

Accreditation Report

Originelle Fertility Clinic and

‡ = Centre/
Originelle Clinique de Fertilité et

femme

Montreal, QC

On-site survey dates: May 14, 2018 - May 16, 2018

Report issued: May 31, 2018

About the Accreditation Report

Originelle Fertility Clinic and Women's Health Centre/Originelle Clinique de Fertilité et Centre de santé de la femme (referred to in this report as "the organization") is participating in Accreditation Canada's Qmentum accreditation program. As part of this ongoing process of quality improvement, an on-site survey was conducted in May 2018. Information from the on-site survey as well as other data obtained from the organization were used to produce this Accreditation Report.

Accreditation results are based on information provided by the organization. Accreditation Canada relies on the accuracy of this information to plan and conduct the on-site survey and produce the Accreditation Report.

Confidentiality

This report is confidential and is provided by Accreditation Canada to the organization only. Accreditation Canada does not release the report to any other parties.

In the interests of transparency and accountability, Accreditation Canada encourages the organization to disseminate its Accreditation Report to staff, board members, clients, the community, and other stakeholders.

Any alteration of this Accreditation Report compromises the integrity of the accreditation process and is strictly prohibited.

A Message from Accreditation Canada

On behalf of Accreditation Canada's board and staff, I extend my sincerest congratulations to your board, your leadership team, and everyone at your organization on your participation in the Qmentum accreditation program. Qmentum is designed to integrate with your quality improvement program. By using Qmentum to support and enable your quality improvement activities, its full value is realized.

This Accreditation Report includes your accreditation decision, the final results from your recent on-site survey, and the instrument data that your organization has submitted. Please use the information in this report and in your online Quality Performance Roadmap to guide your quality improvement activities.

Your Client Engagement Lead is available if you have questions or need guidance.

Thank you for your leadership and for demonstrating your ongoing commitment to quality by integrating accreditation into your improvement program. We welcome your feedback about how we can continue to strengthen the program to ensure it remains relevant to you and your services.

We look forward to our continued partnership.

Cester Thompson

Sincerely,

Leslee Thompson

Chief Executive Officer

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Executive Summary

Originelle Fertility Clinic and Women's Health Centre/Originelle Clinique de Fertilité et Centre de santé de la femme (referred to in this report as "the organization") is participating in Accreditation Canada's Qmentum accreditation program. Accreditation Canada is an independent, not-for-profit organization that sets standards for quality and safety in health care and accredits health organizations in Canada and around the world.

As part of the Qmentum accreditation program, the organization has undergone a rigorous evaluation process. Following a comprehensive self-assessment, external peer surveyors conducted an on-site survey during which they assessed this organization's leadership, governance, clinical programs and services against Accreditation Canada requirements for quality and safety. These requirements include national standards of excellence; required safety practices to reduce potential harm; and questionnaires to assess the work environment, patient safety culture, governance functioning and client experience. Results from all of these components are included in this report and were considered in the accreditation decision.

This report shows the results to date and is provided to guide the organization as it continues to incorporate the principles of accreditation and quality improvement into its programs, policies, and practices.

The organization is commended on its commitment to using accreditation to improve the quality and safety of the services it offers to its clients and its community.

Accreditation Decision

Originelle Fertility Clinic and Women's Health Centre/Originelle Clinique de Fertilité et Centre de santé de la femme's accreditation decision is:

Accredited (Report)

The organization has succeeded in meeting the fundamental requirements of the accreditation program.

About the On-site Survey

• On-site survey dates: May 14, 2018 to May 16, 2018

Location

The following location was assessed during the on-site survey.

1. Centre de reproduction de Montréal / Montreal Reproduction Centre

Standards

The following sets of standards were used to assess the organization's programs and services during the on-site survey.

System-Wide Standards

1. Leadership Standards for Small, Community-Based Organizations

Service Excellence Standards

- Assisted Reproductive Technology (ART) Standards for Clinical Services Service Excellence Standards
- Assisted Reproductive Technology (ART) Standards for Laboratory Services -Service Excellence Standards
- 4. Assisted Reproductive Technology (ART) Standards for Working with Third Party Donors Service Excellence Standards

Instruments

The organization administered:

- 1. Governance Functioning Tool (2016)
- 2. Canadian Patient Safety Culture Survey Tool: Community Based Version
- 3. Worklife Pulse
- 4. Client Experience Tool

Overview by Quality Dimensions

Accreditation Canada defines quality in health care using eight dimensions that represent key service elements. Each criterion in the standards is associated with a quality dimension. This table shows the number of criteria related to each dimension that were rated as met, unmet, or not applicable.

Quality Dimension	Met	Unmet	N/A	Total
Population Focus (Work with my community to anticipate and meet our needs)	14	3	0	17
Accessibility (Give me timely and equitable services)	9	1	0	10
Safety (Keep me safe)	87	9	2	98
Worklife (Take care of those who take care of me)	40	1	0	41
Client-centred Services (Partner with me and my family in our care)	69	8	0	77
Continuity (Coordinate my care across the continuum)	10	0	0	10
Appropriateness (Do the right thing to achieve the best results)	176	21	15	212
Efficiency (Make the best use of resources)	7	0	0	7
Total	412	43	17	472

Overview by Standards

The Qmentum standards identify policies and practices that contribute to high quality, safe, and effectively managed care. Each standard has associated criteria that are used to measure the organization's compliance with the standard.

System-wide standards address quality and safety at the organizational level in areas such as governance and leadership. Population-specific and service excellence standards address specific populations, sectors, and services. The standards used to assess an organization's programs are based on the type of services it provides.

This table shows the sets of standards used to evaluate the organization's programs and services, and the number and percentage of criteria that were rated met, unmet, or not applicable during the on-site survey.

Accreditation decisions are based on compliance with standards. Percent compliance is calculated to the decimal and not rounded.

	High Priority Criteria *		Other Criteria			al Criteria iority + Other	·)		
Standards Set	Met	Unmet	N/A	Met	Unmet	N/A	Met	Unmet	N/A
Standards Set	# (%)	# (%)	#	# (%)	# (%)	#	# (%)	# (%)	#
Leadership Standards for Small, Community-Based Organizations	38 (95.0%)	2 (5.0%)	0	67 (95.7%)	3 (4.3%)	0	105 (95.5%)	5 (4.5%)	0
Assisted Reproductive Technology (ART) Standards for Clinical Services	49 (83.1%)	10 (16.9%)	2	115 (93.5%)	8 (6.5%)	0	164 (90.1%)	18 (9.9%)	2
Assisted Reproductive Technology (ART) Standards for Laboratory Services	44 (77.2%)	13 (22.8%)	3	60 (89.6%)	7 (10.4%)	4	104 (83.9%)	20 (16.1%)	7
Assisted Reproductive Technology (ART) Standards for Working with Third Party Donors	7 (100.0%)	0 (0.0%)	1	19 (100.0%)	0 (0.0%)	7	26 (100.0%)	0 (0.0%)	8
Total	138 (84.7%)	25 (15.3%)	6	261 (93.5%)	18 (6.5%)	11	399 (90.3%)	43 (9.7%)	17

^{*} Does not includes ROP (Required Organizational Practices)

Overview by Required Organizational Practices

A Required Organizational Practice (ROP) is an essential practice that an organization must have in place to enhance client safety and minimize risk. Each ROP has associated tests for compliance, categorized as major and minor. All tests for compliance must be met for the ROP as a whole to be rated as met.

This table shows the ratings of the applicable ROPs.

		Test for Comp	oliance Rating
Required Organizational Practice	Overall rating	Major Met	Minor Met
Patient Safety Goal Area: Safety Culture			
Patient safety incident disclosure (Leadership Standards for Small, Community-Based Organizations)	Met	4 of 4	2 of 2
Patient safety incident management (Leadership Standards for Small, Community-Based Organizations)	Met	6 of 6	1 of 1
Patient safety quarterly reports (Leadership Standards for Small, Community-Based Organizations)	Met	1 of 1	2 of 2
Patient Safety Goal Area: Communication			
Client Identification (Assisted Reproductive Technology (ART) Standards for Clinical Services)	Met	1 of 1	0 of 0
Information transfer at care transitions (Assisted Reproductive Technology (ART) Standards for Clinical Services)	Met	4 of 4	1 of 1
Medication reconciliation as a strategic priority (Leadership Standards for Small, Community-Based Organizations)	Met	4 of 4	2 of 2

		Test for Comp	oliance Rating
Required Organizational Practice	Overall rating	Major Met	Minor Met
Patient Safety Goal Area: Medication Use			
Infusion Pumps Training (Assisted Reproductive Technology (ART) Standards for Clinical Services)	Met	4 of 4	2 of 2
Patient Safety Goal Area: Worklife/Workfo	orce		
Patient safety plan (Leadership Standards for Small, Community-Based Organizations)	Met	2 of 2	2 of 2
Patient safety: education and training (Leadership Standards for Small, Community-Based Organizations)	Met	1 of 1	0 of 0
Preventive Maintenance Program (Leadership Standards for Small, Community-Based Organizations)	Met	3 of 3	1 of 1
Workplace Violence Prevention (Leadership Standards for Small, Community-Based Organizations)	Met	6 of 6	2 of 2
Patient Safety Goal Area: Infection Contro	ı		
Hand-Hygiene Compliance (Assisted Reproductive Technology (ART) Standards for Clinical Services)	Met	1 of 1	2 of 2
Hand-Hygiene Education and Training (Assisted Reproductive Technology (ART) Standards for Clinical Services)	Met	1 of 1	0 of 0

Summary of Surveyor Team Observations

The surveyor team made the following observations about the organization's overall strengths, opportunities for improvement, and challenges.

Leadership

This centre was incorporated in 2009 but opened their doors for clients in 2011 when they were issued a permit to perform all fertility services. The situation changed in July 2014 following a disagreement with the McGill Health Centre, and then 2 years later the changes to the funding that the province of Québec made related to fertility. All embryology services are now outsourced to Procrea, another private fertility organization with sites in Québec, Ontario and Manitoba. The centre continues to do all procedures for andrology. The Physicians from OriginElle go the Procrea site in Montreal to perform any procedure required. The Physicians at OriginElle have privileges at the McGill Health Centre should their patient require admission or more intensive care.

This centre performs fertility consultation and treatment for women up to and in excess of age 46, although in Québec it is illegal to do fertility treatments to women aged 46. These women must agree to egg donation. Should a woman insist on getting fertility treatment, they must go outside the province.

This organization already has a clinic in China and they will be soon opening a new centre in Ottawa, Ontario. They have numerous patients from outside the city, outside the province or from outside the country. They encourage and facilitate their clients to do as much of their prep work in their community to minimize travel for the client.

The clinic is under the leadership of a Board of Directors, which is basically the Physicians who work at the centre. They are in constant contact with each other but meet officially for a more lengthy discussion every 3 months. The information pertinent to the clinic and their clients is available to all of them on the shared drive. Although the procedures for embryology are done off-site, Procrea sends all the statistics and information relevant to their patients.

The services provided has expanded beyond fertility treatments as they also are available for consultation and services related to gynecology. Issues of gyne-oncology are referred to an oncologist. They have an Advisory Board for their research projects and to share advances in their field of expertise internationally. They are associated with the McGill Health Centre for their Research Ethics Board approval and the fertility centre has 2 benches for research at the Research Institute.

Physicians and clinical staff members are very up to date in their practice, and have a presence in the national fertility community. The leadership of the centre is very receptive to comments or suggestions from colleagues, community partners and clients.

Detailed On-site Survey Results

This section provides the detailed results of the on-site survey. When reviewing these results, it is important to review the service excellence and the system-wide results together, as they are complementary. Results are presented in two ways: first by priority process and then by standards sets.

Accreditation Canada defines priority processes as critical areas and systems that have a significant impact on the quality and safety of care and services. Priority processes provide a different perspective from that offered by the standards, organizing the results into themes that cut across departments, services, and teams.

For instance, the patient flow priority process includes criteria from a number of sets of standards that address various aspects of patient flow, from preventing infections to providing timely diagnostic or surgical services. This provides a comprehensive picture of how patients move through the organization and how services are delivered to them, regardless of the department they are in or the specific services they receive.

During the on-site survey, surveyors rate compliance with the criteria, provide a rationale for their rating, and comment on each priority process.

Priority process comments are shown in this report. The rationale for unmet criteria can be found in the organization's online Quality Performance Roadmap.

See Appendix B for a list of priority processes.

INTERPRETING THE TABLES IN THIS SECTION: The tables show all unmet criteria from each set of standards, identify high priority criteria (which include ROPs), and list surveyor comments related to each priority process.

High priority criteria and ROP tests for compliance are identified by the following symbols:



High priority criterion

Required Organizational Practice

MAJOR Major ROP Test for Compliance

MINOR Minor ROP Test for Compliance

Priority Process Results for System-wide Standards

The results in this section are presented first by priority process and then by standards set.

Some priority processes in this section also apply to the service excellence standards. Results of unmet criteria that also relate to services should be shared with the relevant team.

Priority Process: Planning and Service Design

Developing and implementing infrastructure, programs, and services to meet the needs of the populations and communities served.

The organization has met all criteria for this priority process.

Surveyor comments on the priority process(es)

The organization has a values statement, mission and vision that is updated periodically, and was done so recently to focus on the research applications that they are involved in and exploring internationally.

The care that the organization provides is personalized and caring as they are cognisant that infertility issues are very stressful for the clients. They have a practice of returning phone calls on the same day, even though it might be just to inform the client that they will get back to her/him as soon as they have an answer to their question. Each client is assigned a coordinator to ensure that there are no gaps in the care provided.

Following a procedure, even when it is off-site at Procrea, they call the client to ensure that all is well, that pain is appropriately managed and that they are taking their medications as ordered.

Their strategic plan is focused on providing a full range of service at as low a cost as possible, nationally and internationally. Their environmental scans cover the different regions and countries that they are investigating doing business in. They have close working relationships with the other fertility centres in the province and outside the province.

Priority Process: Resource Management

Monitoring, administering, and integrating activities related to the allocation and use of resources.

The organization has met all criteria for this priority process.

Surveyor comments on the priority process(es)

The owner of the centre and the directors are actively involved in the development of the resource allocations. There is a policy in place for the standardization of clinical equipment. The annual and capital budgets are developed with the participation of the accountants and the financial reports are closely monitored on a regular basis.

Priority Process: Human Capital

Developing the human resource capacity to deliver safe, high quality services.

The organization has met all criteria for this priority process.

Surveyor comments on the priority process(es)

Recruitment and retention are no longer an issue as it was in the past, mainly because the staffing has already been reduced drastically since the downsizing of services in 2014 and the reduced competition of experienced health care providers since the cutting of positions in health care across the province. The centre follows the wage rates of the Ordre des Infirmières du Québec.

The team working at the Centre is very cohesive and works well together. There is a family atmosphere and staff members reported feeling valued by the leaders and by their colleagues. There is evidence that the leaders take the opportunity to frequently promote a healthy and friendly atmosphere.

The leaders of the Centre listen to the staff members who have concerns about the workload and implement changes to ensure a healthy worklife. Support is provided to the staff members to attend ongoing learning.

There is an expectation that the staff members will perform their work in a respectful and collegial manner. We encourage the organization to ensure that all staff members sign a copy of the Code of Conduct document as it shows knowledge of the code and commitment to abide by it, as well as the consequences of not abiding by it.

The Worklife Pulse Tool was recently completed by the staff members and issues and suggestions that came out of the results are being addressed systematically. The clinic director is in the process of redoing all the positions profiles with input from the staff members.

Priority Process: Integrated Quality Management

Using a proactive, systematic, and ongoing process to manage and integrate quality and achieve organizational goals and objectives.

The organization has met all criteria for this priority process.

Surveyor comments on the priority process(es)

They have an incident reporting system in place that is paper based and then the information is entered in an Excel spreadsheet for reporting purposes. The information, including actions taken, is shared with all the staff members and disclosed to the client as required. The clinic direction has taken the initiative to encourage the completion of incident forms, and at the same time, promote a just culture for a staff member who would be fearful of repercussions. A disclosure policy is in place and adhered to.

Medication reconciliation occurs at the initial intake between the client and the Physician; updates required at subsequent visits are entered in the patient record. The clients are encouraged to provide information on any natural products and over the counter medications. The Physician enters all the information on his/her notes. A copy of the prescription is attached to the patient record.

A risk assessment and mitigation plan was recently developed and responsibility for addressing the issues has been fixed to an appropriate person. This is an ongoing process. We encourage the organization to further develop a patient safety plan.

The clinic direction is initiating different modalities for seeking feedback on satisfaction from the client instead of the paper-based format they were using previously.

Priority Process: Principle-based Care and Decision Making

Identifying and making decisions about ethical dilemmas and problems.

Unm	et Criteria	High Priority Criteria
Stan	dards Set: Leadership Standards for Small, Community-Based Organizations	
1.7	An ethics framework to support ethical practice is developed or adopted, and implemented with input from clients/residents and families.	!
1.8	Support is provided to build the capacity of the governing body, leaders, and teams to use the ethics framework.	
1.9	The ethics framework includes a procedure for reviewing the ethical implications of all research activities in which the organization is involved.	!

Surveyor comments on the priority process(es)

The organization has a well-developed and comprehensive code of conduct policy as well as descriptions of professional behaviour. They also have a Psychologist working with them who sees many of the clients. They do not have a formalized Ethics Framework that is not related to behaviour but more to help in making difficult decisions. We encourage the organization in doing some networking with similar organizations to seek examples of Ethics Frameworks.

We encourage the organization to automatically offer support (i.e. Psychologist or other team member) to clients when the procedures are not successful or when a client is evidently stressed.

There is a great deal of research conducted at this centre and the Physicians are associated with the McGill Health Centre and the Research Institute for the Research Ethics Board process. They also participate in international research teams.

Priority Process: Communication

Communicating effectively at all levels of the organization and with external stakeholders.

The organization has met all criteria for this priority process.

Surveyor comments on the priority process(es)

There is a comprehensive and informative website where potential clients can look at the services provides, review the qualifications of the health care providers and learn how to access the services. The marketing is done extensively in the Montréal Chinese language newspaper as 1/3 of their clients are Asians. They also have a contract with an outside agency to manage their social media platform.

The patient record is completely electronic and any paper-based record that might be faxed or brought to the organization is scanned into the patient record. Access to the record is restricted based on the department and on the role of the employee and any questionable access to a patient record is immediately investigated and addressed.

Patients have access to their record and can request a copy by completing a consent form.

Physicians and health care providers are supported to attend continuing education opportunities and every Thursday there is an onsite educational session where they also invite outside speakers.

Priority Process: Physical Environment

Providing appropriate and safe structures and facilities to achieve the organization's mission, vision, and goals.

The organization has met all criteria for this priority process.

Surveyor comments on the priority process(es)

The physical environment at the OriginElle Fertility Clinic and Women's Health Centre is very spacious, well organized and very clean. The cleanliness of the clinic is very good which is ensured by a strong relationship with the contracted cleaners with documented inspections. They have designated, physically separated spaces according to their functions which helps in patient flow. All the medical gases are stored in a secure area. All the restricted areas are very well labelled and secure with access codes entry. The spaces allocated to the personnel really supports the team functioning. The operating of critical equipment in the operating room, recovery room, IT and the laboratory are supported by the generator which is tested on a weekly basis. The security of the team is ensured by the addition of cameras at the reception and the external door for the elevator. The clinic is very aware of its impact on the environment and has undertaken steps to recycle as much as possible. The clinic is very receptive to suggestions and very prompt in the implementation of improvements.

Priority Process: Emergency Preparedness

Planning for and managing emergencies, disasters, or other aspects of public safety.

The organization has met all criteria for this priority process.

Surveyor comments on the priority process(es)

Even if OriginElle Fertility Clinic is a small clinic, it has taken emergency preparedness very seriously. The emergency preparedness manual is very complete and easy to use with the presence of many decision trees which ensures fast and proper response to emergencies. An internal emergency plan has been established for critical areas such as the OR, recovery and nurses station to visually alert the team if patients are present in those rooms and help might be needed for the evacuation. They have addressed their challenges such as stairs and are aware of the challenge of the elevator and are in the process of addressing this situation in the case of evacuation of patients. Power point presentation is an added tool to help in training and education. The roles and responsibilities are clearly defined, and team members are familiar with the plan. Measures are in place to support the activities in an event of an emergency. We continue to encourage to plan for scheduled and especially unscheduled fire and emergency drills to really test the knowledge of the team regarding roles and responsibilities. The team was able to have discussions and input in the new revised emergency preparedness plan. The emergency preparedness plan contains all the signage, but none of this signage are visible in the clinic. It is very important to have signage on doors identifying the content of the room (medical gases, biohazard, etc.) to alert the first responders (fire department, etc.) to make them aware of the dangers in rooms. Also, proper signage will alert visitors and clients that certain danger exists in the clinic.

Priority Process: People-Centred Care

Working with clients and their families to plan and provide care that is respectful, compassionate, culturally safe, and competent, and to see that this care is continuously improved upon.

Unm	et Criteria	High Priority Criteria		
Stan	dards Set: Assisted Reproductive Technology (ART) Standards for Clinical Services			
1.1	Services are co-designed with clients and families, partners, and the community.	!		
2.4	Space is co-designed with clients and families to ensure safety and permit confidential and private interactions with clients and families.			
Stan	dards Set: Assisted Reproductive Technology (ART) Standards for Laboratory Service	s		
1.1	Services are co-designed with clients and families, partners, and the community.	!		
2.4	Space is co-designed with clients and families to ensure safety and permit confidential and private interactions with clients and families.			
Stan	dards Set: Leadership Standards for Small, Community-Based Organizations			
4.3	Services are planned with input from clients/residents, families, and the broader community.			
9.2	There are mechanisms to gather input from clients/residents and families in co-designing new space and determining optimal use of current space to best support comfort and recovery.			
Surv	Surveyor comments on the priority process(es)			

The philosophy of the OriginElle Fertility Centre is that every client is an individual and the care provided to them is personalized to their needs or their culture. They listen to the needs of the patient population and adjust the services to meet those needs. The space at the centre is welcoming, well maintained and spacious.

A comprehensive orientation is provided to new staff members and part and parcel of that orientation is to inform about client centered care. A comprehensive assessment is done of each client, options and possible outcomes of each treatment modality is presented to the clients so that they can make an informed choice that this is best for them. A plan of care is then developed in partnership with the client/family. Feedback from clients/families is sought and welcomed by the care providers.

We would encourage the organization to seek input from clients for the proposed expansion on the site of a medical centre. There are numerous ways and means of gathering input from clients and as many as possible should be explored.

Priority Process: Patient Flow

Assessing the smooth and timely movement of clients and families through service settings.

The organization has met all criteria for this priority process.

Surveyor comments on the priority process(es)

There are numerous ways of accessing the services of the centre, from self-referral to referrals from other fertility centres or from family physicians. In an emergency, patients are advised to go the nearest emergency room.

The team works diligently to ensure that new clients are seen in a timely manner, i.e. within 2 to 3 weeks of making a request. There is flexibility in the daily schedule to see clients on a more urgent basis. The wait list is assessed on a regular basis by one of the leaders to ensure that it does not get too long; based on the need, they will open booking times and slot patients in.

Priority Process: Medical Devices and Equipment

Obtaining and maintaining machinery and technologies used to diagnose and treat health problems.

The organization has met all criteria for this priority process.

Surveyor comments on the priority process(es)

The medical devices and equipment follow a very stringent preventive maintenance schedule which is supported by preventive maintenance contracts for all the equipment in the clinic. The clinical information is very well protected by the information backup being done instantly and on an internal and external server. The clinic uses the 2-5 years formula for equipment and medical devices replacement and pays very close attention to the recommendations of the preventive maintenance reports to make replacement decision. Replacement or acquisition of equipment or medical devices are always approved if justifiable. Incident and accident reports are used to disclose either equipment malfunction or patient incidents related to equipment which are immediately declared to the patient. The equipment for sterilization is very well maintained and monitored, the instructions for the operation of equipment is available but should be formalized to ensure proper use of the equipment.

Service Excellence Standards Results

The results in this section are grouped first by standards set and then by priority process.

Priority processes specific to service excellence standards are:

Clinical Leadership

Providing leadership and direction to teams providing services.

Competency

• Developing a skilled, knowledgeable, interdisciplinary team that can manage and deliver effective programs and services.

Episode of Care

• Partnering with clients and families to provide client-centred services throughout the health care encounter.

Decision Support

• Maintaining efficient, secure information systems to support effective service delivery.

Impact on Outcomes

 Using evidence and quality improvement measures to evaluate and improve safety and quality of services.

Medication Management

Using interdisciplinary teams to manage the provision of medication to clients

Infection Prevention and Control

 Implementing measures to prevent and reduce the acquisition and transmission of infection among staff, service providers, clients, and families

Standards Set: Assisted Reproductive Technology (ART) Standards for Clinical Services - Direct Service Provision

Unm	et Criteria	High Priority Criteria
Prior	rity Process: Clinical Leadership	
1.5	Service-specific goals and objectives are developed, with input from clients and families.	

2.3 An appropriate mix of skill level and experience within the team is determined, with input from clients and families. The effectiveness of resources, space, and staffing is evaluated with input 2.5 from clients and families, the team, and stakeholders. 3.1 Work is conducted with national organizations to promote reproductive health, with input from clients and families.

Priority Process: Competency

The organization has met all criteria for this priority process.

	. ,,	
Priori	ty Process: Episode of Care	
10.2	Target response times to requests for services and information are set with input from clients and families, and achievement of those targets is monitored.	!
11.15	A process to investigate and respond to claims that clients' rights have been violated is developed and implemented with input from clients and families.	!
12.2	The assessment process is designed with input from clients and families.	
Priori	ty Process: Decision Support	
15.8	There is a process to monitor and evaluate record-keeping practices, designed with input from clients and families, and the information is used to make improvements.	!
Priori	ty Process: Impact on Outcomes	
17.2	The procedure to select evidence-informed guidelines is reviewed, with input from clients and families, teams, and partners.	
17.3	There is a standardized process, developed with input from clients and families, to decide among conflicting evidence-informed guidelines.	!
17.4	Protocols and procedures for reducing unnecessary variation in service delivery are developed, with input from clients and families.	!
17.5	Guidelines and protocols are regularly reviewed, with input from clients and families.	!
17.6	There is a policy on ethical research practices that outlines when to seek approval, developed with input from clients and families.	!
18.2	Strategies are developed and implemented to address identified safety risks, with input from clients and families.	!

18.4 Safety improvement strategies are evaluated with input from clients and families.



19.11 Quality improvement initiatives are regularly evaluated for feasibility, relevance, and usefulness, with input from clients and families.

Priority Process: Medication Management

The organization has met all criteria for this priority process.

Priority Process: Infection Prevention and Control

The organization has met all criteria for this priority process.

Surveyor comments on the priority process(es)

Priority Process: Clinical Leadership

This is a well planned and organised service. Patients and families are appreciative but there is no formal involvement of patients and families in the planning. This should be done.

Priority Process: Competency

There is good and ongoing development of the abilities of all staff.

Priority Process: Episode of Care

High quality current contemporary care is provided. There is very desirable use of patient navigators. These health care professional (often doctors from other countries and not licensable in Canada) facilitate patient care and certainly increase patient satisfaction. They are appreciated resources by the patients. They also provide feed back to the program about issues from patients and partners.

Priority Process: Decision Support

There is comprehensive use of electronic records. All policies are appropriate and properly applied. The only deficiency is lack of formal patient and family input into the development of the policies - and that is mostly not a reasonable expectation.

Priority Process: Impact on Outcomes

High-quality services are provided and the methods used are consistent with current best evidence. However, there is no systematic process amongst the physicians and staff working at OriginElle to achieve consistency of methods used. It is acknowledged that there may not be compelling evidence that one approach is better than another. There is strong evidence however that patient care is enhanced when there is consistency with any one method even if the selection of that one is a somewhat arbitrary choice amongst relatively equal alternatives.

There is the highly desirable existence of Patient Navigators which improves both the process of care and patient satisfaction. It also provides an opportunity for feedback of patient impressions and responses.

However, there is no systematic and formal involvement of patients in the planning of how care will be provided. This is really required for truly patient centred care.

There is the proposal to have a much more robust and systematic sampling of patient opinion collected electronically. OriginElle is strongly encouraged to bring this innovation to a conclusion and introduce it.

Priority Process: Medication Management

There is an effective relationship for the fertility drugs with an adjacent specialized private pharmacy. Their App for patient teaching is an excellent idea. Patients may see and be seen by a pharmacist. Each gynecologist apparently has a slight; y different protocol for ovarian stimulation. There could be an advantage from consistency if they could accept one common approach.

Priority Process: Infection Prevention and Control

There are appropriate and well documented infection control processes that are rigorously applied.

Standards Set: Assisted Reproductive Technology (ART) Standards for Laboratory Services - Direct Service Provision

Unm	et Criteria	High Priority Criteria
Prior	ity Process: Clinical Leadership	
1.3	Service-specific goals and objectives are developed, with input from clients and families.	
Prior	ity Process: Competency	
6.6	Education and training are provided on how to identify, reduce, and manage risks to client and team safety.	!
Prior	ity Process: Episode of Care	
8.3	Effective alarms and monitoring systems are used to ensure the safety of cryopreserved gametes and embryos.	!
11.3	Records are maintained for all supplies, solutions, and media which include the manufacturer and supplier information; batch and lot number; date of receipt and preparation; date placed in use; expiration date; technical identification; chemicals used; and certificates of analysis.	!
11.9	The conditions necessary for proper use and storage of supplies, solutions, and media are clearly defined and documented.	!
Prior	ity Process: Decision Support	

The organization has met all criteria for this priority process.

Prior	ity Process: Impact on Outcomes	
15.1	A proactive, predictive approach is used to identify risks to client and team safety, with input from clients and families.	!
15.2	Strategies are developed and implemented to address identified safety risks, with input from clients and families.	!
15.3	Verification processes are used to mitigate high-risk activities, with input from clients and families.	!
15.4	Safety improvement strategies are evaluated with input from clients and families.	!
16.4	The laboratory participates in a proficiency testing program, where available.	!

Indicator(s) that monitor progress for each quality improvement 16.8 objective are identified, with input from clients and families. 16.9 Quality improvement activities are designed and tested to meet objectives. 16.10 Quality improvement initiatives are regularly evaluated for feasibility, relevance, and usefulness, with input from clients and families. 16.11 New or existing indicator data are used to establish a baseline for each indicator. There is a process to regularly collect indicator data and track progress. 16.12 16.13 Indicator data is regularly analyzed to determine the effectiveness of the quality improvement activities. Quality improvement activities that were shown to be effective in the testing phase are implemented broadly throughout the organization. 16.15 Information about quality improvement activities, results, and learnings is shared with clients, families, teams, organization leaders, and other organizations, as appropriate. Surveyor comments on the priority process(es) **Priority Process: Clinical Leadership**

The ART laboratory is under the guidance of a very highly motivated, competent and dedicated team. The laboratory personnel are very involved in the day-to-day activities. There is a sense of family in the laboratory. Very well-established process to ensure the inventory of supplies, media and solutions are always available. To continue to increase quality of services, specific objectives should be established for the laboratory. Objectives must be clear, have measurable outcomes and success factors, and are realistic and time-specific. Objectives are meaningful to the team. They are reviewed annually or as needed and their achievement is evaluated. The implementation of the new inventory and ordering system ensure proper inventory is always available and guarantees no interruption of services. The addition of specific DNA fragmentation testing to accommodate their clients needs speaks to the leadership of the laboratory.

Priority Process: Competency

The laboratory is comprised of experience and passionate staff that is reflected on the quality of their work. The clinic promotes and encourages continuing education for staff. This is very apparent by the organization of the weekly education session. Funding is available to staff to pursue their continuing education. The organization has an established effective working relationships with the clinical staff, management, and other programs and services. Since there is only 2 staff members for the laboratory, communication is not an issue, but as the clinic evolves and as other clinics come on board, it would be good for the laboratory to establish a universal standardized communication process such as a log book.

The laboratory has access to many experts in the field they can call upon for guidance, such as the laboratory director. No formal training on risk assessment has been done but is planned in the very near future. Risk assessment needs to be done for every process in the laboratory and should include challenges with equipment, handling spills, waste, or infectious materials; and challenges with handling, storing of reagents or samples. Common risks to the team may include lack of training on safety issues, performing improper lifts, improper use of equipment, or working alone. This exercise will be of great value to identify potential risks, a grading scale could be used to identify the severity of the risk and the solutions put or to be put in place to reduce the risks.

Priority Process: Episode of Care

Since the clinic does not offer any embryology services, many of the criteria are not applicable. The physical space in the laboratory is generous, clean and well organized. The SOP's are all up to date and have been reviewed. Proper consent is documented and well done. Client double verification is taken very seriously and rigorously applied. The cross-checks are very well done and a reliable system for tracking cryopreserved specimens is in place. The process in place for the cryogenic storage of gametes is very good, consent is done, follow-up is done, and a process is in place for those non-compliant clients. The process for expediting and receiving shipment is well done, the expedition is done using a private company. The implementation of new inventory system has had a very positive impact on the laboratory guaranteeing that supplies will always be available and close monitoring of expiry dates is done. This new system ensures no interruption of service will occur. Presently the date place is used is documented on the reagent. To be able to trace which supply or reagent that was used on each patient the date placed in use must be documented. The reagents are properly stored, but there is no documentation of temperature monitoring of the refrigerator or freezer. To guarantee that the refrigerator and freezer are working effectively, proper monitoring with documentation must be done to be able to see if any trends or variation of temperature occur during storage or equipment performance. The cryogenic tanks are stored in a secure room and are locked. A physical monitoring process is done every Friday to fill the cryogenic tanks, but there is no effective alarm or monitoring systems in place. Even if this is a small clinic, there needs to be an investment to purchase a proper alarm and monitoring system to ensure gametes safety. The instance of an incident could be detrimental to patients. In conclusion, the laboratory is a very efficient, productive and a quality facility.

Priority Process: Decision Support

Client confidentiality is taken very seriously, and extra measures are in place to monitor patient charts. Record-keeping practices are very well established and monitored. The addition of the new IT system since the last visit has really had a positive impact on the laboratory. Patient files are complete and all the information including laboratory results are easy to retrieve. This addition also ensures the flow of client information. Policy is in place for electronic communication through the new IT system which is capable of encrypting the information for patient confidentiality.

Priority Process: Impact on Outcomes

The laboratory needs to develop quality management programs. The key elements such as objectives, goals, indicators and risk assessments should be part of the program. To continue to increase quality of services, specific objectives should be established for the laboratory. Objectives must be clear, have measurable outcomes and success factors, and are realistic and time-specific. Goals and objectives are meaningful to the team. Clients could take part in this exercise. Risk assessment is a very important exercise to identify high-risk activities and reduce risks. The laboratory would certainly gain from external quality control activities. The participation in an external proficiency program would increase the safety to patients and would give an extra validation of the excellent work being done in the laboratory. This participation would give patients that extra confidence in the performance of the clinic.

Standards Set: Assisted Reproductive Technology (ART) Standards for Working with Third Party Donors - Direct Service Provision

Unmet Criteria

High Priority
Criteria

Priority Process: Episode of Care

The organization has met all criteria for this priority process.

Surveyor comments on the priority process(es)

Priority Process: Episode of Care

Since the clinic does not do any recruitment for third party donors, the process is very simple, well established, followed with the implication of the psychologist. Appropriate counselling is provided to potential third-party donors. The donor consent is very well documented. The process is explained in detail including the possibility of unexpected results that could prevent them from donating to the donor. If there should be any inclination of doubt on the donor, she can withdraw her consent at any time. Since the clinic does not do any recruitment of donors, it can be exempt from all responsibilities towards the donor. Many of the criteria do not apply to this process since no recruitment is done.

Instrument Results

As part of Qmentum, organizations administer instruments. Qmentum includes three instruments (or questionnaires) that measure governance functioning, patient safety culture, and quality of worklife. They are completed by a representative sample of clients, staff, senior leaders, board members, and other stakeholders.

Governance Functioning Tool (2016)

The Governance Functioning Tool enables members of the governing body to assess board structures and processes, provide their perceptions and opinions, and identify priorities for action. It does this by asking questions about:

- Board composition and membership
- Scope of authority (roles and responsibilities)
- Meeting processes
- Evaluation of performance

Accreditation Canada provided the organization with detailed results from its Governance Functioning Tool prior to the on-site survey through the client organization portal. The organization then had the opportunity to address challenging areas.

• Data collection period: March 15, 2018 to March 23, 2018

• Number of responses: 1

Governance Functioning Tool Results

	% Strongly Disagree / Disagree Organization	% Neutral Organization	% Agree / Strongly Agree Organization	%Agree * Canadian Average
We regularly review and ensure compliance with applicable laws, legislation, and regulations.	0	0	100	94
2. Governance policies and procedures that define our role and responsibilities are well documented and consistently followed.	0	0	100	95
3. Subcommittees need better defined roles and responsibilities.	0	0	0	70
4. As a governing body, we do not become directly involved in management issues.	0	0	100	85
5. Disagreements are viewed as a search for solutions rather than a "win/lose".	0	0	100	95

	% Strongly Disagree / Disagree Organization	% Neutral Organization	% Agree / Strongly Agree Organization	%Agree * Canadian Average
6. Our meetings are held frequently enough to make sure we are able to make timely decisions.	0	0	100	96
7. Individual members understand and carry out their legal duties, roles, and responsibilities, including subcommittee work (as applicable).	0	0	100	96
8. Members come to meetings prepared to engage in meaningful discussion and thoughtful decision making.	0	0	100	94
9. Our governance processes need to better ensure that everyone participates in decision making.	0	0	100	59
10. The composition of our governing body contributes to strong governance and leadership performance.	0	0	100	95
11. Individual members ask for and listen to one another's ideas and input.	0	0	100	97
12. Our ongoing education and professional development is encouraged.	0	0	100	86
13. Working relationships among individual members are positive.	0	0	100	98
14. We have a process to set bylaws and corporate policies.	0	0	100	95
15. Our bylaws and corporate policies cover confidentiality and conflict of interest.	0	0	100	98
16. We benchmark our performance against other similar organizations and/or national standards.	0	0	100	77
17. Contributions of individual members are reviewed regularly.	0	0	100	71
18. As a team, we regularly review how we function together and how our governance processes could be improved.	0	0	100	84
19. There is a process for improving individual effectiveness when non-performance is an issue.	0	0	100	60
20. As a governing body, we regularly identify areas for improvement and engage in our own quality improvement activities.	0	0	100	84

	% Strongly Disagree / Disagree	% Neutral	% Agree / Strongly Agree	%Agree * Canadian Average
	Organization	Organization	Organization	
21. As individual members, we need better feedback about our contribution to the governing body.	0	100	0	44
22. We receive ongoing education on how to interpret information on quality and patient safety performance.	0	0	100	81
23. As a governing body, we oversee the development of the organization's strategic plan.	0	0	100	97
24. As a governing body, we hear stories about clients who experienced harm during care.	0	0	100	86
25. The performance measures we track as a governing body give us a good understanding of organizational performance.	0	0	100	91
26. We actively recruit, recommend, and/or select new members based on needs for particular skills, background, and experience.	0	0	100	86
27. We lack explicit criteria to recruit and select new members.	100	0	0	77
28. Our renewal cycle is appropriately managed to ensure the continuity of the governing body.	0	0	100	89
29. The composition of our governing body allows us to meet stakeholder and community needs.	0	0	100	94
30. Clear, written policies define term lengths and limits for individual members, as well as compensation.	0	0	100	93
31. We review our own structure, including size and subcommittee structure.	0	0	100	87
32. We have a process to elect or appoint our chair.	0	0	100	86

^{*}Canadian average: Percentage of Accreditation Canada client organizations that completed the instrument from July to December, 2017 and agreed with the instrument items.

ı	Overall, what is your assessment of the governing body's impact over the past 12 months, in terms of driving improvements to:	% Poor / Fair	% Good	% Very Good / Excellent	%Agree * Canadian Average
		Organization	Organization	Organization	J J
	33. Patient safety	0	0	100	80

Overall, what is your assessment of the governing body's impact over the past 12 months, in terms of driving improvements to:	% Poor / Fair	% Good	% Very Good / Excellent	%Agree * Canadian Average
	Organization	Organization	Organization	
34. Quality of care	0	0	100	81

^{*}Canadian average: Percentage of Accreditation Canada client organizations that completed the instrument from July to December, 2017 and agreed with the instrument items.

Canadian Patient Safety Culture Survey Tool: Community Based Version

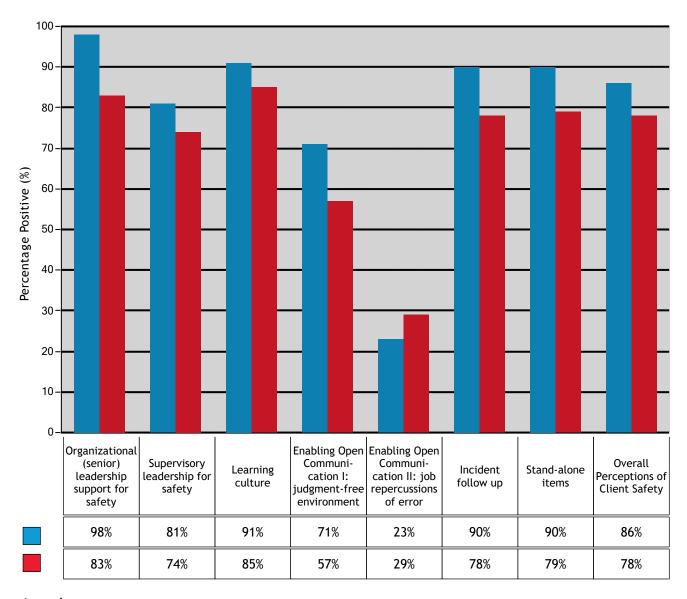
Organizational culture is widely recognized as a significant driver in changing behavior and expectations in order to increase safety within organizations. A key step in this process is the ability to measure the presence and degree of safety culture. This is why Accreditation Canada provides organizations with the Patient Safety Culture Tool, an evidence-informed questionnaire that provides insight into staff perceptions of patient safety. This tool gives organizations an overall patient safety grade and measures a number of dimensions of patient safety culture.

Results from the Patient Safety Culture Tool allow the organization to identify strengths and areas for improvement in a number of areas related to patient safety and worklife.

Accreditation Canada provided the organization with detailed results from its Patient Safety Culture Tool prior to the on-site survey through the client organization portal. The organization then had the opportunity to address areas for improvement. During the on-site survey, surveyors reviewed progress made in those areas.

- Data collection period: March 1, 2018 to March 15, 2018
- Minimum responses rate (based on the number of eligible employees): 9
- Number of responses: 11

Canadian Patient Safety Culture Survey Tool: Community Based Version: Results by Patient Safety Culture Dimension



Legend

Originelle Fertility Clinic and Women's Health Centre/Originelle Clinique de Fertilité et Centre de santé de la femme

* Canadian Average

*Canadian average: Percentage of Accreditation Canada client organizations that completed the instrument from July to December, 2017 and agreed with the instrument items.

Worklife Pulse

Accreditation Canada helps organizations create high quality workplaces that support workforce wellbeing and performance. This is why Accreditation Canada provides organizations with the Worklife Pulse Tool, an evidence-informed questionnaire that takes a snapshot of the quality of worklife.

Organizations can use results from the Worklife Pulse Tool to identify strengths and gaps in the quality of worklife, engage stakeholders in discussions of opportunities for improvement, plan interventions to improve the quality of worklife and develop a clearer understanding of how quality of worklife influences the organization's capacity to meet its strategic goals. By taking action to improve the determinants of worklife measured in the Worklife Pulse tool, organizations can improve outcomes.

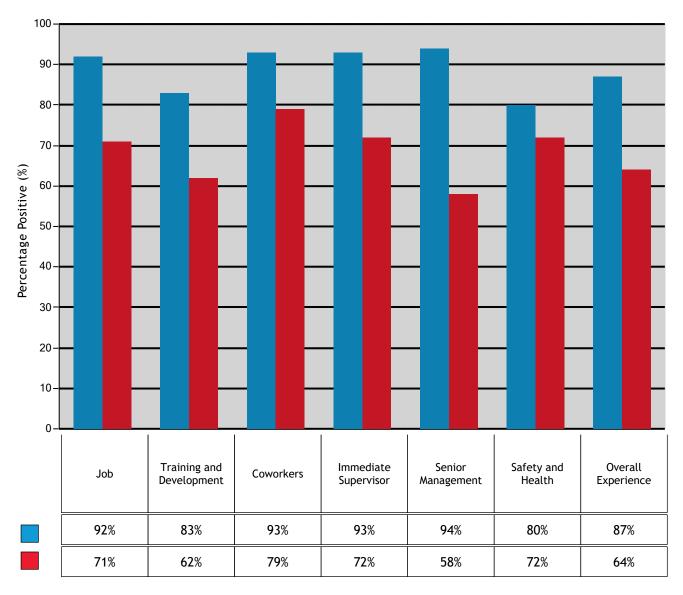
Accreditation Canada provided the organization with detailed results from its Worklife Pulse Tool prior to the on-site survey through the client organization portal. The organization then had the opportunity to address areas for improvement. During the on-site survey, surveyors reviewed progress made in those areas.

• Data collection period: March 1, 2018 to March 23, 2018

Minimum responses rate (based on the number of eligible employees): 14

• Number of responses: 15

Worklife Pulse: Results of Work Environment



Legend

Originelle Fertility Clinic and Women's Health Centre/Originelle Clinique de Fertilité et Centre de santé de la femme

* Canadian Average

*Canadian average: Percentage of Accreditation Canada client organizations that completed the instrument from July to December, 2017 and agreed with the instrument items.

Client Experience Tool

Measuring client experience in a consistent, formal way provides organizations with information they can use to enhance client-centred services, increase client engagement, and inform quality improvement initiatives.

Prior to the on-site survey, the organization conducted a client experience survey that addressed the following dimensions:

Respecting client values, expressed needs and preferences, including respecting client rights, cultural values, and preferences; ensuring informed consent and shared decision-making; and encouraging active participation in care planning and service delivery.

Sharing information, communication, and education, including providing the information that people want, ensuring open and transparent communication, and educating clients and their families about the health issues.

Coordinating and integrating services across boundaries, including accessing services, providing continuous service across the continuum, and preparing clients for discharge or transition.

Enhancing quality of life in the care environment and in activities of daily living, including providing physical comfort, pain management, and emotional and spiritual support and counselling.

The organization then had the chance to address opportunities for improvement and discuss related initiatives with surveyors during the on-site survey.

Client Experience Program Requirement	
Conducted a client experience survey using a survey tool and approach that meets accreditation program requirements	Met
Provided a client experience survey report(s) to Accreditation Canada	Met

Organization's Commentary

After the on-site survey, the organization was invited provide comments to be included in this report about its experience with Qmentum and the accreditation process.

Accreditation Canada results review (May 24/2018)

- Do the findings accurately capture the successes and challenges of the organization?
- o In general, I would say that this statement is true. The results were generally positive and key criteria to be improved upon spoke to a few key points that, once corrected/added, would respond to several areas of the evaluation.
- One key point that needs addressing is with respect to the focus on the need for patient and external involvement in policy and or procedural changes at the clinic. It feels as if the level of importance placed on this point, and in so many subcategories, is more aligned with a business model that is much larger than ours (ie Hospital Environment where they have teams and departments available to better facilitate and respond to this criteria). There were even comments in agreement to this point expressed by the evaluators verbally as well as in their notes and therefore suggest strongly that this focus on patient and external input be made more relative to clinic size.
- What has the organization learned through assessing its level of compliance against the Accreditation Canada standards?
- o We were very happy to be commended on the level of quality with regards to our current policies and procedures based on previous evaluations which shows our desire to be in a constant state of improvement as we seek to be the best in our field. This said, there is always room for improvement, and the suggestions not only imposed by Accreditation Canada but also through the 'real-life' experiences of the evaluators were greatly appreciated and will provide the basis for improved care of staff and patients. We are proud that the level of detail in which the evaluators addressed certain areas spoke to an already high level of care and attention put into patient and clinic management at OriginElle, and that the fine details only seek to add yet another level of exemplary care.
- Are there any actions currently underway to address the identified areas for improvement?
- o I am pleased to say that there were actions underway as of day one of the evaluators visit. Comments and suggestions were met with immediate response where capable, as well as solicited positive dialogue to seek the best course of action to respond to subsequent comments and needed criteria. This speaks to the level of dedication of our highly specialized and valued team.
- o We have also solicited the assistance of our representatives at Accreditation Canada to seek further clarification regarding certain points as we seek to respond as quickly as possible to the needed criteria outlined in the evaluation.
- o Please also see below.
- What are the organizations immediate and long term actions to improve its quality of care and diminish any risks that may exist?

- The creation of a new position in operations, which started at the beginning of the year (Jan 2018), is a testament to the commitment of the clinic to not only, complement existing roles providing them with key support and experience, but also filling a big need in the management team to add support to our patients and staff while driving positive change and growth.
- o We are going to upgrade our current EMR which will provide even greater improvements in security, Staff and patient communication and patient management efficiency
- o We have drafted an amendment to our primary patient evaluation forms with a focus on soliciting patient involvement in future policy changes and service improvements.
- o We have improved key clinic signage to improve visibility (Ex: external wheelchair access options and directions, indications pertaining to medical gas locations for emergency responders)
- o We are constantly developing and improvement our website and social media platforms with the goal of providing improved patient access to information and services. This also supports the need for more patient involvement by providing a forum for surveys, and suggestions soliciting change and improvements.
- o We are developing new internal and external survey templates to be offered to our patients at all levels of care with the goal of providing continuous feedback with measurable, quantitative data that can be used to constantly monitor our success and drive patient supported initiative and change.
- o We have ordered a 24/7 digital cryo-storage and sample monitoring system to add another level of security and failsafe measure ensuring the safety of our samples.
- o We have formalized an ethics and support management protocol clarifying how to respond to certain situations
- o Additions to Weekly meetings agendas continue to allow for constant positive dialogue and flow of information between team.
- o The clarification and updating of a staff code of Conduct letter (adding their signatures) as a mandatory part of each employees file will be completed shortly
- o The clarification and development of our code of ethics with respect to how we respond to issues related to: Staff and patient management, Incident reporting, Medical Procedures management
- o The development of an Ethics committee to respond to above document when issues arise.
- o The development of our risk management protocol system (already in place and in conjunction with our weekly meetings) to better monitor and respond to all internal issues as they arise with the goal of preventing future problems through on-going communication and education.
- o Actual Emergency drills (and emergency systems tests) are planned for completion within the next months to compliment our bi-annual reviews of emergency procedures presented at our staff meetings

We also look forward to receiving the finalized documents and action plan that will be developed in partnership with Accreditation Canada to support any other criteria not covered by the aforementioned planned initiatives.

Appendix A - Qmentum

Health care accreditation contributes to quality improvement and patient safety by enabling a health organization to regularly and consistently assess and improve its services. Accreditation Canada's Qmentum accreditation program offers a customized process aligned with each client organization's needs and priorities.

As part of the Qmentum accreditation process, client organizations complete self-assessment questionnaires, submit performance measure data, and undergo an on-site survey during which trained peer surveyors assess their services against national standards. The surveyor team provides preliminary results to the organization at the end of the on-site survey. Accreditation Canada reviews these results and issues the Accreditation Report within 10 business days.

An important adjunct to the Accreditation Report is the online Quality Performance Roadmap, available to client organizations through their portal. The organization uses the information in the Roadmap in conjunction with the Accreditation Report to ensure that it develops comprehensive action plans.

Throughout the four-year cycle, Accreditation Canada provides ongoing liaison and support to help the organization address issues, develop action plans, and monitor progress.

Action Planning

Following the on-site survey, the organization uses the information in its Accreditation Report and Quality Performance Roadmap to develop action plans to address areas identified as needing improvement.

Appendix B - Priority Processes

Priority processes associated with system-wide standards

Priority Process	Description
People-Centred Care	Working with clients and their families to plan and provide care that is respectful, compassionate, culturally safe, and competent, and to see that this care is continuously improved upon.