasing the risk to the population of exposure to vaccine preventable disease (PHAC, 2007).

As previously identified, the exposure of vaccines to freezing conditions is the most common temperature error. The freezing of vaccines has the potential to cause permanent damage to the immunogenicity of the vaccine. Three studies conducted lab experiments to assess the potency of various vaccines after exposure to freezing

temperatures (**Adu**, Adedeji, Esan, & Odusanya, 1996; **Boros** et al.; **Chen** et al.). The results indicated a significant drop in potency after exposure to freezing conditions in many of the tested vaccines. Where non-statistically significant results were noted, the titers still trended towards a decrease in vaccine potency (**Adu** et al.; **Boros** et al.). The studies all assessed the immune response in mice due to the similarities in genetic makeup and biological characteristics to humans. Two of the studies were completed in Australia and the USA, which are developed countries with storage standards closely resembling Canadian recommendations (**Boros** et al.; **Chen** et al.). One study was completed in Nigeria; however the authors noted that the study methods were guided by World Health Organization (WHO) standards (**Adu** et al.), which allows for a better generalizability of the results.

Exposure to conditions above the recommended temperature range does not appear to be as detrimental to vaccine potency as exposure to freezing temperatures; however heat exposure can still result in damage to the vaccine. A single exposure to high temperatures is often not associated with a decrease in potency; however it has the potential to shorten the vaccine's shelf life (Arya & Agarwal, 2004). Repeated exposures to high temperatures or a single exposure to extreme high temperatures is often associated with the deactivation of a vaccine (Arya & Agarwal).

How to Maintain the Cold Chain

PHAC (2007) has published national recommendations that are intended to guide health care workers within Canada to adequately maintain the cold chain. The first recommendation involves the necessity of having well-trained personnel with a designated staff member responsible for coordinating the various activities of vaccine

management. The vaccine coordinator would need to ensure all local policies and procedures are up to date with current recommendations; all staff members that have access to vaccine are trained in proper handling protocols; routine, day to day procedures are maintained; and a plan exists to protect vaccine in instances of power failure. This individual worker ultimately is responsible to maintain the cold chain for all vaccine present within the facility.

The national recommendations outlined by PHAC (2007) also contain advice for the use of an established protocol for management of both the daily and urgent vaccine storage and handling needs. The recommendations for routine protocols involve monitoring temperatures twice daily; completing regular vaccine inventory; ensuring proper placement of vaccine within the storage refrigerator; and ensuring proper functioning of the storage unit. Urgent protocols need to be in place in cases of inclement weather, national disasters, or equipment malfunction, where power may be lost impacting the ability to adequately maintain temperatures. PHAC recommends the use of a backup power generator, or if this is not possible, then the creation of a standing agreement with another facility where vaccine can be sent for the maintenance of proper storage conditions. When vaccine needs to be transported off site, or removed from the storage unit for any reason aside from immediate administration, PHAC recommends that it be packed in an insulated container along with ice packs, an insulating barrier, a temperature monitor, and finally a filler to ensure limited shifting of the layers within the package.

PHAC's (2007) national recommendations also contain specifications for proper storage devices. The gold standard in vaccine storage is considered a purpose-built

refrigerator due to its ability to adequately regulate temperatures. A domestic frost-free refrigerator is also considered acceptable as long as modifications are in place to prevent the vaccine from being impacted by temperature fluctuations. In this type of refrigerator, the air around vents is typically at or below 0°C, potentially exposing vaccine to detrimental freezing conditions. Due to this, vaccine must only be stored on the interior shelves, away from the back of the unit. Vaccine also cannot be stored on the door shelves of a refrigerator due to the regular exposure to warm temperatures. Water bottles also need to be used in these units to help stabilize the temperatures. Bottles should be stored along the shelves on the door, in any drawers, and along the walls and floor of a unit. PHAC also notes that the use of water bottles is also very helpful in the event of a power outage, as they will help maintain the temperatures for a significant period of time after power loss. Bar style refrigerators are considered unacceptable due to their inability to maintain temperatures. PHAC notes that the use of bar style refrigerators is considered the leading cause of cold chain break across Canada.

A temperature-monitoring device is a must in order to ensure vaccine is maintained within the recommended range (PHAC, 2007). PHAC makes recommendations for a variety of different monitors and discourages the use of mercury, bi-metal stem, or liquid thermometers. The recommendations include using only devices that are calibrated within $\pm 1^{\circ}\text{C}$; using a continuous monitoring device that regularly records temperatures; or using a well supervised minimum/maximum thermometer. Where large inventories of vaccine are held, the best practice is to use an alarm system that monitors temperatures 24 hours a day and notifies either the vaccine coordinator or a

central depot when temperatures are noted outside of the recommended range. This way, maintenance of the cold chain can be guaranteed during and after hours.

Vaccine Storage and Handling in the General Practice Area

Current evidence shows that compliance with recommended vaccine storage and handling practices is often lacking in the general practice setting (**Carr**, Byles, & Durrheim, 2010; **Lewis**, Reimer, & Dixon, 2001; **Turner**, Laws, & Roberts, 2011; **Weltermann**, Markic, Thielmann, Gesentiues, & Hermann, 2014; **Yuan**, Daniels, Naus, & Brcic, 1995). The most commonly noted areas of concern include the use of improper refrigerators, inadequate temperature monitoring, not having a single individual responsible for maintaining vaccine, poor organization of product inside a refrigerator, including the storage of extraneous products inside the vaccine fridge, and the lack of any written instructions for staff to follow in maintaining the cold chain (**Haworth**, Booy, Stirzaker, Wilkes, & Battersby, 1993; **Lewis** et al.; **Turner** et al.; **Welterman** et al.; **Yuan** et al.). There is also some evidence indicating inadequate knowledge of the recommendations for vaccine storage and handling, and poor attitudes about the importance of maintaining cold chain by general practitioners.

Compliance with Recommendations

Several studies, completed in developed countries, found concerns with the maintenance of an optimal vaccine storage temperature range of 2-8°C in the general practice setting. Results from various cross-sectional studies suggested that 30% to more than 60% of storage units had fluctuating temperatures that exposed vaccine to temperatures outside of the recommended range (**Carr** et al., 2010; **Gopal-Krishnan** et al., 2014; **Page**, Earnest, Birden, Deaker, & Clark, 2008). A predictor of recorded

temperatures outside of 2-8°C was the type of refrigerator used. Bar fridges are a popular choice among many clinics due to their price and compact size (**Carr et al.**, 2010; **Lewis et al.**, 2001; **Page et al.**). However, this style refrigerator is significantly less likely to maintain optimal vaccine storage temperatures (**Carr et al.**; **Page et al.**). A cross-sectional study by **Carr et al.** audited 256 refrigerators used in general practice clinics. Trained investigators installed an electronic data logger in each fridge and temperatures were monitored regularly over a period of 72 hours. The results indicated that only 58% of bar-style refrigerators were maintaining acceptable storage temperatures during the study period. In general, domestic frost-free fridges were deemed capable of maintaining consistent temperatures, however regular maintenance, and some minor alterations were required (**Carr et al.**). Purpose built refrigerators are the gold standard for maintaining appropriate vaccine storage conditions as they have been found to have minimal temperature variation, however these were rarely found in general practice clinics (**Lewis et al.**; **Page et al.**; **Turner et al.**, 2011).

Inadequate or non-existent temperature monitoring was a concern noted in the research (**Haworth et al.**, 1993; **Lewis et al.**, 2001; **Weltermann et al.**, 2014). Multiple cross-sectional studies found minimal use of temperature monitoring where vaccine was stored. In one of these studies, completed almost twenty years ago, the researchers administered a standardized auditing tool to assess the vaccine storage and handling procedures in a random sample of 29 general practice clinics in two health authorities in England (**Haworth et al.**). They noted that the majority of the clinics had a thermometer in place, however very few used a minimum/maximum temperature monitor, and less than 14% of surveyed clinics took a daily reading. Other studies completed in Australia

and Germany found that a minority of general practice clinics monitored vaccine temperatures (**Lewis** et al., 2001; Weltermann et al., 2014). In the study by **Lewis** et al., completed almost ten years after the study by Haworth et al., a trained investigator repeated three standardized surveys over a period of three years in 97 general practice clinics. At baseline, they noted that only 53% of refrigerators had a thermometer installed. The recently published study by Welterman et al. found similar results to the audit, which only 51% of physicians reported monitoring temperatures. Welterman et al. note that there were no published national recommendations available in Germany at the time of their study, which limits the generalizability when comparing these results to countries with written procedures; however, practitioners were still expected to comply with storage recommendations of vaccine manufacturers and WHO guidelines and so the consistency of these recent results with other similar studies completed in the past does warrant attention.

As noted in the discussion of how to maintain cold chain, the way that vaccine is organized within a storage unit can have a significant impact on the maintenance of quality. Several authors, who completed a visual inspection of various general practice vaccine fridges, utilizing similar data collection methods and standardized audit tools in line with WHO and national standards, noted organizational concerns related to how vaccine was stored within the fridge (**Carr** et al., 2010; **Gopal-Krishnan** et al., 2014; **Haworth** et al., 1993; **Lewis** et al., 2001; **Yuan** et al., 1995). **Yuan** et al. completed a cross sectional study of 135 general practice clinics in the Toronto area, and found that 89% of the clinics were storing other medications, clinical specimens, and food and drink within the vaccine refrigerators. **Yuan** et al. also noted that only 27%-56% of practices

were not storing vaccine on the door of the refrigerators. When vaccine is stored on the door of the fridge, it is regularly exposed to suboptimal temperatures each time the door is opened. The study completed by **Haworth** et al. on a random sample of 29 general practice clinics in two health regions within England noted that approximately 75% of clinics were using vaccine fridges to store extraneous items. A baseline inspection completed in an Australian study noted a smaller percentage of practices storing vaccine along with other items than these previously mentioned studies, however approximately one quarter of vaccine were still being stored incorrectly (**Lewis** et al.). While these three pieces of research are older, the issues likely remain valid as more recent research, completed in Australia and Malaysia, has found similar results. **Carr** et al. audited the vaccine storage and handling practices of 256 general practice clinics in Australia using a standardized tool and trained investigators. Whether or not vaccine was stored alongside extraneous items was one of several criteria assessed. While the exact percentage of clinics meeting this specific criterion was not explicitly stated, it was mentioned as an area needing improvement as 24% of clinics were not meeting all audited criteria.

Gopal-Krishnan designed and implemented an intervention aimed at collecting data related to the cold chain practices in general practice clinics and impacting a positive change where necessary. At the baseline measurement of 442 clinics, only 31.8% were meeting the WHO criteria related to the organization of vaccine within a fridge. While these results are more difficult to generalize due to the Malaysian setting, the vaccine storage and handling recommendations were based on WHO guidelines and methods ensured the collection of quality data. The concern with storing extraneous items in a fridge along with vaccine is that these items may alter the temperature of their

surroundings, potentially exposing the vaccine to temperatures outside of the optimal range. As well, storing multiple items in a vaccine refrigerator could mean that the door is regularly being opened, making it difficult to maintain a constant temperature.

Two separate studies completed in England and Australia noted that approximately 50% of clinics had named a single individual responsible for managing vaccine (**Haworth** et al., 1993; **Lewis** et al., 2001). It was also noted that very few clinics had a written copy of storage recommendations available for staff (**Lewis** et al.). A study completed within Canada noted that approximately 90% of physician clinics had a single person responsible for this task (**Yuan** et al., 1995). While not all of these clinics had a physical copy of the recommendations available, they were all able to identify a reputable source of information, such as a public health authority, the Ontario Ministry of Health, and the Canadian Immunization Guide (**Yuan** et al.). However, even with a policy or a source of information on vaccine storage requirements, concerns were still noted in regards to storage practices (**Yuan** et al.). Only one study assessed the availability of a back-up power source to protect the vaccine in the event of a power failure at the clinic (**Haworth** et al.). The authors found that only 65% of clinics in their study had a power source to maintain the quality of their vaccine in an emergency situation. These studies are all examples of older research; however study methods helped ensure the collection of quality data at the time. The current status is unknown as no recent studies have published data related to these variables so there is no way of knowing if the situation has changed without further assessment.

The majority of studies assessed only the storage of vaccine product, and not the handling aspect; however two older studies did look at handling practices. **Haworth** et

al. (1993) assessed whether or not clinics maintained cold chain when transporting their vaccine off site. They noted that 0-25% of the clinics involved within their study actually used an insulated container for vaccine transport. Most clinics sent vaccine without any attempts to maintain a controlled environment (**Haworth** et al.). In the results of the survey completed by **Yuan** et al. (1995) it was noted that several clinics reported leaving vaccine at room temperature for up to eight hours before returning it to the storage refrigerator. A more recent systematic literature review completed by Matthias et al. (2007) analyzed a total of 35 articles in order to review global data of the exposure of vaccine products to freezing temperatures. Six studies covered the handling of vaccines via transportation and noted that 75-100% of products were not maintained at the appropriate temperatures. The results of this review suggest that concerns may still exist related to the handling of vaccines.

Knowledge and Attitudes

Several authors identified issues in the level of knowledge of vaccinating primary care practitioners regarding cold chain. **Yuan** et al. (1995) found that only 6% of surveyed physician practices were able to correctly answer all the survey questions related to vaccine storage and handling. They concluded that the poor knowledge likely contributed to low compliance with the recommendations. **Page** et al. (2008) reaffirmed this conclusion when they assessed general practitioner knowledge of storage and handling recommendations using a standardized set of ten questions; they noted that for every unit increase in knowledge score, the odds ratio associated with maintaining optimal storage conditions increased by 1.69 (95% CI: 1.15-2.49). A study completed in Malaysia found that 78% of their local general practitioners scored well on a validated

questionnaire assessing their knowledge of cold chain recommendations, however performed poorly in regards to their compliance with these recommendations (**Azira**, Norhayati, & Norwati, 2013). Only 20% of the surveyed physicians actually felt that it would be important to protect vaccine through maintaining cold chain. The authors concluded that a good attitude and commitment to quality is very important in improving vaccine practices. This study is limited by its small sample size and cross-sectional design, and because it was completed in Malaysia it could not be generalized to Canada. However, this study indicates that simply increasing knowledge may not be sufficient enough to achieve appropriate cold chain practices.

Vaccine Storage and Handling in the Newfoundland General Practice Area

In Newfoundland, responsibility for administering vaccine to the public is shared between the public health nurses and local general practitioners. The general practice area administers the majority of the influenza vaccine to the general public; they are also responsible for administering approximately 10% of childhood primary series vaccines. In the urban St. John's region of Newfoundland, procedures are in place to dictate the ordering of this vaccine from the Communicable Disease Control vaccine depot. For primary series vaccines, the physician offices submit an email order form on a monthly basis to the depot (Eastern Health, 2010). The ordering process is more stringent for influenza vaccine. The vaccine they are provided with is based on completed tally forms from the previous year; the physicians are only provided with the amount of vaccine that they used the previous year (Eastern Health). Weekly tally forms can be submitted if demand is higher and more vaccine is needed at their clinic. When vaccine orders are filled they are packed in insulated containers and temperatures are monitored until

delivery at the individual clinics (Eastern Health). Once the vaccine is handed off, the maintenance of the cold chain becomes the clinics' responsibility.

The physicians in Newfoundland are required to adhere to guidelines from the College of Physicians and Surgeons of Newfoundland and Labrador (2010) that are in line with the recommendations put forth by PHAC (2007) but there are currently no procedures in place to assess their adherence to these guidelines. Currently, very little evidence exists to indicate how well local general practitioners are complying with the recommendations. Almost 15 years ago, O'Keefe (2000), a Master of Science student at Memorial University, completed a thesis study within this population of interest. The study targeted family physicians within the jurisdiction of St. John's Health and Community Services on the Avalon Peninsula of Newfoundland. This thesis research investigated some of the vaccine storage and handling procedures as well as the vaccine related knowledge of these general practitioners (O'Keefe). The results indicated that no practice was meeting all aspects of the expected national guidelines; very few practices used proper storage equipment; and the vast majority used no temperature-monitoring device (O'Keefe). A discussion was held with each physician where guidelines were imparted and a second, unannounced clinic visit was held to assess any changes in behavior (O'Keefe). Several practices had invested in a proper thermometer but very few other factors had changed (O'Keefe). There was no mention of statistical significance in any changes, which is a limitation of this study, however with the minimal changes observed it does not appear that the discussion of guidelines alone was enough to bring about a noteworthy change. This study is the most recent research completed on this particular population.

There is no program currently in place in Newfoundland to monitor the vaccine management behaviors of local physicians. Public Health Nurses are guided in vaccine storage and handling practices by local policies and procedures and as per the PHAC national recommendations. Compliance with these recommendations is monitored by the Communicable Disease Control program in Eastern Health and by the Public Health Management team. Physicians are encouraged to report vaccine wastage and any errors in cold chain management, however this is not a mandatory process, and so a concern of underreporting exists. The majority of current evidence on the presence of a problem is largely anecdotal in nature. Local Communicable Disease Control experts have been expressing concern; however with no solid evidence, it is impossible to make any conclusions about the current extent of the local issue.

Solutions

Multiple solutions to deal with the concerns surrounding vaccine storage and handling practices can be noted in the literature. A number of authors made recommendations for providing staff training and education, and completing routine audits of compliance (**Gopal-Krishnan** et al., 2014; **Lewis** et al., 2001; **Turner** et al., 2011). In Malaysia, **Gopal-Krishnan** et al. designed and implemented a comprehensive intervention that involved providing non-financial incentives, training sessions, and educational resources to vaccine providers, in addition to completing regular, in-person audits of storage and handling practices. This study had a large sample size with a 95% participation rate and incurred very little loss to follow up. At baseline measurement, no clinics were meeting all WHO recommendations for appropriate handling. At one-year post intervention, many clinics continued to use inappropriate refrigerators, however

50.9% were meeting all other criteria, which was a statistically significant improvement. **Lewis** et al. completed three audits of 102 refrigerators over a 3-year period in Australia using a standardized checklist and trained investigators; individual feedback and education was provided whenever concerns were noted. Statistically significant improvements were noted in staff cold chain practices at the completion of the final intervention phase. **Turner** et al. described the impact of national policy changes that occurred over a 6-year period in New Zealand. These changes involved increasing vaccine provider training and education in addition to supplying all vaccine providers with a purpose-built fridge. Their investigation utilized temperature monitors attached to vaccines to audit their exposure to suboptimal storage conditions in the general practice setting. At the completion of the study period, a statistically significant decrease in annual vaccine wastage from 17% to 2% was noted. The study methods were unable to pinpoint exactly which policy changes were the most significant in creating change, however due to widespread improvements across the entire cold chain, they concluded that all policies had likely made an impact.

Appointing a single staff member for vaccine maintenance responsibilities is a common recommendation for meeting the vaccine storage and handling guidelines; however, as already discussed, this practice is not always adequately met in the general practice setting. After noting that many practices did not designate one person for cold chain responsibility, **Yuan** et al. (1995) recommended that all professionals that could possibly be involved in vaccination should receive proper training on management of the vaccine storage cold chain (**Yuan** et al., 1995). Several authors noted that clinics that did appoint an individual as having primary responsibility for vaccine maintenance, and used

a health care professional, such as a physician or a nurse as this individual, often had better rates of compliance to recommendations than clinics that used a secretary, or other lower skilled worker (**Yuan et al.**; **Carr et al.**, 2010). **Carr et al.** noted in particular that hiring a staff nurse in general practice to take responsibility for vaccine management was a significant predictor of maintaining cold chain integrity and that 95% of practices that had a nurse responsible for vaccine were meeting recommendations.

Even with adequate education and good compliance with recommendations, an inadequate storage device can limit the maintenance of optimal storage conditions. Research completed by **Page et al.** (2008) noted that a purpose built fridge had the lowest mean temperature fluctuations at 0.26°C. They found that a bar-style fridge was significantly less likely than a purpose build fridge to be able to maintain optimal temperatures (OR: 0.005, 95% CI: 0.001-0.044). **Lewis et al.** (2001) found no significant relationship between compliance with vaccine storage recommendations and maintenance of appropriate temperature range, suggesting that a significant concern was the refrigerator. Several authors recommended that physicians purchase a purpose built refrigerator in order to help improve storage (**Carr et al.**, 2010; **Lewis et al.**, 2001; **Page et al.**, 2008). However, due to the average price, this would be difficult for many individual clinics to do. It is suggested that because regional health authorities would likely be the ones to incur financial losses due to cold chain breaks, that they should aid clinics in purchasing approved storage devices (**Page et al.**). In instances where this is not possible, a much more cost effective solution is to provide detailed information on how to properly modify existing vaccine refrigerators to help maintain consistent temperatures, and to provide appropriate temperature monitoring devices (**Lewis et al.**).

Several Canadian provinces have already made a commitment to improving vaccine storage and handling practices. British Columbia provides regular training to vaccine professionals, including the use of multiple informative videos that are easily accessible via the Internet, in order to promote acceptable vaccine management (ImmunizeBC, 2012). The Ministry of Health in Ontario requires each Public Health Authority to complete annual inspection of the storage and handling practices in all general practice clinics using a standardized, province-wide electronic checklist (Ontario, 2013). Peel Public Health (2014) uses this checklist to complete these regular audits, and in addition have created a comprehensive education program that provides detailed information on vaccine management expectations. The Alberta Health region in the province of Alberta responded to a large vaccine loss at their local vaccine depot due to a serious break in the cold chain (Henneigh, 2014). They implemented procedures that are similar to those currently used in the Public Health department of Eastern Health. Through the use of regular data logging, the provision of comprehensive staff training, the removal of all bar-style fridges, and the implementation of an annual cold chain audit, they improved the overall maintenance of the cold chain within this region (Henneigh). As there is currently limited data to describe the current vaccine storage and handling status in Newfoundland general practice clinics, further exploration is necessary. The development and implementation of an audit tool could help to identify areas of concern and could inform the creation of education programs and incentives to promote adherence to national guidelines for vaccine storage and handling in the general practice area.

Conclusion

The available literature supports the concern that the overall compliance with and knowledge of adequate vaccine storage and handling in the general practice area is generally low. Even where guidelines exist, minimum standards are often not being met. When the cold chain is not maintained, it could potentially compromise the potency of vaccines, thereby putting the public at risk for contracting vaccine preventable communicable diseases. As evidenced by the literature, when a commitment is made to enhancing vaccine management through the provision of education and support, and the completion of regular storage and handling audits, it can produce significant improvements to the management of vaccine, and in turn, protect the safety and quality of vaccines. The resulting reduction in vaccine wastage would also financially benefit the health care system. There is very limited information available on the current state of the cold chain maintenance in the province of Newfoundland. There has been no follow up on the concerns identified by O'Keefe in 2000 and no strategies have been implemented to support the vaccine practices of general practitioners in Newfoundland. This literature review supports the need to further assess the current situation in Newfoundland. The development and implementation of an auditing tool could highlight the potential need to improve the current systems, equipment, and education of general practice staff in this province, as it has in other locations.

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Appendix – Literature Summary Tables

Source	Relevant Methods	Results	Conclusions
<p>Adu et al. (1996).</p> <p>Objective: To assess the potency of various vaccines at each link in the cold chain.</p> <p>Design: Lab based study</p> <p>Setting: Nigeria</p>	<ul style="list-style-type: none"> - Tracked the temperature exposures of a random sample of three vaccine types (measles, polio, and yellow fever) along 3 links in the cold chain: national level storage, state level storage, and the vaccination center where the vaccine is then administered to the public. - At each site, vaccine was selected from the original sample for potency testing. - Vaccine was in freeze-dried state at national and state level centers; vaccine was in reconstituted form at local vaccine center to closely simulate the field condition. - Temperatures of vaccine samples were closely monitored during transport to lab facility for testing. - Vaccine products titrated according to WHO recommendations: Polio: titrated in Hep-2 cells using 9 replicate wells; Measles: titrated in vero cells using 9 replicate wells per dilution; Yellow Fever: titrated in 28-35 day old mice. - Vaccine selected from the national storage center was labeled as the control. - A physical assessment was completed of each facility at the time of vaccine selection to note the presence of temperature monitors, storage refrigerators, power supply, and handling procedures. 	<ul style="list-style-type: none"> - Found that storage was adequate and up to WHO standards at only the national storage level. - Storage and handling procedures were progressively worse through each link in the cold chain. - Test vaccine was subjected to repeat freezing temperatures throughout storage and transport from each site. - Measles: titers ranged from 3.3-4.8 log₁₀ TCID₅₀ per dose at national storage level; through other links in cold chain the titers ranged from 1.0-4.6; this drop in potency was statistically significant. - Polio: titers ranged from 4.5-5.6 at national storage and decreased to 3.5-5.6 through the other cold chain levels. - Yellow Fever: titers ranged from 3.15-3.94 and decreased to 0-3.85 through the other levels. - The drops in potency for Polio and Yellow fever were not statistically significant. 	<ul style="list-style-type: none"> - High quality. - Study was completed in Nigeria, which limits applicability of results; however staff was trained in vaccine storage and handling procedures up to WHO standards, which are comparable to Canadian recommendations. - Findings from the physical assessment of each storage site may not be applicable due to the significant differences in available resources between Nigeria and Canada; however the resulting lowered potency due to exposure to adverse temperatures is in line with the results of similar studies in developed countries.

Source	Relevant Methods	Results	Conclusions
<p>Boros et al. (2001).</p> <p>Objective: To assess the immunogenicity of both the acellular and whole cell pertussis vaccines after storage in freezing temperatures.</p> <p>Design: Randomized controlled trial.</p> <p>Setting: Australia</p>	<ul style="list-style-type: none"> - Selected only vaccine that could be confirmed as stored within the recommended temperature range of 2°C to 8°C. - Test vaccine was stored at -3°C for 24h; control vaccine was maintained at 2°C-8°C during the same 24h period. All vaccine was then brought to room temperature prior to testing - Vaccine was titred in mice equal in age and size. Mice were randomly selected to receive whole cell pertussis, acellular pertussis or N/S. There were 45 mice in each pertussis treatment group and the control group; 5 mice received only N/S. - Blood collection was completed immediately prior to vaccination and then again 28 days later and tested for the presence of antibodies. 	<ul style="list-style-type: none"> - A significant reduction in the immune response was noted when acellular pertussis vaccine was stored at -3°C for 24h. - Acellular pertussis: % differences in geometric mean concentration (GMC) per antigen after exposure: <ul style="list-style-type: none"> • PT: 178.6% • FHA: 522.2% • PRN: 43.5% - Whole cell pertussis: <ul style="list-style-type: none"> • PT: 35.9% • FHA: 14% • PRN: 52.9% - While the whole cell pertussis did decrease in potency the differences were not statistically significant. 	<ul style="list-style-type: none"> - High quality. - Some vaccine is the study was titred in mice due to ethical issues present in testing this vaccine on humans. This impacts the generalizability of these results, however mice are considered biologically similar to humans and so response in humans can often be assumed by the response in mice. - The study used vaccine brands from Belgium and Australia that are not used in Canada; however the components of the acellular pertussis vaccine are similar to the vaccine currently used in Canada; whole cell pertussis is not currently used in Canada. - Vaccine was brought to room temperature prior to testing. This is outside of the accepted temperature range so could have negatively impacted the potency.
<p>Chen et al. (2009).</p> <p>Objective: To evaluate any changes in the physical appearance and potency of Hepatitis B vaccine after exposure to freezing temperatures.</p> <p>Design: Combo of lab based and RCT.</p> <p>Setting: USA</p>	<ul style="list-style-type: none"> - Vaccine was exposed to freezing temperatures from 0°C to -20°C up to three times for a period of time ranging from 24hrs up to 7 days. - Control vaccine was maintained at 4°C for the duration of the study. - Some vaccine was agitated in order to simulate normal vibrations involved in the transportation process. - After thawing, vaccine was inspected under a microscope to assess physical changes to the 	<ul style="list-style-type: none"> - Vibrations expedited freezing time. - After exposure to a single freezing event of 24hrs there was a small statistically significant decrease in the percentage of small particles from 99% to 94%. - Exposure to freezing temperatures for longer than 24hrs or repeated freezing and thawing events was associated with a much larger, statistically significant increase in particle size. 	<ul style="list-style-type: none"> - Strong design with high quality data. - There was no discussion of vaccine selection methods so unsure if vaccine was of good quality prior to start of study. - No discussion of sample sizes. - Study used only one brand of Hepatitis B that is not used in Canada at this time; different manufactures' vaccine may respond differently to freezing temperatures. - There was no long-term

Source	Relevant Methods	Results	Conclusions
	particles. - The vaccine was then tittered in mice to assess the immunogenicity.	- Samples that were exposed to freezing temperatures but did not actually freeze were physically indistinguishable from the control group. - Repeated freezing and thawing resulted in a significant loss of in vivo potency from 100% in the control to 10-50% in the experimental groups; a single freezing event was not associated with a decrease of in vivo potency. - Mice vaccinated with a 2µg dose of previously frozen vaccine had lower titers than the control group (100+µg/ml of antibody in control; 15µg/ml antibody in freeze group). - Repeated freezing events were associated with a lower antibody titer.	assessment of potency; even with no potency loss noted after a single freeze event the shelf life may have been altered or there could have been a delayed decrease in potency present that could not be identified by the study methods.

Assessment of compliance with recommended storage and handling guidelines and overall knowledge of recommendations

Source	Relevant Methods	Results	Conclusions
Azira et al. (2013). Objective: To determine the knowledge, attitudes, and adherence to vaccine storage and handling among general practitioners. Design: Cross-sectional. Setting: Kelantan, Malaysia.	- Initial contact made via phone call with 110 eligible clinics. - Consenting clinics provided signed consent. - A trained researcher completed a visual inspection of each clinic's fridge using a standardized checklist according to WHO guidelines. - A Min/Max thermometer was placed in each fridge and assessed after 24h.	- A total of 89 clinics participated (80.9%). - 78.7% scored well on knowledge questions: mean score 79.9% with a range from 66.7-93.3%. - 79.8% scored poorly on attitude questions: 12.4% felt recording temperatures was unimportant; 11.2% responded that proper vaccine organization within a fridge was important; and 4.5% felt that	- High quality. - Used validated tools, trained investigators, and audit checklist according to WHO standards. - The study setting of Malaysia limits generalizability due to differences in education and culture that could impact knowledge and attitudes; however the relationship shown between attitude and adherence to proper cold chain

Source	Relevant Methods	Results	Conclusions
	<ul style="list-style-type: none"> - A validated questionnaire was used to assess knowledge and attitude and was completed by each physician during the researcher's clinic visit. 	<ul style="list-style-type: none"> maintaining appropriate temperatures was important. - 5.6% had acceptable cold chain practices. 	<ul style="list-style-type: none"> warrants attention.
<p>Carr et al. (2010).</p> <p>Objective: To assess the compliance with national guidelines for vaccine storage and handling.</p> <p>Design: Cross-sectional</p> <p>Setting: General practice clinics in Hunter region of New South Wales, Australia.</p>	<ul style="list-style-type: none"> - Clinic visits were completed to visually inspect vaccine refrigerators. - Fridge was audited using a checklist that reflected both the national recommendations and WHO guidelines. - While fridge was inspected, a staff member responsible for handling vaccine completed a standardized questionnaire that assessed knowledge and practices. - Collected data about whether or not a nurse was employed in the clinic and responsible for vaccine management and delivery. - Data logger installed that monitored temperatures q15m for 72h. - Ethical approval received. 	<ul style="list-style-type: none"> - Participation rate of 256 general practice clinics. - Clinics that hired a nurse with vaccine responsibilities had 95% compliance with cold chain practices than general practice clinics that did not have a nurse employed; this was statistically significant. - 19% of refrigerators did not maintain recommended temperature range. - Bar fridges were significantly more likely to have temperatures outside of the recommended range (42%) than non-bar fridges (3%) (p<.0001). - 24% of all general practices did not meet all vaccine cold chain recommendations. 	<ul style="list-style-type: none"> - Moderate quality. - Validated questionnaire and audit checklist were used which is a strength. - Study limitations included the use of some subjective questions in the knowledge questionnaire; and the use of recall in the questionnaire. - There is no discussion of specific knowledge issues and practice issues identified from the questionnaire; it is just noted that not all clinics were meeting recommendations.
<p>Haworth et al. (1993).</p> <p>Objective: To assess the compliance with recommendations and maintenance of cold chain.</p> <p>Design: Cross-sectional study of a random sample of general practices.</p> <p>Setting: General practice clinics in West Berkshire and Aylesbury Vale</p>	<ul style="list-style-type: none"> - Authors completed a pilot study in three clinics to test a questionnaire and gain some experience in reading WHO vaccine temperature monitors. - Set inclusion and exclusion criteria. - All practices were invited to participate and sample of 29 clinics was randomly selected from consenting clinics. 	<ul style="list-style-type: none"> - Noted low compliance with storage requirements. - 26/33 refrigerators stored vaccines with other miscellaneous items. - ~50% had one person responsible for vaccine management. - 54-70% used a thermometer in fridge. - 0-14% monitored temperatures daily. - 46-65% had back up power 	<ul style="list-style-type: none"> - Moderate quality. - Relying on an informant to decipher the cold chain monitor upon vaccine delivery could have resulted in inaccurate readings; however the authors note that it was a reliable monitor that was easy to read; staff members were shown how to assess the monitors and so this was considered an acceptable method.

Source	Relevant Methods	Results	Conclusions
in England.	<ul style="list-style-type: none"> - Reliable temperature monitor was included with vaccine orders for each participating clinic. - Upon delivery, each clinic contacted an investigator and interpreted the monitor; the monitor was then stored with the vaccine in the refrigerator. - 1-2 weeks later, trained investigators visited each clinic to complete a structured questionnaire with staff re: storage practices; the monitors were then read by the investigator. - Investigators completed a third monitor reading 8 weeks post-delivery. - WHO guidelines were followed in interpreting the cold chain monitors. 	<p>protection.</p> <ul style="list-style-type: none"> - 0-25% protected vaccine temperatures when transferred out of clinic. - No cold chain breaks occurred prior to delivery of vaccine to each general practice clinic. - Storing vaccine for 8 or more weeks was more likely to result in a decrease in potency due to exposure to sub-optimal conditions ($p=0.003$). 	<ul style="list-style-type: none"> - Questionnaire used followed WHO guidelines and was tested in a pilot of 3 general practice clinics prior to beginning study. - Results indicated need for more attention to education and supports in order to maintain vaccine integrity.
<p>Page et al. (2008).</p> <p>Objective: To assess the temperature of different types of refrigerators that are used to store vaccine in general practice clinics and to assess the knowledge of general practice clinic staff members related to storage requirements.</p> <p>Setting: Australia</p>	<ul style="list-style-type: none"> - Approached 32 general practice clinics to request participation. - Used calibrated thermometers that were placed on the middle shelf of each fridge. - Thermometer logged data electronically q12minutes for 10 days. - Administered a validated survey of 10 knowledge-based questions according to guidelines from the Australian Immunization Handbook. - Main outcome measure was an optimal temperature range of 2-8°C; secondary outcome measure was related to the relationship between level of knowledge and optimal 	<ul style="list-style-type: none"> - A total of 28 clinics participated in the study. - The least variation in temperatures was in the purpose built fridge (approximately 1.5°C-8.5°C) while the bar-style fridge had the most variation (approximately -4°C-10°C). - All fridges were significantly less likely to maintain the temperature range when compared with the purpose built models: <ul style="list-style-type: none"> • Bar: Odds Ratio=0.005 (95% CI: 0.001-0.044; $p<0.001$) • Cyclic: OR=0.008 (95%CI: 0.001-0.080; $p<0.001$) 	<ul style="list-style-type: none"> - High quality study. - Used trained investigator; validated tools; frequent temperature monitoring with calibrated tool. - Supports the use of purpose built fridges and the need for education.

Source	Relevant Methods	Results	Conclusions
	storage conditions.	<ul style="list-style-type: none"> • Frost free: OR=0.006 (95% CI: 0.001-0.071; p<0.001) • Other: OR=0.009 (95%CI: 0.001-0.070; p<0.001) <p>- Knowledge of vaccine storage was positively associated with maintaining optimal storage conditions; OR increased by 1.69 (95%CI: 1.15-2.49; p=0.008) for every unit increase in knowledge score.</p>	
<p>Yuan et al. (1995).</p> <p>Objective: Assess the knowledge level and practices re: vaccine storage and handling in primary care offices.</p> <p>Design: Cross-sectional study</p> <p>Setting: Primary care physician offices in Toronto and just outside of the city.</p>	<p>- Participating clinics selected by choosing every 10th practice that ordered vaccine from a central depot.</p> <p>- Verbal consent was obtained via telephone and clinic visits were arranged.</p> <p>- Investigators visited consenting clinics and administered a questionnaire to one individual that had greatest responsibility for vaccine management.</p> <p>- Consent was obtained to inspect refrigerator.</p> <p>- Assessed interior temperature and also noted presence of extraneous items, organization of vaccine within the fridge, and presence of any expired vaccine.</p>	<p>- 86.5% participation rate (n=135).</p> <p>- Outside Toronto (n=110):</p> <ul style="list-style-type: none"> • 92.3% had a single person responsible for maintaining vaccine; 57% used a nurse as the person responsible for vaccine maintenance; 10.9% used secretary • 10.9% had written procedures available. • 55.5% stored vaccine on door of fridge. • 10.9% of fridges were used exclusively for vaccines. • 10% of refrigerators had a thermometer installed. • Vaccine was left outside refrigerator for up to 8hrs when being used. • 83.6% knew heat was harmful to vaccines; 27.3% knew freezing was harmful; 45.5% knew light exposure was harmful; 5.5% answered all knowledge 	<p>- Moderate quality.</p> <p>- Analyzing data for inside and outside metro Toronto separately helped to control for different demographics of the two groups.</p> <p>- No discussion of ethical approval for the study.</p> <p>- Clinics were not informed of fridge inspection in advance, which likely allowed for more accurate results.</p> <p>- 8% of clinics had multiple staff members responsible for vaccine so one person had to be selected for questionnaire completion by investigators; it's possible that this person reported their own behaviors, which could have been different from other individuals' behaviors.</p> <p>- Used trained investigators and a standard questionnaire.</p> <p>- Temperature was measured using the same thermometer at each site but only on one occasion. This gives a narrow view of the picture</p>

Source	Relevant Methods	Results	Conclusions
		<p>questions correctly.</p> <p>- Inside Toronto (n=25):</p> <ul style="list-style-type: none"> • 90% had single person responsible for vaccine management; 40% used secretary. • Vaccine was left outside of refrigerator 3-5h while being used. • 40% stored vaccine on the door of fridge. • 0% had a thermometer installed in fridge. • 84% knew heat was harmful to vaccines; 32% knew freezing was harmful; 48% knew that light exposure was harmful; 4% answered all questions correctly. <p>- 31.9% had refrigerator temperatures outside of recommended range.</p> <p>- Fridges older than 12y were more likely to have inappropriate temperatures (52.2% vs. 26.4%, $p=0.018$).</p>	<p>as they were unable to assess fluctuations; it is possible that a fridge with an adequate reading at the time of measurement also frequently strayed outside of the expected range.</p>
<p>O'Keefe. (2000).</p> <p>Objective: To assess the immunization practices in general practice clinics with a focus on the storage, handling, and documentation of vaccines as compared with established guidelines.</p>	<ul style="list-style-type: none"> - All general practice clinics providing publically funded vaccinations were approached to request participation. - A questionnaire was created based on vaccine storage and handling recommendations. - Phase one included a prearranged clinic visit where consent for 	<ul style="list-style-type: none"> - No practice was meeting all expected recommendations at phase one. - 15% used a thermal bag for transport. - 63% used no thermometer, - 4% took daily readings of temperatures. - 89% of fridges were measured 	<ul style="list-style-type: none"> - Moderate quality. - Methods and instruments were tested in a small pilot. - All data collected by a single inspector and all collection methods were standardized; likely all data was collected in the same way. - Most recent research on this population; no ability to know if

Source	Relevant Methods	Results	Conclusions
Setting: General practice clinics on the Avalon Peninsula of Newfoundland, Canada	<p>participation was obtained, the questionnaire was administered, and the vaccine storage area was assessed.</p> <ul style="list-style-type: none"> - Feedback was provided at this initial clinic visit. - In phase two, the researcher performed an unannounced clinic visit to assess for any changes in vaccine storage conditions resulting from feedback provided. - Participant confidentiality was protected and codes were used to protect identities. 	<p>within the appropriate range.</p> <ul style="list-style-type: none"> - 8% of clinics had a contingency plan for instances of power loss. - 4% of clinics used water bottles as a temperature stabilizer. - In phase two the only notable change was that 8 of the 17 clinics that were not using a thermometer had invested in one. 	concerns remain valid.

Interventions

Source	Relevant Methods	Results	Conclusions
<p>Turner et al. (2011).</p> <p>Objective: Assess the effectiveness of New Zealand cold chain and identify impact of policy changes over time.</p> <p>Setting: Auckland, New Zealand general practice clinics.</p>	<ul style="list-style-type: none"> - Study occurred over a 6-year period. - 21,431 Cold-chain monitors were attached to 5% of randomly selected childhood vaccine products at a central depot. - A record card that was required to be completed at each transport and storage stage accompanied each monitor. - Data was collected q6months and frequencies of heat/cold exposures were compared over time. - During study period new policies were implemented within New Zealand: National Guidelines published; intensive training for all 	<ul style="list-style-type: none"> - 44.2% return rate of monitor cards; 5.5% of these were incorrectly completed and therefore excluded. - Frequency of heat failures was reduced from 3% at baseline to 0.3% at completion ($p < 0.0001$); freeze failures decreased from 16% to 2% ($p < 0.0001$). - Vaccine wastage decreased from 17% to 2% ($p < 0.0001$). - The most common site for cold chain failure was the general practice setting (49%). 	<ul style="list-style-type: none"> - Moderate quality. - Impossible to know which policy had the biggest impact on the changes. - Low return rate of monitor cards could have impacted results.

Source	Relevant Methods	Results	Conclusions
	vaccinators was completed; initiative that funded the full purchase price of a purpose-built vaccine refrigerator for all general practices; the introduction of an accreditation process for all vaccine providers.		
<p>Gopal-Krishnan et al. (2014).</p> <p>Objective: Assess the impact of a non-controlled community trial on improving private practice vaccine storage practices.</p> <p>Setting: Malaysia</p>	<ul style="list-style-type: none"> - Trial involved 4 audits of vaccine storage practices over 1 year: (1) baseline; (2) 1 month post intervention; (3) 3 months post intervention; and (4) at 1 year post intervention. - Participant confidentiality was assured. - Participation requested by letter. - Inclusion and exclusion data set. - Used convenience sampling based on availability of clinics. - Target sample size calculated to be 100; 430 participated. - Intervention consisted of: <ul style="list-style-type: none"> • Training program for staff and immediate feedback post audits. • Thermometers and monitoring charts were provided. • Educational materials included: posters, power point presentation, and copy of WHO recommendations. • Incentives: sticker for fridge stating “My Refrigerator is Safe for Vaccines;” and certificate 	<ul style="list-style-type: none"> - At baseline, compliance was low with all but criteria #5 (Temperature range between 2-8°C). - Improvement in all other criteria was statistically significant at 1 year. - Criteria #1: Increased from 21.8% at baseline to 25.5% after one year. - Criteria #2: Increased from 8.8% at baseline to 39.4% after one year. - Criteria #3: Increased from 0.9% at baseline to 20.7% after one year. - Criteria #4: Increased from 31.7% at baseline to 75% after one year. - Criteria #5: Increased from 56.9% at baseline to 88.2% after one year. - Criteria #6: Increased from 2.3% at baseline to 84.1% after one year. - The majority of clinics felt the intervention was positive in helping them improve their practice. - Items rated most helpful were the posters, thermometers, temperature-monitoring chart, and copy of WHO recommendations. 	<ul style="list-style-type: none"> - Weak design but moderate quality. - Good sample size. - Accountability ensured by having both the research nurse and the physician sign the audit results form. - Ethical approval was received. - Methods were not able to assess temperature fluctuations over time – only measured one temperature with each audit, which may not give the full picture of the situation. - Convenience sampling was used, however more than 50% of all clinics were audited so sample is likely representative. - Unable to generalize results to Canada however improvements that were noted due to program components such as education and regular audits are similar to improvements noted in other interventions and may have success here.

Source	Relevant Methods	Results	Conclusions
	<p>appropriate for display in clinic were provided depending on audit results.</p> <ul style="list-style-type: none"> - Measured adherence to 6 criteria based on WHO guidelines: 1) Type of refrigerator; 2) Dedicated vaccine refrigerator; 3) Placement of refrigerator away from heaters, direct sunlight, and cold areas; 4) Placement of vaccine in refrigerator; 5) Appropriate temperature range of 2-8°C; and 6) Monitor temperature. 		
<p>Lewis et al. (2001).</p> <p>Objective: Assess the effectiveness of the implementation of vaccine storage and handling guidelines on achieving optimum storage temperatures in refrigerators.</p> <p>Setting: New South Wales (NSW), Australia</p>	<ul style="list-style-type: none"> - Used three cross-sectional surveys completed over time period of 3-years. - Phase 1 included all general practices on the Central Coast region of NSW; the subsequent two phases used a sample of these practices. - An Environmental Health Officer (EHO) visited each site to assess vaccine storage practices. - Temperature data loggers were placed in each clinic and retrieved at the end of the study period. - A graph of the temperature range was sent to each clinic when temperatures were noted outside of the optimal range, along with advice to correct problem. - A questionnaire was administered by the EHO at the initial visit to assess compliance with recommendations. - When temperature logger was placed, the fridge was visualized to 	<ul style="list-style-type: none"> - Response rate of 99% for phase 1 and 100% for phases 2&3. - At baseline, 25-35% had temperatures below 0°C; 95% of these instances were maintained at freezing temperatures for a 30min period. - Over the following phases, there was a statistically significant increase in fridges maintaining temperatures in the appropriate range. - A non-statistically significant trend was noted of decreasing exposure to freezing temperatures. - There was very little change in the number of practices that had a single person responsible for vaccine management. 	<ul style="list-style-type: none"> - Moderate quality. - Even though improvements were noted, significant concerns still existed at the end of the study period, suggesting the implementation of recommendations is not significant enough to produce a change. - Difficult to generalize the results to Canada as guidelines have existed for several years; however may indicate the need for more intensive interventions in order to ensure practitioners are complying with guidelines.

Source	Relevant Methods	Results	Conclusions
	note the presence of extraneous items and a thermometer.		

Appendix B – Consultation Report

Consultation Report

N6660

Amy Barnes

Memorial University

Table of Contents

Overview of Project

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Conclusion

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Appendix B: Health Research Ethics Authority Screening Tool

Appendix C: Interview Questions for Communicable Disease Control Colleagues

Appendix D: Summary of Data Collected from Peel Public Health

Appendix E: Summary of Data Collected from CDC Colleagues

Appendix F: Letter Used by Peel Public Health

Appendix G: Peel Public Health Inspection Tool

Appendix H: Grading Criteria

Appendix I: Eastern Health Inspection Checklist

Overview of Project

Vaccines are sensitive biological products that are vulnerable to a variety of environmental conditions, including exposure to extreme temperatures and light (Public Health Agency of Canada [PHAC], 2007). Maintaining vaccines within a cold chain is important in preserving vaccine quality (Eastern Health, 2010; PHAC). The term cold chain refers to the maintenance of appropriate conditions through each link in the chain from the manufacture, transport, storage, handling, and administration of vaccine products. Publically funded vaccines that are used in the province of Newfoundland need to be carefully maintained in a temperature range of 2-8°C (Eastern Health). There is much evidence in the literature to suggest that the cold chain is not being maintained in the general practice area (Carr, Byles, & Durrheim, 2010; Haworth, Booy, Stirzaker, Wilkes, & Battersby, 1993; Yuan, Daniels, Naus, & Brcic, 1995). The most common areas of concern include the use of improper refrigerators; inadequate or non-existent temperature monitoring; the storage of extraneous items in the refrigerator along with the vaccine; not assigning a single staff member for maintaining the vaccine; the lack of a back-up power source; and poor knowledge and attitudes of immunizing physicians in regards to the components of the cold chain (Carr et al.; Haworth et al.; Yuan et al.; Welterman, Markic, Thielmann, Gesentives, & Herman, 2014).

Currently in Newfoundland, no process exists to audit the compliance with national vaccine storage and handling recommendations in the general practice setting, however anecdotal evidence, and thesis research completed by O'Keefe (2000), suggests that concerns are similar to what can be identified in the majority of the literature. The overall goal of this practicum project is to develop a comprehensive program to monitor

and promote the appropriate vaccine storage and handling practices of staff working in the general practice area. A tool will be developed that can be used by Communicable Disease Control (CDC) nurses to assess the storage and handling practices of General Practitioners (GP); through use of this tool, specific problem areas can be identified and appropriate services and resources can then be recommended to help address the issues.

Consultations have been undertaken with a key representative from Peel Public Health in Ontario, Canada, and with several staff members working within the Communicable Disease Control (CDC) department with Eastern Health. The province of Ontario has mandated an annual audit of vaccine storage and handling practices in every facility that offers publically funded vaccines. In addition to completing these audits, Peel Public Health has created a comprehensive system that both monitors and promotes adherence to the recommended vaccine storage and handling guidelines. They were consulted to obtain specific details related to their program and to obtain advice for creating a similar system in Newfoundland.

The Eastern Health CDC program staff members have responsibilities in providing general practice staff with publically funded vaccine. They have voiced concerns related to the storage of vaccine in this setting but have no methods on hand to assess the true extent of the problem. As a result of rolling power outages in Newfoundland in 2014, significant cold chain failures occurred in the general practice setting, highlighting the need for some intervention. CDC staff members have been consulted to exchange information learned from the Peel Public Health consultation, to gather anecdotal information on some of the perceived current issues, and to gain input on how the monitoring system should be designed.

Participants and Methods

Consultation with Peel Public Health

A telephone call was placed to the Vaccine Management Team at Peel Public Health. The individual who answered the call was identified as a Public Health Nurse (PHN) with direct involvement in the auditing process for vaccine storage and handling. The reason for calling was disclosed and verbal permission was received for participation in data collection and sharing of information with other health professionals. This key informant reported that the Peel Region regularly shared details on best practices with other health regions.

The interview questions were administered and notes were taken through the duration of the conversation. Email contact details were exchanged and some electronic resources were received in this manner. A second consultation occurred via email as well to ask some follow up questions. The specific questions asked can be found in Appendix A.

Prior to beginning this consultation, the Health Research Ethics Authority (HREA) Screening Tool was completed. The results of this tool indicated that review by an ethics board would likely be unnecessary prior to implementation. The primary goal of the consultation was related to gathering information on the components of a program specific to the Peel Public Health unit; it was not designed for purposes of research. A copy of the HREA tool with a complete interpretation can be found in Appendix B.

Consultation with CDC Staff Members

Email contact was made with a nurse manager working within Eastern Health's Communicable Disease Control (CDC) program. This individual and all other CDC staff

members were already aware of the specifics of this practicum project. Convenient meeting times were arranged via email with two individuals from the CDC management team, and two nurses from the front-line CDC team. Each meeting was face-to-face in the privacy of an office. Verbal permissions to participate in a short interview were received from each staff member prior to administering any questions. The specific questions that were asked can be found in Appendix C. Notes were taken throughout each interview.

The HREA Screening Tool was also completed prior to this consultation. The results of this tool indicated that the purpose was related to quality and evaluation and not research; therefore it would not be necessary to seek review by an ethics board prior to implementation of the consultation. A copy of this tool with a summary of the interpretation can be found in Appendix B.

Data Management, Analysis, and Confidentiality

Peel Public Health

The notes taken during the interview were typed and organized in a narrative format. All notes were shared with the practicum advisor. A summary of this program can be found in Appendix C.

Full disclosure related to the reason for calling and how the collected data would be used was provided to the key informant. Verbal permissions were received prior to beginning the interview. Permissions were also received to share any collected information with other professionals for the reasons of developing the proposed project and spreading best practice information. The name of the key informant has been kept confidential. Any notes taken have been stored in a locked filing cabinet when not in use.

CDC Staff Members

Any notes taken during the planned interviews were typed and organized. The staff members were already aware of the reasons for the interviews due to ongoing communication throughout the practicum project, however full disclosure of how the results would be used to inform the development of the project were provided. To protect the privacy of each respondent, names have been kept private and the interview notes have been labeled as A, B, C, and D.

The notes were then analyzed for content; the text from each interview was coded into general categories and compared. All notes have been shared with the practicum supervisor. A summary of the data collected from the consultation can be found in Appendix D.

Results

Peel Public Health

Peel Public Health employs four PHNs in full time positions, whose responsibility involves the completion of the annual audits of facilities storing publically funded vaccine products and the provision of education services when necessary. During the peak of the influenza vaccination season, temporary nurses are hired to assist, as there is an increased demand at this time. The PHNs send a letter to each facility advising that a clinic visit will be occurring over the next 12-weeks. A copy of this letter can be found in Appendix E. Each clinic is given the opportunity to contact the nurse to arrange an appointment, and if no appointment is made, the visit will be completed at the PHN's convenience with no further notice given.

During each visit, a checklist is administered, as per the mandate of the Ministry of Health and Long Term Care, in Ontario. A copy of this tool can be found in Appendix F. The outcome of these audits results in a pass, fail, or conditional score, and specific criteria exist to inform the overall decision (Appendix G). A passing grade results in no further action. A conditional or fail score would typically result in a temporary hold on future vaccine orders until the clinic has corrected the problems and completed education and training, when necessary.

There are also processes in place that go beyond the annual audit and ensure continual monitoring of the storage and handling of vaccine in the Peel Public Health region. These processes involve the submission of all recorded temperatures with each facilities vaccine order. If temperatures are noted outside the appropriate range of 2-8°C, then a hold is placed on the order until at least 72 hours of appropriate temperatures are recorded and submitted to Peel Public Health.

No formal evaluation has been completed thus far on the program used by Peel Public Health and so no concrete evidence exists to indicate the true strengths or weaknesses of this program. Cold chain failures continue to occur fairly regularly in the region, however the informant did report that the incidence of human related errors has decreased over time. Equipment failure is the primary reason for the majority of breaks in the cold chain in the Peel region, specifically, the use of bar-style fridges and malfunctioning temperature monitors. The comprehensive education and regular monitoring of cold chain practices may be the cause of the decreases noted in human error, however without financial resources to support the upgrading of storage equipment, some cold chain failures will likely continue to occur.

CDC Staff Members

A full summary of all themes identified from the data collected in the interviews with Eastern Health's CDC staff can be found in Appendix D. The most common concern revealed in the interviews is the occurrence of limited and in some cases non-existent temperature monitoring in general practice clinics. Telephone follow up was completed in January of 2014 after significant periods of power loss likely left vaccine products exposed to warm temperatures for extended periods of time. While no specific statistics were available at the time of the interview, an interviewee reported that fewer than 50% of general practice fridges actually had a thermometer installed, and of those that had a thermometer, regular temperature monitoring was rare. Due to the inability to accurately measure the exposure to inappropriate temperatures, the CDC staff requested the vaccine be returned to the depot. There was only a 20% compliance rate with this request. Tallies received at the end of the flu vaccine season revealed that the influenza vaccine had still been used. CDC had no measures to assess if any of the impacted primary series vaccine was also used but the assumption is that it was. This potentially put large populations of people at risk for receiving poor quality vaccine and in turn, contracting vaccine preventable diseases.

Some other significant concerns noted were related to the use of bar-style fridges, and the storage of extraneous items within a vaccine fridge. Due to space issues within many clinics, only one fridge is present, and due to the low cost and compact size, a bar-style fridge is the most popular. This means that items such as food, beverages, specimens, and other drugs may be stored along side vaccine products in a fridge that is already well known to have fluctuating temperatures, which is potentially compromising

the integrity of the vaccine.

The data collected from Peel Public Health were shared with the CDC staff members. This program in its entirety was seen as an ideal long-term goal. However, at this time it was felt that more concrete evidence of the current issues would be necessary before a program like the one offered through Peel would be able to be implemented in Newfoundland. A large amount of anecdotal evidence exists describing the issues; however without solid data to back these stories up, it would be difficult to find support for a big change. A standardized audit tool was identified as being the most beneficial component of the Peel Public Health toolkit. The checklist tool currently used by Peel Public Health nurses helps to identify areas of concern, and then also provides strategies that should be used to resolve any issues. With a standardized tool similar to this, a thorough assessment of the issues can be made, and recommendations for change can be easily imparted whenever concerns are noted. Public Health managers in Eastern Health currently audit the vaccine storage and handling practices throughout the Public Health program using a basic checklist. It was noted during the interviews that this checklist may benefit from a new design similar to the one used in Peel Region. One standardized form could then be used to inspect all fridges that are currently storing vaccine products, regardless of the setting. A copy of the checklist that is currently used in Eastern Health can be found in Appendix H.

Engaging the general practice staff in participating in methods designed to improve vaccine cold chain practices was also a significant theme. General Practitioners have been requested to report instances of vaccine wastage and occurrences of cold chain failure to the CDC depot; however this is not a practice that has been well followed. The

Community Medical Advisory Committee (CMAC) is a group of physicians that act as a liaison between Eastern Health and the community physicians. They have involvement in the development of any policies or programs that could impact the practice of General Practitioners. Seeking the involvement of this committee was noted as likely having a positive impact on program acceptance; however this is often a long process. Advising this committee of the data collection procedures was described as a good first step in the process as this could aid in physicians agreeing to participate in data collection. However prior to the implementation of any new policies or procedures that would impact the general practice population, extensive involvement would likely be necessary. Aside from involving the CMAC in the process, other methods to improve participation were identified as providing incentives such as continuous learning hours, providing good quality temperature monitors where none exist, and providing a “safety certificate” for each refrigerator that passes an inspection. The overall opinion was that early phases of change should be non-punitive and about supporting best practices.

Conclusion

The consultations proved to reveal valuable information that can be used to inform the development of this practicum project. The details provided by the Peel Public Health key informant can be used to begin the development of a similar program in the Eastern Health region. Given that there is very little data to describe the true extent of any actual vaccine storage and handling issues in the population of Newfoundland General Practitioners, a thorough needs assessment is important. The consultations with CDC staff revealed that what is most needed is concrete evidence. Until there is solid data available that indicates a true concern, it would be difficult to drive a significant change.

The audit tool provided by the informant from Peel could be modified for use in data collection in Newfoundland. CDC staff with Eastern Health felt that the program offered in the Peel Region would be a beneficial program for Newfoundland in the future, once a better picture of existing issues is achieved. Based on this, recommendations can be made for future direction to take to meet a long-term goal of fully supporting best practice procedures in the general practice population.

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Appendix A: Interview Questions for Peel Public Health Informant

- 1) How are the vaccine storage and handling practices monitored?
- 2) Who administers the audit?
- 3) How long has this system been in place?
- 4) Have any formal evaluations taken place since its introduction? If no, have you noticed any improvements?
- 5) If a particular clinic is not meeting the standards, what happens?
- 6) What are some common areas of concern that continue to be noted?
- 7) Can a copy of the program and/or evaluation be provided?
- 8) What resources are used to support proper vaccine storage and handling practices?
- 9) Is this system well received by physicians? Has there ever been resistance?
- 10) How many inspections are completed each year and how many nurses are necessary to complete the process?

Appendix B: Health Research Ethics Authority Screening Tools

Peel Public Health Consultation:

Appendix B: Health Research Ethics Authority Screening Tool

	Question	Yes	No
1.	Is the project funded by, or being submitted to, a research funding agency for a research grant or award that requires research ethics review		X
2.	Are there any local policies which require this project to undergo review by a Research Ethics Board?		X
	IF YES to either of the above, the project should be submitted to a Research Ethics Board. IF NO to both questions, continue to complete the checklist.		
3.	Is the primary purpose of the project to contribute to the growing body of knowledge regarding health and/or health systems that are generally accessible through academic literature?		X
4.	Is the project designed to answer a specific research question or to test an explicit hypothesis?		X
5.	Does the project involve a comparison of multiple sites, control sites, and/or control groups?		X
6.	Is the project design and methodology adequate to support generalizations that go beyond the particular population the sample is being drawn from?		X
7.	Does the project impose any additional burdens on participants beyond what would be expected through a typically expected course of care or role expectations?		X
LINE A: SUBTOTAL Questions 3 through 7 = (Count the # of Yes responses)		0	
8.	Are many of the participants in the project also likely to be among those who might potentially benefit from the result of the project as it proceeds?		X
9.	Is the project intended to define a best practice within your organization or practice?		X
10.	Would the project still be done at your site, even if there were no opportunity to publish the results or if the results might not be applicable anywhere else?	X	
11.	Does the statement of purpose of the project refer explicitly to the features of a particular program, Organization, or region, rather than using more general terminology such as rural vs. urban populations?	X	
12.	Is the current project part of a continuous process of gathering or monitoring data within an organization?		X

LINE B: SUBTOTAL Questions 8 through 12 = (Count the # of Yes responses)		2	
	SUMMARY See Interpretation Below		

Interpretation:

The sum of Line B is greater than Line A and so the most probable purpose of this consultation is quality/evaluation and likely does not require review by an ethics board. The purpose of this consultation involves gathering information specific to the features of a program offered through the Peel Public Health department and has not been designed to answer specific research questions.

Communicable Disease Control Colleagues Consultation

	Question	Yes	No
1.	Is the project funded by, or being submitted to, a research funding agency for a research grant or award that requires research ethics review		X
2.	Are there any local policies which require this project to undergo review by a Research Ethics Board?		X
	IF YES to either of the above, the project should be submitted to a Research Ethics Board. IF NO to both questions, continue to complete the checklist.		
3.	Is the primary purpose of the project to contribute to the growing body of knowledge regarding health and/or health systems that are generally accessible through academic literature?		X
4.	Is the project designed to answer a specific research question or to test an explicit hypothesis?		X
5.	Does the project involve a comparison of multiple sites, control sites, and/or control groups?		X
6.	Is the project design and methodology adequate to support generalizations that go beyond the particular population the sample is being drawn from?		X
7.	Does the project impose any additional burdens on participants beyond what would be expected through a typically expected course of care or role expectations?		X
LINE A: SUBTOTAL Questions 3 through 7 = (Count the # of Yes responses)		0	
8.	Are many of the participants in the project also likely to be among those who might potentially benefit from the result of the project as it proceeds?		X
9.	Is the project intended to define a best practice within your organization or practice?		X
10.	Would the project still be done at your site, even if there were no opportunity to publish the results or if the results might not be applicable anywhere else?	X	
11.	Does the statement of purpose of the project refer explicitly to the features of a particular program, Organization, or region, rather than using more general terminology such as rural vs. urban populations?	X	
12.	Is the current project part of a continuous process of gathering or monitoring data within an organization?	X	
LINE B: SUBTOTAL Questions 8 through 12 = (Count the # of Yes responses)		3	
	SUMMARY See Interpretation Below		

Interpretation:

The sum of Line B is greater than the sum of Line A; therefore the purpose of this consultation is likely related to quality and evaluation, rather than research. This consultation was completed to gather details specific to a local population of general practices, and gain input into the development of a protocol to evaluate the cold chain activities in the general practice area.

Appendix C: Interview Questions for Communicable Disease Control Colleagues

- 1) What are some concerns that you have related to the management of vaccine in the general practice area?
- 2) What are the current resources available to educate and promote adherence to the cold chain?
- 3) What is the current process for a GP to report a cold chain failure?
- 4) How exactly is cold chain monitored in the Public Health setting?
- 5) What would be some important components to include in a monitoring and education system for general practice staff?
- 6) Data collected related to Peel Public Health vaccine storage and handling program will be shared:
 - Are there any particular components of this program that you think would be helpful in the Newfoundland general practice area?
 - What particular components would be difficult to implement?
 - Are there any factors not considered in this program that you think should be included in this practicum project?
- 7) How could participation in data collection and education be promoted in this population?

Appendix D: Summary of Data Collected from Peel Public Health

Program Specifics:

- The vaccine storage and handling practices of all facilities that house publically funded vaccine products are extensively monitored by the PHNs working with Peel Public Health (PPH). The Ministry of Health and Long Term Care have mandated a routine, annual inspection of all vaccine fridges in order to help alleviate vaccine wastage due to cold chain failures. In addition to completing these regular audits, PPH has also created a process that provides regular education and training to vaccine providers, and monitors vaccine fridge temperatures all year long. PPH employs four nurses in full time positions for the completion of over 600 audits each year. These nurses also have responsibilities in providing education to staff in need. Extra, temporary nurses are hired during the influenza vaccine season as more facilities are housing vaccine at this time and therefore there is an increase in necessary inspections.
- The process begins with a letter that is sent to each clinic due an inspection. This letter serves to notify the clinic staff that an inspection will occur within the next 12 weeks. The clinic is given a period of time to call and arrange an appointment; if no appointment is made in advance, then the inspection will occur at the PHNs convenience.
- A standardized checklist is used province-wide in Ontario to audit the storage and handling compliance. The checklist is scored on Pass, Fail, or Conditional, and guidelines are in place to inform the overall score. All sections of the auditing checklist must be passed in order to receive a passing grade.

- The various components assessed in the audit checklist are based on the recommendations supplied by the Ministry of Health and Long Term Care in Ontario, which are in line with the recommendations provided by the Public Health Agency of Canada.
- This process has been in place for a long period of time, however became the responsibility of PHNs in 2005. The PHNs were well situated to be able to complete these inspections, as they were already responsible for processing and filling vaccine orders from these facilities. The facilities that typically store vaccine products in the Peel Region include Public Health clinics, General Practice clinics, Long Term Care Facilities, and more recently, Pharmacies.
- If an annual inspection is passed, no further actions are taken until the next routine audit. When an inspection is failed, the vaccine is removed from the facility. The facility then is required to complete storage and handling education. The facility does not receive any further vaccine orders until this education is complete and the inspection has been passed.
- A conditional grade is occasionally given if the fridge is not meeting all standards, however has not been putting the vaccine products at significant risk. When a conditional grade is received, a temporary hold is placed on vaccine orders until the identified issues have been resolved.
- PPH ensures the maintenance of appropriate temperatures by requiring each facility to install an electronic data logger. When a facility notes a temperature that is outside of the approved range, the Vaccine Management Team with PPH must be notified immediately. In the majority of the cases, the vaccine must be

returned to the vaccine depot. Temperatures must continue to be monitored in the fridge, and when there are 72 hours of appropriate temperatures, the vaccine is returned.

- A copy of the temperatures recorded with the data logger must be submitted with each monthly order of vaccine products. The team reviews this data and if inappropriate temperatures are observed, a temporary hold is placed on all vaccine orders to that particular facility. When a recording of a minimum of 72-hours of appropriate temperatures is received by PPH, the hold is lifted and the facility is permitted to store vaccine again.
- Whenever there is a vaccine cold chain failure, the total cost of all impacted vaccine products are calculated. A letter is then sent to the facility detailing the total financial loss due to the failure. The facility is not required to pay this amount, but it does help serve to promote the importance of maintaining adequate storage and handling procedures. Each month, the five facilities with the highest calculated wastage are required to participate in additional education.

Concerns:

- The PPH informant was unaware of any formal evaluations that have occurred since the initiation of the auditing program. Since 2005, PPH has tracked cold chain failures on a spreadsheet. These failures continue to occur, however are becoming less frequent. Human errors are less frequently the cause of a cold chain failure; instead, the most common cause has been linked to the use of a bar-style fridge. The second most common error is related to a malfunctioning data logger, or an improperly installed data logger.

Resources

- The Vaccine Management Team working with PPH are available to aid in training new staff members in proper procedures and can be contacted via telephone or email to answer any questions.
- An online package exists with extensive information on vaccine storage and handling procedures. This package can be found at:
<http://www.peelregion.ca/health/professionals/vaccine-storage/>
- A copy of the provincial guidelines is required to be present at each site. These guidelines can be printed from:
http://www.health.gov.on.ca/en/pro/programs/publichealth/flu/uiip/prequalification/uiip_pg_guidelines_2012_en.pdf

Appendix E: Summary of Data Collected from Communicable Disease Control Colleagues

Concerns:

- Primary identified concern is inadequate or non-existent temperature monitoring.

One interviewee reported that telephone contact was made to many general practice clinics after a power outage in January 2014 left vaccine exposed to warm temperatures for a significant period of time. No specific statistics could be reported but the individual recalled that fewer than 50% of clinics had a thermometer in place at that time.

- The use of bar-style fridges was a significant concern with each interviewee.
- There were no formal observations to report, but multiple interviewees expressed concern that fridges were likely not used exclusively for vaccine products.
- There is likely a significant underreporting of cold chain failures and vaccine wastage. GPs are requested to complete an occurrence form and submit a vaccine wastage report with each cold chain failure, however very few of these are received. When the telephone calls were made in January 2014, any clinic that had been impacted by the power loss was requested to return all vaccine products to the depot so that it could be replaced. There was only a 20% compliance with this request and vaccine tally forms indicated that the potentially expired vaccine products were still being used.
- Each Public Health depot is available to be used as a back-up plan in cases of approaching inclement weather. The vaccine is able to be sent back to the depot

for protection and can then be returned to the clinic when the danger has passed.

This service has not been used by any general practice clinic thus far.

Available resources:

- The primary source of information comes from the Public Health Agency of Canada national guidelines. All sites that store vaccine are encouraged to have a copy of this available, along with a copy of the Provincial Immunization Manual, which also has some details related to cold chain.
- The contact information of CDC staff members is known by each clinic and they are available to provide guidance as necessary.
- There are some handouts available such as a checklist, and a magnet that can be affixed to each fridge to give a visual reminder of appropriate cold chain procedures.

How cold chain is monitored in Public Health program:

- In the Public Health program the vast majority of refrigerators are purpose built. These fridges contain a graph data logger that monitors temperatures 24-hours a day. The fridge has an alarm attached that sounds when power is lost and when temperatures are close to the lower and upper limits of the recommended range. This alarm is connected to the Bio-Medical department with Eastern Health and they will respond with issues arise after hours. When the alarm sounds during normal working hours, the temperature must be monitored every 10-minutes by the nurse responsible for vaccine management. If temperatures rise or drop too close to the accepted limits, the vaccine is packed in insulated containers and returned to the depot.

- There are a small amount of bar-style fridges used within the program at very small sites. These fridges are monitored via an electronic data logger that is also alarmed to Bio-Medical.
- If a cold chain failure occurs, an occurrence report must be completed and submitted to CDC staff for advice. If vaccine has been frozen, it is considered expired. A wastage report is completed and all impacted vaccine is returned to the depot. If vaccine has been exposed to warmer temperatures, the product manufactures are contacted for further advice. Typically, shorter duration exposures of less than 24-hours are simply labeled with 'cold chain break' and moved to the front of the fridge for quick usage. An exposure of longer than 24-hours often results in expiration of the vaccine and it is considered wastage. If vaccine that has already been labeled with 'cold chain break' is involved in another exposure, it results in wastage.
- Weekly temperature reports from each refrigerator are sent to CDC staff and reviewed.
- Public Health Managers use a checklist to audit each vaccine fridge every 6 months.

Creation of cold chain monitoring and education system in general practice:

Reaction to Peel Public Health program:

- The overall opinion on the Peel Public Health program was that it was a very inclusive program that would be a great long-term goal for NL. The inspection tool was identified as the most beneficial part of the program. Providing each

clinic with the details of the total cost of the vaccine in the fridge was considered an appropriate way to promote the importance of proper vaccine storage and handling. Creating an education package was also voiced as an important way to support appropriate practices.

- Requiring the submission of temperatures with each vaccine order was considered an excellent way to ensure temperature monitoring was occurring, however this would be a difficult policy to pass at this time. Another issue that would be difficult is removing vaccine or refusing the delivery of vaccine due to cold chain failure.
- With no official data available at this time, the auditing tool plus some basic education components were most valued.

Input for creation of auditing tool in NL:

- In the short-term, a tool that could be used to collect data would be very valuable.
- Most interviewees also felt that the promotion of the completion of vaccine wastage reports and appropriate temperature monitoring were significant priorities. Encouraging the creation of a plan to protect vaccine during periods of power loss and reiterating the importance of maintaining the cold chain were also identified.

Promoting participation of general practice staff

- Right now, there is no solid data that indicates the true existence of a problem. Starting small with data collection and the provision of resources that are meant to support best practices would be a good starting point in the short term.

- Once there is a better indicator of the actual issue, more interventions can be completed, similarly to what Peel Public Health is doing.
- Incentives for participation were discussed and included: offering continuous learning hours for completion of vaccine storage and handling training; providing good quality electronic data loggers; and offering a certificate if fridge inspection is passed.
- Involving the Community Medical Advisory Committee would be a necessity in promoting the participation of local GPs. Notifying this committee of the methods for initial data collection would be a good start, however if policies were going to change and impact the way GPs practice, then extensive involvement of the committee would likely be necessary. This would be in the long-term.

Appendix F: Letter Used by Peel Public Health



The Region of Peel is the proud recipient of the National Quality Institute Of Excellence, Quality; the National Quality Institute Canada Award of Excellence Gold A Healthy Workplace; and a 2008 IPAC/Deloitte Public Sector Leadership Gold A

Insert date

Dear Vaccinator,

As per the Ontario Public Health Standards (2008), the Ministry of Health and Long Term Care (MOHLTC) mandates that Public Health Units inspect all premises where publicly funded vaccines are stored, at least once annually. Your annual fridge inspection is now due. A Peel Public Health Nurse (PHN) will be contacting you within the next 12 weeks to book a time for your annual inspection or feel free to call us at 905-791-7800 x 2840 to book a date and time that is convenient for you.

To prepare for the inspection, you are asked to review and complete the attached **MOHLTC Vaccine Cold Chain Maintenance Inspection Report** including the **inventory section** prior to the scheduled inspection. You will be asked to provide these completed forms to the PHN at the time of inspection.

During your inspection, the public health nurse will be evaluating the vaccine storage and handling practices within your facility based on the MOHLTC Vaccine Storage and Handling Protocol (2012). Education and support to resolve any identified concerns will be provided and your inspection results will be reviewed with you at the end of the inspection.

If you have any questions, please call at 905-791-7800 ext. 2840.

Thank you for your time and assistance.

Colleen Comerford
Supervisor, Vaccine Management and Physician Information
Peel Public Health

Appendix G: Peel Public Health Inspection Tool



Ontario

Ministry of Health
and Long-Term CarePublic Health Protection
and Prevention Branch**Vaccine Cold Chain Maintenance
Inspection Report**

Client ID (if applicable)		Type of inspection <input type="checkbox"/> Initial <input type="checkbox"/> Re-inspection no.:		Date of inspection (yyyy/mm/dd)	
Name of Premises			Premises Contact Name (First name, Last name)		
Telephone no. (include area code)		Email		Fax no. (include area code)	
Address					
Building No.		Street Name		Suite/Apt. Number	
Lot/Concession/Rural Route		City/Town		Postal Code	
Number of refrigerators in this premises		This inspection is for refrigerator no./ID		Temperature monitoring device <input type="checkbox"/> Max-min thermometer <input type="checkbox"/> Chart recorder <input type="checkbox"/> Data logger <input type="checkbox"/> Other: _____	
Type of Refrigerator <input type="checkbox"/> Bar style <input type="checkbox"/> Domestic <input type="checkbox"/> Purpose-built <input type="checkbox"/> Alarmed		Age of Refrigerator <input type="checkbox"/> 0 yrs to <1yr <input type="checkbox"/> 1 yr to <5yrs <input type="checkbox"/> 5 yrs to <10 yrs <input type="checkbox"/> >10 yrs			
Premises type					
<input type="checkbox"/> Physician office (FP solo)		<input type="checkbox"/> Long-term care home		<input type="checkbox"/> Nursing agency	
<input type="checkbox"/> Physician office (Ped solo)		<input type="checkbox"/> Hospital		<input type="checkbox"/> Public health unit	
<input type="checkbox"/> Physician office (FP group)		<input type="checkbox"/> Community Health Centre		<input type="checkbox"/> School	
<input type="checkbox"/> Physician office (Ped group)		<input type="checkbox"/> Correctional facility		<input type="checkbox"/> First Nations facility	
				<input type="checkbox"/> Retirement home	
				<input type="checkbox"/> Other: _____	

*Rating: P - Pass C - Conditional F - Fail

1. Vaccine Refrigerators Temperature and Readings	Compliant? ✓ if Yes	Strategies	*Rating
a. Temperature monitoring device is present and is able to record maximum, minimum and current temperatures	<input type="checkbox"/>	<input type="checkbox"/> Premises given a temperature monitoring device or advised to obtain a temperature monitoring device <input type="checkbox"/> Conducted a cold chain incident inspection <input type="checkbox"/> Implemented troubleshooting measures	
b. Current temperature of refrigerator using premises' temperature monitoring device _____ °C Current temperature of refrigerator using public health unit's temperature monitoring device _____ °C c. Temperature variance between public health unit's temperature monitoring device and premises' temperature monitoring device is no greater than +/- 2°C (Note: the degree of variability is dependent on the devices that are being checked for accuracy)	<input type="checkbox"/>	<input type="checkbox"/> Temperature variance between public health unit's temperature monitoring device and premises' temperature monitoring device was +/- _____ °C: <input type="checkbox"/> Replaced premises' temperature monitoring device's battery <input type="checkbox"/> Accuracy of the premises' temperature monitoring device was checked using the slush test <input type="checkbox"/> Replaced premises' temperature monitoring device <input type="checkbox"/> Conducted a cold chain incident inspection <input type="checkbox"/> Implemented troubleshooting measures	<input type="checkbox"/> P <input type="checkbox"/> C <input type="checkbox"/> F
d. Maximum-minimum thermometer sensor properly located (if applicable)	<input type="checkbox"/>	<input type="checkbox"/> Placed maximum-minimum thermometer sensor on the middle shelf inside an empty vaccine box <input type="checkbox"/> Labelled the vaccine box as empty <input type="checkbox"/> Conducted a cold chain incident inspection <input type="checkbox"/> Implemented troubleshooting measures	

Comments: Please remember to change thermometer batteries for transport cooler and vaccine fridge every 6 months.

Client ID/Name of Premises:

Vaccine Cold Chain Maintenance Inspection Report – Page 2

*Rating: P - Pass C - Conditional F - Fail			
2. Log Book Review	Compliant? ✓ If Yes	Strategies	*Rating
a. <i>Temperature Log Book</i> present	<input type="checkbox"/>	<input type="checkbox"/> Given <i>Temperature Log Book</i> .	<input type="checkbox"/> P <input type="checkbox"/> C <input type="checkbox"/> F
b. Maximum, minimum and current temperatures are checked twice daily and documented in the <i>Temperature Log Book</i>	<input type="checkbox"/>	<input type="checkbox"/> Instructed to record maximum, minimum and current temperatures twice daily (once in the morning and once in the afternoon) and the time the temperatures were taken in <i>Temperature Log Book</i> <input type="checkbox"/> Conducted a cold chain incident inspection	
c. Maximum, minimum and current temperatures are maintained between +2°C to +8°C	<input type="checkbox"/>	<input type="checkbox"/> Instructed premises to notify the public health unit when temperatures are outside the required range. <input type="checkbox"/> Conducted a cold chain incident inspection <input type="checkbox"/> Implemented troubleshooting measures <input type="checkbox"/> Suspended vaccine ordering for ____ days	
d. Maximum-minimum thermometer is being reset twice daily (if applicable)	<input type="checkbox"/>	<input type="checkbox"/> Provided education regarding the importance of resetting the maximum-minimum thermometer twice daily after recording minimum and maximum temperatures <input type="checkbox"/> Conducted a cold chain incident inspection	
e. Office staff demonstrates resetting or downloading data from the temperature monitoring device	<input type="checkbox"/>	<input type="checkbox"/> Provided temperature monitoring device resetting instructions/demonstration <input type="checkbox"/> Conducted a cold chain incident inspection	
f. Office staff demonstrates reading temperature monitoring device	<input type="checkbox"/>	<input type="checkbox"/> Provided temperature monitoring device reading instructions/demonstration <input type="checkbox"/> Conducted a cold chain incident inspection	
Comments: Please keep temperature logs onsite for minimum 3 years.			
3. Ministry Cold Chain Material	Compliant? ✓ If Yes	Strategies	*Rating
a. <i>How to monitor your refrigerator temperature</i> magnet is mounted on exterior of vaccine refrigerator	<input type="checkbox"/>	<input type="checkbox"/> Given <i>How to monitor your refrigerator temperature</i> magnet and placed on exterior of vaccine refrigerator	<input type="checkbox"/> P <input type="checkbox"/> C <input type="checkbox"/> F
b. <i>Protect your vaccines – Protect your patients</i> poster is mounted on exterior of vaccine refrigerator	<input type="checkbox"/>	<input type="checkbox"/> Given <i>Protect your vaccines – Protect your patients</i> poster and placed on exterior of vaccine refrigerator	
c. <i>Vaccine Storage and Handling Guidelines</i> is on hand	<input type="checkbox"/>	<input type="checkbox"/> Given <i>Vaccine Storage and Handling Guidelines</i> .	
d. Insulated vaccine container(s) with packing material and a temperature monitoring device is: i. present ii. used when transporting vaccines iii. used for contingency planning	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> Given or advised to obtain insulated vaccine container(s) with packing material (i.e. ice packs) and temperature monitoring device(s)	
Comments: .			

Client ID/Name of Premises:

Vaccine Cold Chain Maintenance Inspection Report – Page 3

*Rating: P - Pass C - Conditional F - Fail			
4. Organization of Refrigerator	Compliant? ✓ If Yes	Strategies	*Rating
a. Vaccines are stored in the middle of the refrigerator away from the walls, floors and cold air vents	<input type="checkbox"/>	<input type="checkbox"/> Placed vaccines in the middle of the refrigerator away from the walls, floor and cold air vents	<input type="checkbox"/> P <input type="checkbox"/> C <input type="checkbox"/> F
b. Vaccines are stored on internal shelves of the refrigerator (not stored in the door or in drawers)	<input type="checkbox"/>	<input type="checkbox"/> Removed vaccines from the refrigerator door and placed in the middle of the refrigerator	
c. Vaccines are organized by product	<input type="checkbox"/>	<input type="checkbox"/> Organized vaccines by product	
d. Space is maintained between each vaccine product	<input type="checkbox"/>	<input type="checkbox"/> Ensured space is maintained between vaccine products to allow for air circulation <input type="checkbox"/> Removed excess vaccine <input type="checkbox"/> Instructed to obtain larger refrigerator to accommodate required stock or instructed to order and stock less vaccine	
e. Vaccines that sensitive to light are protected	<input type="checkbox"/>	<input type="checkbox"/> Protected the vaccines that are sensitive to light	
f. Vaccine with the longest expiry dates are placed behind shorter-dated vaccines	<input type="checkbox"/>	<input type="checkbox"/> Placed vaccine with the longest expiry dates behind shorter-dated vaccines	
g. Use vaccine that has been previously exposed to a cold chain incident first	<input type="checkbox"/>	<input type="checkbox"/> Instructed to use vaccines that have been previously exposed to a cold chain incident first	
h. Only current dated vaccine present in refrigerator (no expired vaccine)	<input type="checkbox"/>	<input type="checkbox"/> Returned expired vaccines to the public health unit or OGPMS	
i. Only vaccines (no food, beverages and/or medical/laboratory specimens) are stored in the refrigerator	<input type="checkbox"/>	<input type="checkbox"/> Removed food, beverages and/or medical/laboratory specimens from the vaccine refrigerator	
j. Water bottles placed on empty shelves and in refrigerator door	<input type="checkbox"/>	<input type="checkbox"/> Placed water bottles in the refrigerator's empty shelves and doors	
k. Refrigerator is of sufficient size to accommodate required stock	<input type="checkbox"/>	<input type="checkbox"/> Instructed to obtain larger refrigerator to accommodate required stock or instructed to order and stock less vaccine	
l. No more than a 1 month stock is on hand	<input type="checkbox"/>	<input type="checkbox"/> ___ months stock is on hand, inventory control measures have been taken by the public health unit	
Comments:			
5. Vaccine Handling Review	Compliant? ✓ If Yes	Strategies	*Rating
a. Office staff know to remove vaccine from refrigerator for immediate use only	<input type="checkbox"/>	<input type="checkbox"/> Instructed to only remove vaccines from the refrigerator for immediate use	<input type="checkbox"/> P <input type="checkbox"/> C <input type="checkbox"/> F
b. Multi-dose vials (if present in vaccine refrigerator) are marked with the date opened and discarded within 30 days or as per manufacturer's instructions	<input type="checkbox"/>	<input type="checkbox"/> Instructed to mark multi-dose vials with the date opened and dispose as per manufactures' instructions	
Comments:			

Vaccine Cold Chain Maintenance Inspection Report – Page 4

		*Rating:	P - Pass	C - Conditional	F - Fail
6. General	Compliant? ✓ If Yes	Strategies	*Rating		
a. Refrigerator should be optimally placed:		<input type="checkbox"/> Instructed to relocate refrigerator:			
i. In an area that is well ventilated	<input type="checkbox"/>	<input type="checkbox"/> To an area that is well ventilated			
ii. Out of direct sunlight	<input type="checkbox"/>	<input type="checkbox"/> Out from direct sunlight			
iii. Away from external walls	<input type="checkbox"/>	<input type="checkbox"/> Away from external walls			
b. Refrigerator door OR refrigerator room is locked at the end of the day	<input type="checkbox"/>	<input type="checkbox"/> Instructed to install lock on vaccine refrigerator or refrigerator room door			
c. Refrigerator electrical outlet is:		<input type="checkbox"/> Ensured refrigerator's electrical outlet is covered by metal cage or is not easily accessible			
i. Covered by metal cage; OR	<input type="checkbox"/>	<input type="checkbox"/> Given 'do not unplug' sticker and placed beside refrigerator electrical outlet			
ii. Not easily accessible; OR	<input type="checkbox"/>				
iii. Accessible but the <i>Do not unplug</i> sticker sign is posted beside refrigerator electrical outlet	<input type="checkbox"/>				
d. Refrigerator maintenance is performed:		<input type="checkbox"/> Instructed to:			
i. Freezer has been defrosted and ice is < 1 cm thick	<input type="checkbox"/>	<input type="checkbox"/> Defrost refrigerator and move vaccines to a monitored and insulated container while defrosting			
ii. Back (including the coils, if necessary), top and sides are cleaned and dusted	<input type="checkbox"/>	<input type="checkbox"/> Dust and clean the back (including the coils, if necessary), top and sides of the refrigerator			
iii. Door is sealed tightly and properly and has:		<input type="checkbox"/> Replace door seals			<input type="checkbox"/> P
• Adequate door seals	<input type="checkbox"/>	<input type="checkbox"/> Install Velcro door latch			<input type="checkbox"/> C
• Velcro door latch installed (if required)	<input type="checkbox"/>	<input type="checkbox"/> Tighten door hinges			<input type="checkbox"/> F
• Tight door hinges					
e. One office staff member is responsible for vaccine management	<input type="checkbox"/>	<input type="checkbox"/> Assigned one office member and a backup person the responsibility of vaccine management			
f. Office staff know to contact public health unit immediately if vaccines are exposed to temperatures below +2°C or above +8°C	<input type="checkbox"/>	<input type="checkbox"/> Instructed to:			
		<input type="checkbox"/> Report cold chain incidents to the public health unit			
		<input type="checkbox"/> Place vaccine involved in a cold chain incident in a bag marked 'Do Not Use'			
		<input type="checkbox"/> Move this bag of vaccines into a monitored refrigerator or monitored insulated container until evaluated by the public health unit			
g. Office staff know to return expired, damaged and wasted vaccines to the public health unit (in the City of Toronto – OGPMS S) for disposal	<input type="checkbox"/>	<input type="checkbox"/> Instructed to return expired vaccines to the public health unit or OGPMS S for disposal			
h. Contingency (emergency) plan developed in the event of a vaccine refrigerator malfunction, power failure or other emergencies	<input type="checkbox"/>	<input type="checkbox"/> Discussed a contingency plan			
		<input type="checkbox"/> Premises instructed to establish a contingency plan.			
Comments: Please report any temperatures below +2.0 deg C or above +8.0 deg C to Peel Health immediately at 905-791-7800 ext 2840. Stop use of all vaccines until further recommendations have been provided by Peel Health. Place sign on fridge "Do not use vaccines" or the Cold Chain Failure magnet.					

Vaccine Cold Chain Maintenance Inspection Report – Page 5

Inventory			
Vaccine	Cost per dose	No. of Doses	Total Value
Act-Hib®	\$37.79		\$ 0.00
Adacel®	\$32.33		\$ 0.00
BCG Vaccine	\$16.94		\$ 0.00
Boostrix®	\$27.00		\$ 0.00
Engerix B® Adolescent/ Adult	\$20.75		\$ 0.00
Fluviral®	\$10.00		\$ 0.00
Gardasil®	\$134.95		\$ 0.00
Havrix® Adult	\$42.45		\$ 0.00
HyperRAB®	\$274.50		\$ 0.00
Imogam® Rabies	\$264.84		\$ 0.00
Imovax® Polio	\$38.64		\$ 0.00
Imovax® Rabies	\$196.90		\$ 0.00
Menactra®	\$123.63		\$ 0.00
Menjugate®	\$89.00		\$ 0.00
Menomune®	\$144.74		\$ 0.00
M-M-R® II	\$28.43		\$ 0.00
Pediacel®	\$46.81		\$ 0.00
Pneumovax® 23	\$16.80		\$ 0.00
Prevnar®	\$83.75		\$ 0.00
Prevnar® 13	\$86.26		\$ 0.00
Priorix®	\$27.76		\$ 0.00
Priorix Tetra™	\$86.01		\$ 0.00
Quadracel®	\$35.61		\$ 0.00
RabAvert®	\$171.88		\$ 0.00
Recombivax HB® Adolescent/Adult	\$21.35		\$ 0.00
Recombivax HB® Paediatric	\$10.80		\$ 0.00
Recombivax HB® Renal	\$175.00		\$ 0.00
Rotarix™	\$78.57		\$ 0.00
Synflorix™	\$92.13		\$ 0.00
Td	\$18.91		\$ 0.00
Td Polio	\$53.66		\$ 0.00
Tubersol®	\$11.72		\$ 0.00
Vaqt® Adult	\$42.45		\$ 0.00
Vaqt® Paediatric	\$21.23		\$ 0.00
Varilrix®	\$58.25		\$ 0.00
Varivax® III	\$67.85		\$ 0.00
Vaxigrip®	\$9.25		\$ 0.00
			\$ 0.00
			\$ 0.00
			\$ 0.00
Total value of vaccine in this refrigerator			\$ 0.00

Client ID/Name of Premises:

Vaccine Cold Chain Maintenance Inspection Report – Page 6

Recommendations

Final Results of Inspection (Final Rating)

☐ **Pass**

☐ **Conditional**

☐ **Fail**

Name of Premises

Name of Contact (*First name, Last name*)

Signature

Name of Public Health Unit

Name of Inspector (*First name, Last name*)

Signature

Peel Public Health

Appendix H: Grading Criteria

‘Pass’ Criteria

- A purpose-built, domestic, or bar refrigerator, designated for vaccine storage is on-site and functioning
- Digital max-min thermometer is able to record current, maximum, and minimum temperatures
- Documented at least 72 hours of temperatures (current, max and min) between +2.0°C and +8.0°C
- Freezer compartment is free of ice build-up
- Fridge size is adequate to store vaccines

‘Fail’ Criteria

- No refrigerator designated for vaccines
- No digital max-min thermometer (unable to document current, max and min temperatures)
- No documentation of temperatures
- Facility has not maintained 72 hours of consecutive temperatures between +2.0°C and + 8.0°C
- Greater than +/- 2.0°C variance in thermometer readings
- Ice build-up is greater than 1 cm in freezer compartment

Appendix I: Eastern Health Inspection Checklist

Checklist for Safe Vaccine Storage and Handling

We have a designated vaccine coordinator.

We have a designated back-up vaccine coordinator.

All staff receives ongoing training.

All new staff is trained at an appropriate level in proper storage and handling practices.

A vaccine inventory log is maintained that documents:

5 a)	Vaccine name and number of doses received
5 b)	Date the vaccine was received
5 c)	Arrival condition of vaccine
5 d)	Initials of person unpacking shipment
5 e)	Vaccine manufacturer and lot number
5 f)	Vaccine expiration date
5 g)	Type of container of each vaccine
5 h)	Number of doses used
5)	Number of doses remaining

Our refrigerator for vaccines is either a purpose-built or a domestic frost-free style, NOT a bar-style. The freezer compartment has a separate exterior door.

We do NOT store any food, drink or specimens in the refrigerator or freezer.

We store vaccines in the middle of the refrigerator or freezer, and NOT in the door.

We stock and rotate our vaccine supply so that the newest vaccine of each type (with the longest expiration date) is placed behind the vaccine with the shortest expiration date.

We check vaccine expiration dates and use those that will expire soonest first.

We post a sign on the refrigerator door showing which vaccines should be stored in the refrigerator and which should be stored in the freezer.

We always keep a min/max thermometer or data logger in the refrigerator and freezer.

The temperature in the refrigerator is maintained between + 2°C and + 8°C.

We keep extra containers of water in the refrigerator in appropriate areas.
The temperature in the freezer is maintained at -15°C or colder.
We keep ice packs and other ice-filled containers in the freezer.

We record the minimum and maximum temperatures for the refrigerator and freezer, and the room temperature twice daily, first thing in the morning and at clinic closing time.
We know whom to call if the temperature is out of range.

We calibrate the thermometer using the slush test at least once a year and change batteries in thermometer or data loggers on a regular basis.
We defrost the refrigerator regularly.
We have a Do Not Unplug sign next to the refrigerator's electrical outlet.
We check that the door is properly closed and sealed.
In the event of a refrigerator failure, we take the following steps:

23 a)

We assure that the vaccines are maintained under appropriate conditions

23 b)

We mark vaccines as having been exposed and separate them from undamaged vaccines.

23 c)

We note the refrigerator or freezer temperature and the ambient temperature and then always contact the local public health office or immunization program* to determine how to handle the affected vaccines.

23 d)

We follow the local public health office or immunization program* instructions. If useable, we mark the vials with the revised expiration date provided by the program.

We have a detailed written protocol for routine and urgent vaccine storage and handling.

Appendix C – Proposal for a review of the cold chain practices in general practice
clinics

Review of Vaccine Storage and Handling Practices in the General Practice Population: a

Proposal

Amy Barnes B.N., R.N., CCHN(C)

Memorial University

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Appendix D – Telephone Script

Appendix E – Structured Interview with Physicians

Appendix F – Inspection Checklist

Appendix G – Health Research Ethics Authority Screening Tool

Background

Vaccines are sensitive biological products that are vulnerable to a variety of environmental conditions, including exposure to extreme temperatures and light (Public Health Agency of Canada [PHAC], 2007). Maintaining vaccines within a cold chain is important in preserving vaccine quality (Eastern Health, 2010; PHAC). The term cold chain refers to the maintenance of appropriate conditions through each link in the chain from the manufacture, transport, storage, handling, and administration of vaccine products. Publically funded vaccines that are used in the province of Newfoundland need to be carefully maintained in a temperature range of 2-8°C (Eastern Health). There is much evidence in the literature to suggest that the cold chain is not being maintained in the general practice area (Carr, Byles, & Durrheim, 2010; Haworth, Booy, Stirzaker, Wilkes, & Battersby, 1993; Yuan, Daniels, Naus, & Brcic, 1995). The most common areas of concern include the use of improper refrigerators; inadequate or non-existent temperature monitoring; the storage of extraneous items in the refrigerator along with the vaccine; not assigning a single staff member for maintaining the vaccine; the lack of a back-up power source; and poor knowledge and attitudes of immunizing physicians in regards to the components of the cold chain (Carr et al.; Haworth et al.; Yuan et al.; Welterman, Markic, Thielmann, Gesentives, & Herman, 2014).

Administration of the publically funded vaccination program in Newfoundland is a shared responsibility between the Public Health program and General Practitioners. Within Eastern Health's Public Health program, policies and procedures are in place to ensure the maintenance of the cold chain for all vaccine products. At this time no process exists to audit the compliance with national vaccine storage and handling

recommendations in the general practice setting. However, anecdotal evidence and thesis research completed by O’Keefe (2000) suggest that concerns may be similar to what can be identified in the majority of the literature. This proposed review would provide an opportunity to gather valuable data related to the vaccine storage and handling practices in local general practice clinics, while also allowing for the provision of individual feedback when concerns are noted. With an accurate picture of the current situation, resources can be developed to aid in improving practice, ultimately protecting the integrity of the vaccines offered to the public.

Objectives

The overall goal of this proposed review is to gather information on the overall compliance with cold chain maintenance in the general practice population. The specific objectives are:

- 1) Identify specific areas of concern.
- 2) Identify potential resources to aid in best practice.
- 3) Gain input from physicians on areas of concern and acceptable resources.

Methods

This proposed review will take place over much of the spring and summer of 2015 and will be completed through Eastern Health’s Communicable Disease Control (CDC) division. Data will be collected by group of Master of Public Health students who will visit each participating clinic to interview staff and make observations. A proposed timeline can be found in Appendix A. A potential budget to cover any costs associated with this project can be found in Appendix B.

Participants

The population of interest involves physicians and other staff with vaccine related responsibilities working within general practice clinics in the Eastern Health region. Eastern Health's CDC division maintains a list of approximately 100 clinics that are supplied with publically funded vaccine products through various Eastern Health depots; potential participants will be identified through this list.

Recruitment letters, with an attached information sheet, will be mailed to potential participants. This letter will be mailed out by CDC officials and will contain details about the reasons for the proposed review and the expectations around the review process. A copy of the letter and fact sheet can be found in Appendix C. The reviewer will contact each clinic via telephone to discuss any questions or concerns participants may have, and to obtain permission to visit each clinic. A script for this telephone contact can be found in Appendix D.

Data collection methods and instruments

All data will be collected during a single visit to each participating clinic. The individuals conducting the reviews all have a background in the Public Health field and will consist of some Public Health Nurses and Master of Public Health students. The reviewers will all be provided with a training session of approximately two hours in length to ensure a thorough understanding of methods and instruments involved in this review. There are four parts involved in each clinic visit: reviewing the process and obtaining verbal consent for participation; completing a structured interview with a physician practicing within the clinic; conducting an inspection guided by a checklist; and reviewing the checklist results with a participant to provide applicable feedback.

Upon arriving at a participating clinic the reviewer will provide an overview of exactly what the process involves and again obtain verbal consent to conduct the inspection and complete a short interview. A structured interview will be completed with a physician working in the clinic. The interview questions have been designed to gain insight into the cold chain processes present in their clinic, assess their opinions on any perceived issues, and gain their input on the degree of intervention they would find acceptable, as well as any resources they would be interested in receiving to help in supporting appropriate practice. A copy of the interview questions can be found in Appendix E. Notes will be taken during the interview process.

An inspection of storage and handling will be conducted using a checklist, which can be found in appendix F. The checklist was designed based on a checklist tool mandated by the Ontario Ministry of Health and Long Term Care (Ontario, 2013) for conduction of cold chain inspections across their province, and the National Vaccine Storage and Handling Guidelines for Immunization Providers published by PHAC (2007). The usability of the proposed instrument was addressed in a small pilot of the methods and is reported in a separate document.

The checklist is divided into three sections. Section A of the checklist is used to document the review participation code, number of physicians practicing in the clinic, and the date of the clinic visit. Identifying information will not be written directly on the checklist form. Any identifying demographic information will be recorded on a separate page, matched to the various participation codes. A copy of the demographic data sheet can be found in Appendix F. Section B of the checklist involves questions related to compliance with recommendations that may not be physically observable, such as

whether or not a single individual has been assigned to vaccine maintenance responsibility or if a contingency plan exists for power loss or inclement weather warnings. The final section of the checklist, Section C, involves observation of the vaccine storage facility. This will include taking a measurement of the temperature within the refrigerator with a good quality, calibrated thermometer, and completing a visual inspection of the compliance with vaccine storage and handling recommendations. Throughout the inspection process, the reviewer documents whether or not the criteria are met, and can record comments pertaining to each inspection category, as necessary, in the comments sections. Once the inspection process is complete, the auditor will review the checklist with a staff member from the clinic and provide feedback. Wherever criteria are scored as ‘unmet,’ the reviewer will refer the staff members to the third column in the checklist where there is a list of strategies and guidelines to help improve the identified practice concern. The reviewers will sign the bottom of the form and a copy will be provided to the clinic for their own records. A copy of this form will be made after completion of the clinic visit, and will be sent to the clinic via the mail.

Once the interview and inspection are complete, and any concerns have been discussed with a clinic staff member, the exchange is over. The reviewer would provide the contact information for public health in case the clinic staff would like to follow up and request more information on cold chain maintenance, or other vaccine related questions.

Data Analysis

The notes taken during the structured interview with each physician will be typed and organized. The data will be analyzed for content and organized according to common themes.

The individual checklist data will be made available only to the CDC administration staff. The reviewers will enter the data into an Excel database and analyze with descriptive statistics, summarizing the percentages of clinics meeting each criterion. Any reports that will be made available outside of the CDC administration staff will be presented at the aggregate level only in order to protect the confidentiality and privacy of each participating general practice clinic.

Ethical Considerations

The Health Research Ethics Authority screening tool has been completed for this proposed project and can be found in Appendix G. The results of this tool indicate that ethical approval should not be necessary to proceed with the data collection aspect of the proposed review. The design of this project involves quality control rather than research because it involves the evaluation of the vaccine storage and handling practices, based on established guidelines, in order to identify areas of concern so that adequate systems can be developed to promote best practices in the Eastern Health region.

The Community Medical Advisory Committee will be made aware of the proposed review plans prior to beginning the process. Any concerns they may have with the plan will be addressed prior to implementation. Participating physicians will be made aware that any participation in this proposed review is voluntary, and that they can rescind their participation at any point in the process. Verbal consent will be obtained

prior to visiting each clinic and prior to beginning the interview and inspection process at each clinic. No coercion will be used to obtain the consent of any clinic.

The privacy and confidentiality of each participating clinic will be protected throughout the process. Each reviewer will protect results during travel to and from clinics via a locked bag. Results will then be stored in a locked filing cabinet. The review is being completed in partnership with Eastern Health's CDC division and therefore individual level results will be made available to officials working within this department. All collected results will be compiled into a report and will be shared outside of the CDC department at the aggregate level only to protect the privacy of each general practice clinic. The demographic data sheet with attached participation codes will not be shared beyond Eastern Health's CDC staff.

There may not be any immediate benefits for participating in this project; however, individual feedback will be provided to each participant that could potentially lead to immediate improvement in practices. Participants may also benefit in the long term if the information collected leads to the establishment of future resources. There are also risks associated with participation in this project, namely the reporting of results to CDC officials. The vaccine depot associated with this program is also the one that processes vaccine orders from these clinics and releases the vaccine into their care. If significant concerns were noted at these clinics that could be compromising the vaccine being supplied, the CDC department may wish to follow up. However, the individual feedback provided will give participants the opportunity to take corrective action and make the necessary changes. If any follow up is deemed necessary by the CDC authorities, the confidentiality of participants will continue to be maintained. As well, the

authorities would not be contacting any clinics to take punitive action, rather to work with these participants to address the issues and find acceptable solutions.

Conclusion

The data collected through this review will be valuable in creating a picture of the current vaccine storage and handling practices in general practice clinics within the Eastern Health region of Newfoundland. With the availability of current and accurate data, appropriate resources can be recommended and designed to meet any of the identified needs, such as visual reminders like posters; education and training programs; upgraded equipment; policy changes; and regular auditing to monitor continued cold chain practices. The data collection tools allow the participating General Practitioners to identify their own concerns and provide opinions on resources that would be helpful in their own practice, likely leading to improved participation in the future. The improved storage and handling of vaccines will help to ensure the integrity of the products used to protect the health of the population.

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Appendix A – Proposed Timeline

May 18th – 24th, 2015

- Send letters to general practice clinics
- Train the reviewers
- Prepare materials necessary for the clinic visits

May 25th – 29th, 2015: Initiation of recruitment

- Begin calling each general practice clinic to discuss any questions/concerns and obtain verbal consent to visit clinic.
- Schedule appointment times for clinic visits

June 1st - 26th, 2015: Data collection

- Begin completing reviews in each participating clinic
- Enter checklist data into Excel
- Organize and type all notes taken

June 29th – July 10th, 2015: Analysis of Data

- Analyze checklist data using descriptive statistics
- Complete content analysis on any interview data

July 13th – August 14th, 2015

- Compile report
- Present report to Eastern Health CDC department and any other identified stakeholders (Community Medical Advisory Committee; Provincial CDC department).

Appendix B – Proposed Budget

All cost estimates are approximate

Paper cost: \$0.03/pg; to audit 100 clinics using two copies of the checklist + Letter and Fact Sheet mailed to each clinic: 12-15 pages x 100 packages = 1200 – 1500 pages = **\$36 - \$45**

Postage for each letter/fact sheet: For 100 clinics at \$0.85/stamp = **\$85**

Postage for providing a copy of each checklist to participants: 100 clinics at \$0.85/stamp = **\$85**

Travel across Eastern Health Region: 1000km x \$0.3371/km = **\$337.10**

Overnight hotel stay as necessary: \$120/night x 5-10 nights = **\$600 - \$1200**

Meal reimbursement: \$10/meal x approximately 40 clinics outside of urban region = **\$400**

Long distance calling to all clinics in Eastern Health region: \$0.05/minute for 5 minute call = \$0.25/call x 40 clinics in long distance range = **\$10**

Total: Approximately \$1550 - \$2200

Appendix C – Letter to General Practice Clinics

Communicable Disease Control Division
Public Health
Mount Pearl Square – Community Services
760 Topsail Road
Mount Pearl, NL
A1N 3J5

PHYSICIAN NAME
CLINIC ADDRESS

Your participation is being requested in a review that has been designed to evaluate the vaccine storage and handling practices in General Practice clinics in the Eastern Health Region of Newfoundland. This review has been designed by a Memorial University of Newfoundland student in partial completion of a Master of Nursing degree and is being implemented in partnership with Eastern Health's Communicable Disease Control department.

A small pilot has already taken place to validate the tools that will be used in this review and the Community Medical Advisory Committee has been made aware of the project. Please see the attached information sheet for more details on what this assessment entails.

Participation in this project is voluntary. An auditor will contact you via telephone over the next few weeks to request permission to visit your clinic. Our contact information is listed below if you have any questions or concerns.

Sincerely,

CDC STAFF NAME
CONTACT INFORMATION

Vaccine Storage and Handling Review - Information Sheet

What is the purpose of this review?

- To identify any concerns related to vaccine storage and handling and to inform the development of appropriate resources to address any identified concerns.

Why is this review important?

- Vaccines are sensitive biological products that are vulnerable to a variety of environmental conditions, including exposure to extreme temperatures and light.
- Cold chain maintenance is important in ensuring the maintenance of vaccine integrity to help protect the health of the population and prevent the reemergence of vaccine preventable diseases.
- The rotating power outages in 2014 resulted in significant cold chain failure and large amounts of vaccine loss, highlighting the need for increased attention to appropriate vaccine cold chain practices in all vaccination sites.

What are we asking you to do?

- We will be requesting 15-20 minutes of your time to talk to your staff and make observations of your vaccine storage unit.

What will we do when we arrive?

- Permission will be obtained and the process will be reviewed prior to beginning the inspection process in each clinic.
- A structured interview will be administered to a physician practicing at each clinic.
- The storage unit used for vaccine will be inspected using a checklist tool.
- The results of the inspection will be reviewed with a staff member and feedback will be provided on any areas requiring improvement.
- A copy of this checklist will be provided at the end of the appointment for your own records.

How will we use the results?

- The results will be valuable to assess any areas of concern in the vaccine storage and handling practices.
- Results can be used to inform the recommendation or development of pertinent resources and policies that could aid in supporting appropriate practices.

How will ethical considerations be managed?

- **Participation in this review is voluntary.**
- Your permission will be requested prior to visiting your clinic, and prior to beginning the review process when we arrive at your clinic.

- The Health Research Ethics Authority screening tool indicates that this project is related to evaluation and quality assurance, not research; therefore ethical approval was deemed unnecessary prior to the implementation of this review.
- The Community Medical Advisory Committee has been made aware of this plan.
- Checklist and interview data will be secured in a locked bag during travel to and from clinics and will be stored in a locked filing cabinet when not in use.
- Any reports compiled after data collection will be presented at aggregate level only and will protect individual identities.
- Data collected will be shared with the Communicable Disease Control officials within Eastern Health, with whom this project has been designed.

Who can you contact with further questions?

- Auditor's names.
- Auditors contact information.

Appendix D – Telephone Script

Hello, my name is _____, and I am a Master of Public Health student currently working with the Communicable Disease Control division of Eastern Health. I am following up on the letter that was mailed to your clinic recently with details of a review of the vaccine storage and handling practices in general practice clinics.

I am wondering if you have had a chance to review these details and if you had any questions or concerns?

As described in the information sheet that was mailed to you last week, I'd like to come to your clinic. I should only need 15-20 minutes of your time to complete a short interview, conduct an inspection of your vaccine refrigerator, and provide you with feedback. Are you agreeable for myself (or another reviewer) to visit your clinic to complete this inspection process?

YES: Thank you. When would be the most convenient date and time for me to visit?

NO: Thank you for considering participation. If you change your mind in the near future I can be reached at CONTACT INFORMATION.

Appendix E – Structured Interview with Physicians

1) Can you tell me about the processes used to maintain the cold chain in your practice?

(Vaccine secured in refrigerator until use; monitoring temperatures; single person responsible; etc.)

2) What do you feel are some of the primary areas of concern for vaccine storage and handling? (In your own setting? In general?)

3) What resources do you currently use to inform your practices related to cold chain maintenance? (Are you familiar with the PHAC guidelines?)

4) Are there any types of resources you would be interested in to support the maintenance of adequate storage conditions? (Online modules, webinar, pamphlets, posters, regular audits, etc.)

5) In the province of Ontario, there are mandated annual vaccine storage and handling audits accompanied by regular training and education. While cold chain failures occasionally still occur, they have noted a decrease in failures related to human error.

- If a similar process were to be implemented in this province, but were voluntary in nature, would you participate?

IF YES:

- Who would you accept to complete these audits?
- How frequently would you be agreeable to have your storage facility inspected?

6) Are there any comments you would like to share/address related to vaccine storage and handling?

Appendix F – Inspection Checklist

Section A	
Clinic Participation Code:	Date of Inspection:
	# of physicians practicing in clinic:

Section B			
Recommendation	Met ✓	Unmet ✓	Strategies/Guidelines to improve practice
A single individual has been assigned to vaccine maintenance duties.			- Ensure there is a single individual assigned to monitor and maintain vaccine inventory, with a back-up individual assigned in case the original staff member is unavailable.
			Comments:
All staff members receive regular training on storage and handling guidelines. When? What is the training? How often?			- Regular training and education will ensure that all staff members with vaccine-related responsibilities are aware of recommended protocols.
			Comments:
Vaccine storage and handling reference is present at the clinic. What is the resource? Where is it?			- Detailed, written procedures should be available for reference at all times. - Copy can be printed from http://www.phac-aspc.gc.ca/publicat/2007/nvshg1p-ldemv/pdf/nvshg1p-ldemv-eng.pdf
			Comments:
When vaccines are removed from the refrigerator for purposes other than immediate administration, insulated containers and ice packs are used. Where are the containers/ice packs?			- Use insulated containers whenever vaccine is removed for refrigerator maintenance, transportation of products away from site, or any other reason aside from immediate use. - Pack products in an insulated container in layers: ice packs, barrier, vaccine, temperature monitor, and another barrier that prevents shifting of contents.

Recommendation	Met ✓	Unmet ✓	Strategies/Guidelines to improve practice
			Comments:
Refrigerator has a back-up power supply. What is it?			<p>- Ideally, a refrigerator would have a back-up power source to protect vaccine in cases of power failure.</p> <p>Comments:</p>
A contingency plan is in place to protect vaccine inventory in cases of power loss and inclement weather. What is the plan? Is it in writing? Has it ever been used? If so, how effective was it?			<p>- Ensure back up power source.</p> <p>- Monitor weather forecasts; in cases of weather warnings where power loss is likely, send vaccine to a site with back-up power so that inventory can be protected.</p> <p>Comments:</p>
Cold chain failures are reported to public health			<p>- Report all failures to public health for further instruction.</p> <p>- Continue to maintain vaccine under appropriate conditions.</p> <p>- Label vaccine as having been exposed and separate from undamaged vaccines.</p> <p>- Follow instructions from local public health office: either return vaccine to the depot or mark with revised expiration date.</p> <p>Comments:</p>
When vaccine is expired, damaged, or wasted, it is returned to the vaccine depot.			<p>- Complete a vaccine wastage report when vaccine is damaged and submit to public health.</p> <p>- Send all expired or wasted vaccine to depot while maintaining proper cold chain procedures.</p> <p>Comments:</p>

Section C

Recommendation	Met ✓	Unmet ✓	Strategies/Guidelines to improve practice
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Recommendation	Met ✓	Unmet ✓	Strategies/Guidelines to improve practice
Type of refrigerator: <input type="checkbox"/> Bar-style <input type="checkbox"/> Domestic <input type="checkbox"/> Purpose-built <input type="checkbox"/> Other _____ Age of refrigerator? _____ General appearance:			- Bar-style not recommended due to inability to maintain stable temperature range. - Domestic frost-free OK with separate freezer compartment and regular maintenance. - Purpose-built is the gold standard. Comments:
A temperature-monitoring device is installed and working properly.			- Obtain a temperature monitoring device, preferably a min-max thermometer or a device that can provide continuous monitoring. Comments:
Temperature according to clinic's temperature monitor is within recommended range: _____ Temperature according to auditor's calibrated temperature monitor is within recommended range: _____			- Maintain refrigerator temperature in range of 2°C to 8°C at all times. - Obtain a new temperature monitoring device if reading does not appear to be accurate (+/- 2°C from auditors reading). - Ensure temperature monitor is calibrated. - Notify public health of cold chain failure for further instruction. Comments:
Temperature log is present that shows monitoring of temperatures twice daily			- Temperatures should be monitored twice daily, at clinic opening and prior to closing. - Temperatures should be recorded in a log, either manually or electronically. Comments:
No recorded temperatures on log are outside of 2°C – 8°C			- Maintain refrigerator temperatures within the range of 2°C to 8°C at all times. - Notify public health of cold chain failure for further

Recommendation	Met ✓	Unmet ✓	Strategies/Guidelines to improve practice
			instruction.
			Comments:
Vaccine products are stored in the middle of the refrigerator, on internal shelves.			- Remove vaccine products from refrigerator door. - Do not store vaccine against refrigerator walls.
			Comments:
Vaccines are organized according to product and expiry date.			- Store like products together. - Organize so that products with the longest expiration date are placed behind vaccine with the shortest expiration date.
			Comments:
No expired vaccine products are located in refrigerator.			- Return all expired vaccine products to the vaccine depot, while following cold chain procedures.
			Comments:
No extraneous items present in vaccine fridge.			- Store only vaccine products in the refrigerator – no food, beverages, specimens, or other drugs.
			Comments:
Water bottles are placed on refrigerator door, in drawers, and on any empty shelves.			- Place water bottles in any empty spaces inside the refrigerator to help maintain a stable temperature range.
			Comments:
A maximum of one-month vaccine supply is stored in fridge.			- Housing a maximum of a one-month supply of vaccine can prevent significant loss in the event of a cold chain failure.

Recommendation	Met ✓	Unmet ✓	Strategies/Guidelines to improve practice
			Comments:
Any open multi-dose vials have been labeled with date opened and date is within the past 30-days.			- Multi-dose vials often expire within 30-days of opening. Always label properly according to manufactures' directions and discard after 30-days (or otherwise, according to manufacturer's directions.
			Comments:
Refrigerator electrical outlet is protected. (ie: metal cage; 'Do not unplug' label).			- Ensure refrigerator could not be easily unplugged.
			Comments:
<input type="checkbox"/> Inspection checklist reviewed with clinic staff member and feedback provided. Comments:			
Signature of reviewer:			

Appendix G
Health Research Ethics Authority Screening Tool

	Question	Yes	No
1.	Is the project funded by, or being submitted to, a research funding agency for a research grant or award that requires research ethics review	r	x
2.	Are there any local policies which require this project to undergo review by a Research Ethics Board?	r	x
	IF YES to either of the above, the project should be submitted to a Research Ethics Board. IF NO to both questions, continue to complete the checklist.	r	r
3.	Is the primary purpose of the project to contribute to the growing body of knowledge regarding health and/or health systems that are generally accessible through academic literature?	r	x
4.	Is the project designed to answer a specific research question or to test an explicit hypothesis?	r	x
5.	Does the project involve a comparison of multiple sites, control sites, and/or control groups?	r	x
6.	Is the project design and methodology adequate to support generalizations that go beyond the particular population the sample is being drawn from?	r	x
7.	Does the project impose any additional burdens on participants beyond what would be expected through a typically expected course of care or role expectations?	r	x
LINE A: SUBTOTAL Questions 3 through 7 = (Count the # of Yes responses)		0	
8.	Are many of the participants in the project also likely to be among those who might potentially benefit from the result of the project as it proceeds?	x	r
9.	Is the project intended to define a best practice within your organization or practice?	x	r
10.	Would the project still be done at your site, even if there were no opportunity to publish the results or if the results might not be applicable anywhere else?	x	r
11.	Does the statement of purpose of the project refer explicitly to the features of a particular program, Organization, or region, rather than using more general terminology such as rural vs. urban populations?	x	r
12.	Is the current project part of a continuous process of gathering or monitoring data within an organization?	x	
LINE B: SUBTOTAL Questions 8 through 12 = (Count the # of Yes responses)		5	
	SUMMARY See Interpretation Below		

Interpretation:

The sum of Line B (5) is greater than the sum of Line A (0), therefore the most probable purpose of this project is quality/evaluation. This project's main purpose does not involve research and should not need to be reviewed by an ethics board prior to implementation.

Appendix D – Pilot Report

Pilot Report: Review of Vaccine Storage and Handling Practices in the General Practice

Population

Amy Barnes B.N., R.N., CCHN(C)

Memorial University

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Overview of Project

Vaccines are sensitive biological products that are vulnerable to a variety of environmental conditions, including exposure to extreme temperatures and light (Public Health Agency of Canada [PHAC], 2007). Maintaining vaccines within a cold chain is important in preserving vaccine quality (Eastern Health, 2010; PHAC). The term cold chain refers to the maintenance of appropriate conditions through each link in the chain from the manufacture, transport, storage, handling, and administration of vaccine products. There is much evidence in the literature to suggest that the cold chain is not being maintained in the general practice area (Carr, Byles, & Durrheim, 2010; Haworth, Booy, Stirzaker, Wilkes, & Battersby, 1993; Yuan, Daniels, Naus, & Brcic, 1995). A review of the vaccine storage and handling practices in the general practice area has been proposed in a separate document. The review would provide an opportunity to gather valuable data related to the vaccine storage and handling practices in local general practice clinics in order to inform the development of appropriate resources and policies. This pilot project was undertaken to validate the methods and instruments that have been proposed for the review.

The overall goal of this pilot project was to establish the usability and feasibility of the methods proposed in the full-scale review of the vaccine storage and handling practices in the general practice setting. The specific objectives were:

- 1) Determine the feasibility of the proposed instruments and methods.
- 2) Gather input from physicians and other general practice staff on appropriateness of methods.
- 3) Assess approximate time needed to complete data collection during each clinic visit.

4) Determine if changes are necessary to the full-scale review plan.

Participants and Methods

The methods used were as proposed in the planned review of the vaccine storage and handling practices in the general practice setting (see separate document) with a few additions. This pilot was completed over a time period of three weeks in March of 2015 and consisted of visits to five general practice clinics in the St. John's area. A total of six general practice clinics were initially contacted via a mail out letter with an attached information sheet that provided important details regarding the project's purpose and methods. A copy of this letter and information sheet can be found in Appendix A. A follow-up telephone call was then made to answer any questions and to request verbal permission to visit each clinic.

Upon arrival at each clinic, verbal consent for participation was once again requested. Once obtained, a short interview was completed with a physician working within the clinic. These questions were asked as listed in Appendix B. Following this interview, an inspection of the clinic's vaccine storage and handling practices was completed, guided by the checklist proposed in a separate document. Once the inspection process was complete, some follow up questions were asked to the participants to gain their input on appropriateness of the methods used. A copy of these questions can be found in Appendix C. After each visit was over, the reviewers used a list of self-reflection questions to rate how well the proposed methods worked in achieving the desired outcome. These self-reflection questions can be found in Appendix D.

A Public Health Nursing colleague attended one of the clinic visits and completed the full inspection process as per the proposed methods. This colleague has good

knowledge of appropriate cold chain management practices and was provided with a brief training session on the inspection process prior to completing the visit. The reviewer observed the colleague complete the full inspection process and two independent checklist forms were completed and compared. The colleague then used the same self-reflection questions found in Appendix D to reflect on the methods used.

Data Management and Analysis

Notes were taken during throughout each interview with the physicians, during the follow-up discussions, and in the self-reflection process. All notes were typed and organized and then analyzed for content; the text from each interview was coded into general categories and compared. The sample size for the pilot was small, and so checklist data was analyzed based on the frequency of responses rather than through descriptive statistics as proposed in the full review. The two separate checklists, completed by the reviewer and the colleague during a single clinic visit, were compared for congruency.

Ethical Considerations

Participants were provided with full disclosure of how the results of each inspection would be used. No identifying information was included in any notes, or on the completed checklists associated with each clinic inspection. The clinics were made aware that individual level checklist data would only be shared with staff in Eastern Health's CDC department, for whom this project was designed. A code was assigned to each participating clinic and written on all interview data and the completed checklist. A separate document containing clinic demographic details along with their participation code was completed, and protected in a locked bag during travel, and a locked filing

cabinet during storage. The identity of the Public Health colleague that participated in the implementation of this pilot will also be kept confidential.

The Health Research Ethics Authority screening tool has been completed for this pilot project and can be found in Appendix E. The results of this tool indicated that ethical approval was not necessary to proceed with this pilot. The design of this project involved quality control rather than research because it involved the evaluation of the instruments and methods proposed in the cold chain inspection plan.

The Community Medical Advisory Committee (CMAC) was made aware of the pilot objectives and methods via email communication prior to beginning the process. The chair of this committee indicated that they would make contact via telephone or email if they had any further questions or concerns. A follow up email was forwarded to the chair of the CMAC prior to completing initial contact with each clinic. No response was obtained from this committee and so the project was implemented.

Results

A total of six general practice clinics were sent recruitment letters and then contacted via telephone for follow up. A total of five clinics agreed to participate in the pilot; the one clinic that declined participation reported that time constraints related to multiple physicians being away on leave was preventing their ability to participate. The participating clinics employed a range of 4-15 General Practitioners.

Interview with Physicians

A full summary of the key points identified in the interviews with the participating physicians from each clinic can be found in Appendix F. All participants were able to provide details related to their cold chain management procedures. All participants

reported that they used a fridge to store vaccine, and used insulated containers when vaccine was removed from the fridge for extended periods of time. The majority of clinics assigned a single individual to vaccine inventory responsibility, and this individual was typically the clinic manager, who was a nurse. In one large clinic the single person responsible typically changed from day to day, depending on the staff working at the time. All clinics reported that they regularly monitored the internal temperatures of their refrigerator, however the intensity of this monitoring varied.

The biggest concern reported by all physicians was related to lack of space. The limited available storage space within each clinic meant that only small fridges could be used. This meant that there was little space inside each refrigerator to properly store the vaccine product; therefore the product was often crowded, and vaccine was commonly stored in areas of the refrigerators known to have unstable temperatures. Two clinics that had the same under counter purpose built model reported concerns related to the attached temperature monitors. These models did not allow for min/max readings, and while they were alarmed, there was no ability to know whether or not the alarm had sounded after hours.

All participating physicians voiced an awareness of the recommendations published by PHAC (2007). Other resources that were often used included the Provincial Immunization Manual and product monographs. Vaccine product monographs do provide information related to the appropriate temperature range that the product should be stored in, however contain no other guidelines. All resources used were electronic in nature; no clinic had a hard copy of the guidelines on hand.

Two participants voiced that they felt there was low communication between

general practice and Eastern Health related to practice changes, new recommendations, and available resources. The participants reported that cold chain maintenance was not something that was covered in their medical school education and that accessing this important information was left to the responsibility of the individual. The participants reported that they would appreciate access to some Eastern Health resources that could be used to train their staff and increase their own knowledge on appropriate vaccine storage recommendations. All participants identified that a small poster that could be placed on the vaccine fridge, or close to the vaccine fridge would be helpful in providing visual cues to ensure recommendations are being followed. Webinar-based education and online education modules were also identified as acceptable ways to provide vaccine-related information to this population. All participants reported that they would agree to yearly inspections of their vaccine fridges by an individual with good knowledge of the current cold chain recommendations that could provide accurate feedback to correct any concerns. The inspection process was seen as a positive experience that aids in increasing patient safety, which was valued by each clinic.

Checklist Data

The responses to each item on the checklist are summarized in the table found in Appendix G. A significant issue noted was that no clinic provided any form of education or training to staff related to acceptable vaccine storage and handling practices and no clinic had a hard copy of the guidelines on hand. The participants all voiced that they were not aware of any resources they would be able to use in training staff. In addition, it has become a priority in recent years to be paper-free. All clinics were able to identify a source for information related to storage and handling, however all were electronic.

One clinic reported having a backup emergency power source available for times of power loss. All clinics with no backup power supply reported having a contingency plan in place to protect vaccine during periods of power loss. Only one clinic had a proactive plan that would protect vaccine when the likelihood of power loss was high; all other clinics had reactive plans that would protect vaccine only after the power is lost.

Three participating clinics used bar-style refrigerators and two used under-counter purpose built models. All fridges were estimated to be less than six-years old and appeared to be in excellent working condition. The purpose built models had issues related to the type of temperature monitor attached, as described in the previous section. Of the three bar-style fridges, only two were monitored with min/max thermometers; the other fridge used only a glass basal thermometer that was stored on a shelf in the fridge door. This particular thermometer was also noted to be inaccurate when temperatures were tested using a calibrated digital thermometer. Only one of five clinics was actually monitoring and recording refrigerator temperature twice daily as recommended.

Issues were noted in regards to how the products were stored within the refrigerator. In one of the inspected refrigerators, a large amount of vaccine products were being stored in the shelves on the door; in two participating clinics the floor of the refrigerator was being used to store vaccines. As well, only one clinic was noted to be using water bottles to line any door shelving or fill any empty spaces within the fridge. Several participants voiced that the small size of the refrigerator used to store vaccines was the reason for the lack of water bottles and the use of improper shelving.

Follow up Discussion with Participants

Once the interview and inspection process was complete, the checklist form was

reviewed with a participant and applicable feedback was provided. Where any of the checklist criteria were scored as “unmet,” the participant was referred to the list of strategies on the checklist that could be followed in order to resolve the identified issue. This feedback process was well received. Overall, each clinic reported valuing their ability to provide safe and quality care to the population they serve. All participants voiced that they would take action to correct any identified concerns.

Participants were asked to provide opinions regarding the process in its entirety. Overall, it was felt that the interviews and inspections went smoothly and each clinic visit was concluded within an acceptable timeframe. The recruitment letter with attached information sheet was considered to contain enough detail and was easy to read. No changes were suggested to the process. All questions were felt to be appropriate as they were based on current expectations to ensure vaccine safety. Overall the process was viewed as a positive one. Participants voiced a commitment to patient safety and appreciated receiving quality information to help improve practice.

Reviewer Self-reflection

Overall the interview and inspection process ran smoothly during each visit. The interview process flowed well into the checklist component. The process took ten to twenty minutes and all data were collected as planned. Aside from occasional interruptions during the process related to busy clinics, there were no significant issues in data collection; all participants were agreeable to answer all questions and were open to receiving feedback on any concerns.

After the second clinic visit a small change was made in the timing of providing a clinic with a copy of the completed checklist. The first two clinics visited were

experiencing some issues with the photocopier they had on site at the time of the inspection. Therefore, while the checklist was able to be adequately reviewed, a copy had to be made after the visit and mailed to the clinic. This process was actually helpful in providing more time to ensure all written comments were clear and concise, and allowed for a magnetic poster resource to also be sent to each clinic. This poster resource easily affixes to a vaccine refrigerator and provides visual cues related to proper vaccine storage and handling. It was readily available through the CDC department and CDC was happy to be able to provide an informative resource that was identified as acceptable according to the interview results. Therefore, all participants were provided with a copy of the completed checklist and poster resource, by mail, immediately following the inspection instead of at the time of the clinic visit. This is the only change made to the original proposal and will be implemented on a go forward basis as the full implementation begins this spring.

A Public Health colleague completed the third clinic visit, supervised by the reviewer, in order to help establish usability among different reviewers. This colleague felt that the process ran smoothly and expressed no concerns related to the data collection methods. All data were collected as planned and the checklist tool was reported to be clear and easy to follow. The checklist form completed by this colleague matched the responses recorded by the primary reviewer and feedback provided was as per the recommendations. The clinic visit was completed in a fifteen-minute time frame. This colleague did not make any suggestions related to any changes to make in the tools or process.

Conclusion

This pilot project was successful in establishing the feasibility and reliability of the methods proposed in the plan for a review of the vaccine storage and handling practices in the general practice population. The data collection tools collected valuable data on the cold chain management practices in five general practice clinics, and can be used to provide an accurate picture of the current practices around cold chain maintenance in the general practice population of interest.

Based on the collected feedback, no major changes will need to be made to the proposal prior to full implementation. The review plan, implemented as proposed, should allow for the collection of accurate data that can be used in the development of resources designed to support appropriate cold chain management practices, ensuring better vaccine integrity and better protecting the health of the population.

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Appendix A – Copy of Letter/Information Sheet

Communicable Disease Control Division
Public Health
Mount Pearl Square – Community Services
760 Topsail Road
Mount Pearl, NL
A1N 3J5

Attention: Dr. _____
Clinic Address

My name is Amy Barnes and I am a Memorial University of Newfoundland student enrolled in the Master of Nursing program. My professional background is in the area of Public Health Nursing. In partial completion of my degree program I developed a proposal for a review of the vaccine storage and handling practices in General Practice clinics. This project has been designed in consultation with Eastern Health's Communicable Disease Control division.

I am writing to request your participation in a small pilot to test the methods and tools that will be used in the review of cold chain maintenance. This pilot will allow for the identification of any feasibility issues and to ensure that the data collected are useful. I plan to complete this pilot in March of 2015. The Community Medical Advisory Committee has been made aware of the project. Please see the attached information sheet for more details on what this entails.

Participation in this project is voluntary. I will contact you via telephone over the next week to request permission to visit your clinic. My contact information is listed below if you have any questions or concerns.

Sincerely,

Amy Barnes B.N., R.N., CCHN(C)

Master of Nursing Student – Memorial University of Newfoundland
Public Health Nurse – Eastern Health Community Services
(709) 752-4895

Vaccine Storage and Handling Review Information Sheet

What is the purpose of this pilot?

- To test the methods and tools that have been proposed for a review of the vaccine storage and handling practices in General Practice clinics in order to identify and resolve any feasibility issues, and ensure quality data collection.

What is the purpose of the proposed review?

- To identify any concerns related to vaccine storage and handling and to inform the development of appropriate resources to address any identified concerns.

Why is this review important?

- Vaccines are sensitive biological products that are vulnerable to a variety of environmental conditions, including exposure to extreme temperatures and light.
- Cold chain maintenance is important in ensuring the maintenance of vaccine integrity to help protect the health of the population and prevent the reemergence of vaccine preventable diseases.
- The rotating power outages in 2014 resulted in significant cold chain failure and large amounts of vaccine loss, highlighting the need for increased attention to appropriate vaccine cold chain practices in all vaccination sites.

What will be asked of each clinic?

- The target sample size for this pilot is 5 General Practice clinics.
- I will be requesting approximately 20-30 minutes to talk to clinic staff and make observations of the vaccine storage unit.
- Only one visit will be necessary for each participating clinic. Participants will not need to make any preparations or participate in any follow up.

What will the review process consist of?

- Permission will be obtained and the process will be reviewed prior to beginning the inspection in each clinic.
- A structured interview will be administered to one physician practicing at each clinic.
- The storage unit used for vaccine will be inspected using a checklist tool.
- The results of the inspection will be reviewed with a staff member and feedback will be provided on any areas requiring improvement.
- A copy of this checklist will be provided to clinic staff at the end of the appointment.
- After the inspection and feedback process is complete, some follow up questions will be asked to gain input on the appropriateness of the methods used.

How will we use the pilot results?

- The results will be valuable to address any areas of concern related to the methods and instruments that have been designed for use in collecting data related to vaccine storage and handling practices

How will ethical considerations be managed?

- **Participation in this pilot is voluntary.**
- Permission will be requested prior to visiting any clinic and prior to beginning the review process when present in a clinic.
- The Health Research Ethics Authority screening tool indicates that this project is related to evaluation and quality assurance, not research; therefore review by a Research Ethics Board was deemed unnecessary prior to the implementation of this pilot.
- Checklist and interview data will be secured in a locked bag during travel to and from clinics and will be stored in a locked filing cabinet when not in use.
- Checklist and interview data will be assigned a code as an identifier to protect the privacy of participants.
- Any reports compiled after data collection will be presented at aggregate level only and will protect individual identities.
- All data collected will be shared with the Communicable Disease Control officials within Eastern Health, with whom this project has been designed.

Who can you contact with further questions?

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Appendix B - Structured Interview with Physicians

- 1) Can you tell me about the processes used to maintain the cold chain in your practice?
(Vaccine secured in refrigerator until use; monitoring temperatures; single person responsible; etc.)
- 2) What do you feel are some of the primary areas of concern for vaccine storage and handling? (In your own setting? In general?)
- 3) What resources do you currently use to inform your practices related to cold chain maintenance? (Are you familiar with the PHAC guidelines?)
- 4) Are there any types of resources you would be interested in to support the maintenance of adequate storage conditions? (Online modules, webinar, pamphlets, posters, regular audits, etc.)
- 5) In the province of Ontario, there are mandated annual vaccine storage and handling audits accompanied by regular training and education. While cold chain failures occasionally still occur, they have noted a decrease in failures related to human error.
- If a similar process were to be implemented in this province, but were voluntary in nature, would you participate?

IF YES:
 - Who would you accept to complete these audits?
 - How frequently would you be agreeable to have your storage facility inspected?
- 6) Are there any comments you would like to share/address related to vaccine storage and handling?

Appendix C – Follow up Questions

1) Do you have any comments or questions related to the process? (Did it run smoothly?

Are there any changes you would recommend?)

2) Was the clinic visit completed in a reasonable time frame?

3) Do you have any comments on the recruitment process? (i.e. letter and initial phone

call) (Too long? Enough detail? Easy to read/understand?)

4) Do you have any concerns about any of the questions asked?

If Yes: What questions and why? How could they be changed?

Appendix D – Self-reflection Questions

- 1) Overall, how did the process go?
- 2) Were the tools clear and easy to use?
- 3) How long did the process take? Was this more/less than expected?
- 4) Did you achieve the anticipated results?
- 5) Were there any difficulties in data collection?
- 6) Is there anything that you would do differently? (Changes to tools/process?)
- 7) Any further comments?

Appendix E – Health Research Ethics Authority Screening Tool

	Question	Yes	No
1.	Is the project funded by, or being submitted to, a research funding agency for a research grant or award that requires research ethics review	<input type="radio"/>	<input checked="" type="radio"/>
2.	Are there any local policies which require this project to undergo review by a Research Ethics Board?	<input type="radio"/>	<input checked="" type="radio"/>
	IF YES to either of the above, the project should be submitted to a Research Ethics Board. IF NO to both questions, continue to complete the checklist.	<input type="radio"/>	<input type="radio"/>
3.	Is the primary purpose of the project to contribute to the growing body of knowledge regarding health and/or health systems that are generally accessible through academic literature?	<input type="radio"/>	<input checked="" type="radio"/>
4.	Is the project designed to answer a specific research question or to test an explicit hypothesis?	<input type="radio"/>	<input checked="" type="radio"/>
5.	Does the project involve a comparison of multiple sites, control sites, and/or control groups?	<input type="radio"/>	<input checked="" type="radio"/>
6.	Is the project design and methodology adequate to support generalizations that go beyond the particular population the sample is being drawn from?	<input type="radio"/>	<input checked="" type="radio"/>
7.	Does the project impose any additional burdens on participants beyond what would be expected through a typically expected course of care or role expectations?	<input type="radio"/>	<input checked="" type="radio"/>
LINE A: SUBTOTAL Questions 3 through 7 = (Count the # of Yes responses)		0	
8.	Are many of the participants in the project also likely to be among those who might potentially benefit from the result of the project as it proceeds?	<input checked="" type="radio"/>	<input type="radio"/>
9.	Is the project intended to define a best practice within your organization or practice?	<input checked="" type="radio"/>	<input type="radio"/>
10.	Would the project still be done at your site, even if there were no opportunity to publish the results or if the results might not be applicable anywhere else?	<input checked="" type="radio"/>	<input type="radio"/>
11.	Does the statement of purpose of the project refer explicitly to the features of a particular program, Organization, or region, rather than using more general terminology such as rural vs. urban populations?	<input checked="" type="radio"/>	<input type="radio"/>
12.	Is the current project part of a continuous process of gathering or monitoring data within an organization?	<input checked="" type="radio"/>	
LINE B: SUBTOTAL Questions 8 through 12 = (Count the # of Yes responses)		5	
	SUMMARY See Interpretation Below		

Interpretation:

The sum of Line B (5) is greater than the sum of Line A (0), therefore the most probable purpose of this project is quality/evaluation. This project's main purpose does not involve research and should not need to be reviewed by an ethics board prior to implementation.

Appendix F – Interview Data

Brief discussion re: procedures:

- All clinics were able to provide a brief summary of cold chain management practices.
- Refrigerators used to store vaccines and insulated containers used to maintain the cold chain when removed from storage for extended periods of time.
- The majority did assign a single staff member to vaccine duties but in one clinic this changed from day to day depending on staffing. In two clinics the responsibility was assigned to the clinic manager; in two clinics it was a shared responsibility.
- All clinics monitored temperatures, however intensity of this practice varied.
- One clinic was in the process of requesting after-hours temperature monitoring through Eastern Health's Bio-medical services; one site already had access to the facilities emergency power source.

Concerns:

- Lack of space was the most commonly voiced concern – no room for large fridge; all clinics had small fridges in addition to separate, small specimen refrigerators.
- Lack of access to education and training services to teach staff appropriate procedures.
- Two purpose built models had temperature monitor that had no alarm memory and no min/max capabilities. No way to know if temperature was out of range after hours.
- Two clinics expressed that there was little communication between Eastern Health and general practice re: changes, recommendations, resources.
- Education related to cold chain not covered in medical school to a responsibility of individual physicians to seek current information.

Resources used:

- PHAC guidelines
- Provincial Immunization Manual
- Product monographs

Agreeable resources:

- Posters to provide quick visual cues.
- Webinar based sessions.
- Online modules that can be taken according to an individual's schedule.

Interest in Peel Public Health inspection process:

- All participants would be agreeable to participate in a yearly audit process that was aimed at improving practice and passing along best practice guidelines.
- A non-punitive process important.
- Would prefer for the auditing process to be completed by somebody with a background in vaccines and good knowledge of current storage and handling recommendations that could answer questions and provide immediate feedback.
- The inspection process was overall considered to be a positive experience.

Appendix G – Checklist Data

Recommendation	Results
A single individual has been assigned to vaccine maintenance duties.	Met: 3 Unmet: 2 Details: Shared responsibility among all staff in 2 clinics. 1 office reports a single individual responsible but this individual changes from day to day depending on staffing.
All staff members receive regular training on storage and handling guidelines.	Met: 0 Unmet: 5
Vaccine storage and handling reference is present at the clinic.	Met: 0 Unmet: 5 Details: No hard copies available. All clinics identified an electronic resource.
When vaccines are removed from the refrigerator for purposes other than immediate administration, insulated containers and ice packs are used.	Met: 5 Unmet: 0
Refrigerator has a back-up power supply.	Met: 1 Unmet: 4 Details: One of 4 unmet was in process of requesting access to back-up power source at time of inspection. Other unmet sites had no options for back-up power.
A contingency plan is in place to protect vaccine inventory in cases of power loss and inclement weather.	Met: 5 Unmet: 0 Details: 1 site with back-up power; 1 site with proactive plan to protect inventory prior to outage; 3 sites with reactive plan to protect after power loss.
Cold chain failures are reported to public health.	Met: 5 Unmet: 0
When vaccine is expired, damaged, or wasted, it is returned to the vaccine depot.	Met: 5 Unmet: 0
Type of refrigerator/age/general appearance.	3 Bar-style 2 Under counter purpose built All estimated to be less than 6 years old. All appeared to be in good working condition; intact seals.
Temperature-monitoring device is installed and working properly.	All had thermometer. 2 digital min/max; 2 digital thermometers permanently mounted

Recommendation	Results
	to purpose built models – measured only current temperature with no alarm memory; 1 glass basal thermometer (scored as unmet for recommendation)
Temperature according to clinic's thermometer is within recommended range. Temperature according to auditor's thermometer is within recommended range.	4 clinics within recommended range and accurate temperatures confirmed with auditor's thermometer. Glass basal thermometer stored on fridge door and 2°C above recommended range. Door temperature measured 3°C lower than glass thermometer measurement; internal fridge temperature also within recommended range – concluded glass thermometer inaccurate.
Temperature log is present that shows monitoring of temperatures twice daily.	Met: 1 Unmet: 4
No recorded temperatures on log are outside of 2°C – 8°C.	Met: 1 Unmet: 4 Details: Unable to fully assess due to low compliance
Vaccine products are stored in the middle of the refrigerator, on internal shelves.	Met: 2 Unmet: 3 Details: Stored on fridge door in one fridge; stored on bottom of fridge in 2.
Vaccines are organized according to expiry date.	Met: 5 Unmet: 0
No expired vaccine products are located in refrigerator.	Met: 5 Unmet: 0
No extraneous items are present in vaccine fridge.	Met: 5 Unmet: 0
Water bottles are placed on refrigerator door, in drawers, and on any empty shelves.	Met: 1 Unmet: 4 Details: Little available space in many fridges for water bottles.
A maximum of one-month vaccine supply is stored in fridge.	Met: 5 Unmet: 0
Any open multi-dose vials have been labeled with date opened and date is within the past 30-days.	Met: 5 Unmet: 0
Refrigerator electrical outlet is protected.	Met: 4 Unmet: 1