

Ontario Health Clinical Guidance for the Conservation of Iodinated Contrast Media (ICM)

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Table of Contents

xecutive summary	3
Background	5
Dbjectives	
Guiding Principles	
Recommendation Development Approach	
Recommendations	8
References and Additional Resources	11
Appendices	15

Executive summary

lodinated contrast media (ICM) are used in some imaging applications, including computed tomography (CT) and angiography, to help delineate areas of interest, help a radiologist's ability to assess disease, and/or help guide therapeutic interventions by interventional radiologists, cardiologists, and other proceduralists.

Acute COVID-related impacts to both manufacturing and supply chain logistics have led to global shortages of ICM. There are three suppliers of ICM in Ontario, GE Healthcare, Bayer and Bracco. The shortage pertains to the major supplier of ICM in Ontario, GE Healthcare. However, it is unlikely that other suppliers will be able to mitigate the shortage. Initially signalled to healthcare providers in May 2022, the situation is highly dynamic and timelines for complete resolution are currently unknown.

Decision-making should consider the interdependence of our health care system, and how changes in one part of the care continuum may impact others. It is anticipated that some regions and institutions will be better positioned to deal with the shortage due to differences in procurement and warehousing. Asymmetry in ICM availability across the health system signals a need for urgent planning and ongoing collaboration to ensure equitable access for all Ontario patients.

Ontario Health convened a Provincial Clinical Advisory Panel to guide clinical decision-making during this global ICM shortage and to advise during the development of this document: "Ontario Health Clinical Guidance for the Conservation of Iodinated Contrast Media (ICM)."

Immediate Action

Immediate action is required across all system partners to preserve ICM supply and protect the patients who most urgently need care. Recognizing there will be local considerations and that opportunities to conserve ICM will vary across institutions, this document provides a comprehensive set of strategies that can be employed.

Institutions should aim to reduce ICM consumption by 50% from baseline levels, regardless of vendor.

Based on distribution levels, many sites impacted early by shortages have already successfully implemented a 30-60% reduction in ICM utilization, without appreciable reduction in diagnostic image quality. Institutions should enact as many of the strategies in this document as possible, but the following conservation tactics have been highlighted as having the largest impacts:

- 1. Implement ICM dose reduction for all exams and procedures where diagnostic quality will not be adversely affected. In consultation with all relevant stakeholders, use an iterative process to titrate a reduction in ICM volume by 5-10% and ensure diagnostic quality is maintained.
- 2. **Expand the use of non-contrast enhanced scans.** All decisions regarding the protocoling of exams as contrast vs. non-contrast should be made based on clinical indication, and in consultation with all relevant disciplines.
- 3. Consider contrast injection protocols with ICM doses tailored to patient body weight.

- 4. **Implement measures to minimize ICM wastage.** E.g., work with infection control/pharmacy for opportunities to support multi-use delivery.
- 5. **Optimize technical parameters for image acquisition.** E.g., lowering tube voltage, protocol optimization.

Background

Issue

Iodinated contrast media (ICM) are used to facilitate a variety of medical imaging examinations and interventional procedures. In Ontario there are three suppliers of ICM, GE Healthcare, Bayer, Bracco, with GE Healthcare having majority of market share across Canada (source: GE Healthcare, Canada correspondence).

Global shortages of GE Healthcare ICM products were signalled to healthcare providers in May 2022 due to COVID-related lockdowns impacting the main manufacturing site in Shanghai, China. Furthermore, supply chain issues associated with the lockdown have created delays in distribution and transportation. The other GE Healthcare facility producing ICM is in Ireland but has already expanded production to operate at maximum capacity.

GE Healthcare is providing updated information regarding delivery timelines and production levels (please refer to the <u>GE Healthcare</u> and <u>Health Canada Drug Shortage</u> webpages). Timelines to return to initial supply levels in Ontario will likely extend well beyond when full production resumes.

Iodinated contrast media in clinical care

Imaging and interventions using ICM have applications across multiple specialties and areas of patient care. Table 1 provides a cross-section of clinical areas, examinations and procedures that use ICM and will be impacted by ICM shortages. In Ontario, the majority of these clinical activities occur in hospitals but there are a small number of independent health facilities who also provide these services.

Table 1. Key clinical program areas where iodinated contrast media is used (sample list, not intended to be fully comprehensive of all applications)

Program	Imaging	Fluoroscopy	Interventional
			Procedures
Radiology	\boxtimes	\boxtimes	
Cardiology	\boxtimes		\boxtimes
Neurology	\boxtimes		\boxtimes
Neurosurgery	\boxtimes		\boxtimes
Vascular	\boxtimes		\boxtimes
Gastrointestinal			\boxtimes
Urology	\boxtimes	\boxtimes	
General Surgery	\boxtimes	\boxtimes	
Oncology	\boxtimes		
Oncology: Radiation	\boxtimes		
Treatment Planning			
Emergency	\boxtimes	\boxtimes	
Department			
Research	\boxtimes		

There are several decision points as a patient receives care that a) inform the need for contrast, and b) provide opportunities to optimize ICM use. The medical imaging example in Figure 1 provides a

framework to think through each step; similar concepts can be employed beyond medical imaging, and regardless of route of contrast administration (e.g., oral, intravenous, intra-arterial, enteric).

At a fundamental level, a patient presents with a clinical problem, and the subsequent imaging or intervention must be appropriate for the patient's situation and deliver high-quality care.

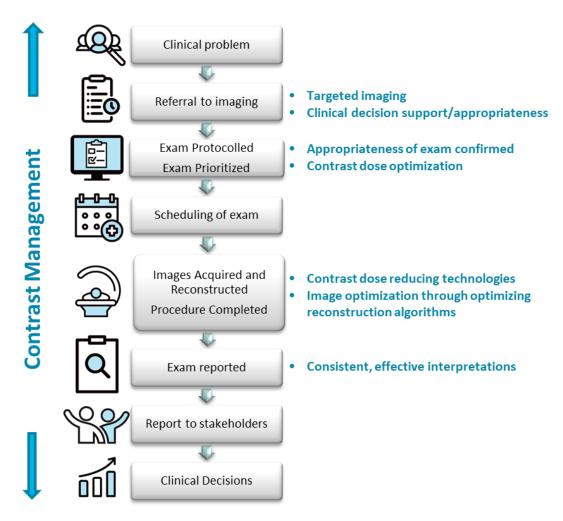


Figure. 1. Patient journey and contrast decision points.

There is a lack of system-level information regarding contrast utilization and inventory. However, administrative data available for CT scanning – a dominant user of ICM – provides a conservative estimate of the number of exams in Ontario that may be impacted (Table 2), with just over 1,000,000 contrast-enhanced CT scans performed in the fiscal year 2021/22 (April 1, 2021 – March 31, 2022). The overall number and percentage of these exams performed with ICM continues to increase year over year, with the exception of during peak COVID impacts in fiscal year 2020/21.

Table 2. Number of CT scans performed, total and with ICM contrast, by fiscal year 2018/19 – 2021/22.

Fiscal Year	CT performed with ICM (number)	Total CT performed (number)	% CT exams performed with ICM		
FY2018/19	846,395	1,697,996	49.8%		
FY2019/20	902,231	1,763,775	51.2%		
FY2020/21	918,203	1,706,871	53.8%		
FY2021/22	1,049,104	1,936,650	54.2%		

Data prepared by: Ontario Health, Health System Performance and Support, Diagnostic Imaging Information Program.

Data source: Ontario Health Insurance Program billing data

System visibility into ICM utilization over the longer term will require approaches to address this information gap and will be helpful both during times of shortage but also as part of understanding quality healthcare utilization. In the short term, institutions will need to actively monitor and manage inventory, with processes in place to support regional and provincial views to inventory.

Objectives

With advice from the Provincial Clinical Advisory Panel, this document provides provincial, regional, organizational, and provider-level guidance to:

- Develop and implement a conservation strategy that focuses on effective management of existing supplies
- Communicate and collaborate with internal and external stakeholders

This document does not focus on the deferral of patients for whom there are evidence-informed indications for ICM-based imaging. If the shortage escalates to a critical level, a supplemental document with a prioritization framework for deferring patients will be developed with the Provincial Clinical Advisory Panel.

Although this guidance has been developed through this period of ICM shortage, many of these recommendations can be applied moving forward as part of providing effective patient care with strategies to support the sustainable, effective use of contrast media.

Guiding Principles

The Provincial Clinical Advisory Panel recommendations are from the perspective of ensuring safe, effective patient care during ICM shortage and beyond, without compromising clinical quality, and taking a vendor agnostic approach to conserve provincial ICM supply.

The Panel followed these guiding principles:

- providing equitable access,
- prioritizing patients according to clinical urgency,
- using a disease-agnostic approach; and
- using a systems approach to coordination and sharing of scarce resources and access across the province

The Panel was further guided by the Ontario Health Quadruple Aim Framework for the health system, which includes Patient Experience, Health Outcomes, Efficiency and Provider Experience.

Recommendation Development Approach

The Provincial Clinical Advisory Panel was co-chaired by Dr. Chris Simpson, Executive Vice President (Medical) and Chief Medical Officer at Ontario Health and Dr. Julian Dobranowski, Provincial Head, Cancer Imaging Program and Clinical Lead for Diagnostic Imaging at Ontario Health. Panel representation was interdisciplinary, and interregional (refer to Appendix A for Panel membership). Members from Ontario Health and the Ministry of Health supported Panel discussions by providing information, data, and system-level expertise from other provincial initiatives. The Panel convened and existing available resources were reviewed and leveraged where appropriate in developing the guidance document.

Recommendations

These recommendations are guidelines for all institutions to aim to reduce ICM consumption by 50% from baseline levels, regardless of vendor. Based on distribution levels, many sites have already successfully implemented a 30-60% reduction in ICM utilization, without any appreciable reduction in diagnostic image quality. It is expected that all sites in Ontario immediately begin implementing these strategies to preserve access for all Ontario patients.

Provincial Guidance

Existing provincial and regional structures will be leveraged to support consistent messaging and efficient information cascades.

Regional Guidance

- 1. Regional approaches will support implementation, including a regional view on ICM supply and demand, and ensuring all institutions are enacting ICM conservation strategies. This should be occurring regardless of which vendor is supplying contrast to the institution.
- 2. In collaboration with Ontario Health Chief Regional Officers (CROs) and Regional Clinical Vice-Presidents, a regional structure for collaboration on contrast use within the region, which includes relevant stakeholders affected by the contrast shortage should be implemented. The regional structure should support the following:
 - a) Assessment of contrast utilization by all programs (refer to Table 1), including on-hand inventory and delivery of expected inventory
 - b) Development of a regional strategy for distribution of contrast, ensuring equitable access
 - c) Support for the implementation of communications strategies and best practices that can be applied across institutions regarding contrast conservation

Organizational and Departmental Guidance

- 1. Consider establishing an organization wide committee to provide real time situational awareness and oversight for the implementation of conservation best practices.
- Organizations should develop strategies to assess contrast utilization, on-hand inventory and demand. In partnership with regional structures at Ontario Health, collect and share contrast usage data. Sample tracking tools to monitor daily usage of contrast and forecast remaining supply are in **Appendix B**

Referring Clinicians

- 1. With conservation in mind, consider appropriateness for patients, and recommendations outlined in Choosing Wisely, evidence-informed clinical practice guidelines, and other relevant guidance documents (e.g., Canadian Association of Radiology Guidance Documents, refer to the Additional Resources section)
- Provide complete, relevant clinical information on all requisitions including patient weight for dose management strategies, to support appropriate prioritization, protocoling, and to help ensure radiology reporting addresses clinical need. eReferral systems may be helpful, where available.
- 3. Avoid duplication of examinations through review of patient's imaging history (e.g., Clinical Connect).

Technical Guidance

To ensure ICM supply is optimized, sites should implement as many relevant strategies as possible, and ensure processes are in place for quality review and shared decision making with all relevant stakeholders (e.g., radiology and referring clinicians)

1. Expanding Use of Non-Contrast CT Exams

a) Where appropriate, non-contrast exams should be employed. This strategy continues to remain as the dominant driver for ICM conservation for hospitals who are experiencing shortages. All decisions regarding the protocoling of exams as contrast vs.

non-contrast should be made based on clinical indication, and in consultation with all relevant disciplines. (e.g., emergency department, treating specialists, radiology).

2. Contrast Dose Reduction Strategies

- a) Implement ICM dose reduction for all exams and procedures where diagnostic quality will not be adversely affected. In consultation with all relevant stakeholders, use an iterative process to titrate a reduction in ICM volume by 5-10% and ensure diagnostic quality is maintained.
- b) Consider contrast injection protocols with ICM doses tailored to patient body weight.
- c) Implement adjustments in the technical parameters of the CT scan (e.g., lowering tube voltage).
- d) Review existing protocols for opportunities to optimize technology. Consider engaging clinical application specialist from vendors to evaluate adjustment of image reconstruction algorithms as necessary.
- e) Consider opportunities for innovative approaches for dose reduction (e.g., dual-energy).
- f) Consider the utility of injector pumps that use flow dynamics, radiation dose and weight in lowering contrast delivery.
- g) During interventional procedures where ICM is used dynamically, consider implementing techniques to reduce ICM use (e.g., optimize injection rates and minimizing contrast volume per case as appropriate).

3. Contrast Media Substitution

- a) Where equally appropriate, consider the use of an alternate oral contrast agent (e.g., barium-based, gastografin).
- b) Where equally appropriate, consider the use of water in lieu of oral contrast for CT Abdomen exams.
- c) Where equally appropriate, consider use of CO² angiography.
- d) Consider use of lower density concentration ICM such as 300 and 240mg/mL products.

4. Alternate Imaging Modalities

a) Where equally appropriate, consider other available imaging modalities. When switching to other modalities, impacts to capacity, wait times, HHR and opportunities to increase operational hours should be considered.

5. Limiting Wastage

- a) Confirm expiry timelines of open contrast vials with pharmacy departments and vendors.
- b) Single dose-use work with infection control/pharmacy where opportunities exist for multi-use delivery.
- c) In consultation with supply chain organization, consider switching from single dose to multi-dose vials using multi-dosing lines.
- d) Where appropriate, adjust scanner scheduling to optimize use of ICM within the expiry timelines.

6. Scheduling Strategies

- a) When scheduling newly referred patients, protocol requests based on appropriateness guidelines.
- b) When booking exams and/or reviewing protocols of exams already booked, assess for ICM dose reduction opportunities. Identify exams that can be non-contrast or imaged using an alternative modality where appropriate. Previous imaging reports may help inform whether ICM is required for the study being booked. Avoid duplication of examinations by reviewing patient's imaging history through Clinical Connect.
- c) To help capture system-level data and understand the impact of the ICM shortage for CT scans, please leverage the Wait Time Information System Delay Reason of Lack of Facility Resources to indicate all examinations that have been delayed or deferred due to ICM supply issues.

References and Additional Resources

The below references and additional resources were collated through a literature review and stakeholder engagement including contributions from institutions and GE Healthcare Canada.

References

Cavallo J, Pahade J. Practice Management Strategies for Imaging Facilities Facing an Acute Iodinated Contrast Media Shortage. *AJR American journal of roentgenology*. May 2022. doi:10.2214/AJR.22.27969

Grist TM, Canon CL, Fishman EK, Kohi MP, Mossa-Basha M. Short-, Mid-, and Long-Term Strategies to Manage the Shortage of Iohexol. *Radiology*. May 2022:221183. doi:10.1148/radiol.221183

Ananthakrishnan L, Kay FU, Zeikus EA et al. What the Baby Formula and Medical Contrast Material Shortages Have in Common: Insights and Recommendations for Managing the Iodinated Contrast Media Shortage May 2022. *Radiology: Cardiothoracic Imaging 2022* 4:3

Omary RA, Allen LM, Davis LT, et al. Rapid Response to the Acute Iodinated Contrast Shortage During the COVID-19 Pandemic: Single-Institution Experience. *Journal of the American College of Radiology: JACR*. May 2022. doi:10.1016/j.jacr.2022.05.005

Additional Resources

Pharmacy & Supply Chain Community

- American Society of Health-System Pharmacists (ASHP) CM Conservation guidancehttps://www.ashp.org/drug-shortages/shortage-resources/considerations-for-imaging-contrastshortagemanagement?loginreturnUrl=SSOCheckOnly.%20In%20addition%20to%20examining%20conser vation%20efforts,%20prioritizatization%20upon%20clinical%20acuity,%20and%20use%20of%20 alternative%20imaging,%20the%20ASHP%20also
- Advancing Health Care through Supply Chain Excellence and American Hospital Association https://www.mhanet.com/mhaimages/QSR/SCRC-Special-Report.pdf
 and
 https://www.ahrmm.org/system/files/media/file/2022/05/SCRC-Special-Report-May-12.pdf

Radiology Community

- American College of Radiology (ACR)- https://www.acr.org/Clinical-Position-Statements/Contrast-Media-Shortage#bookmark and https://www.acr.org/Clinical-Resources/ACR-Appropriateness-Criteria
- Society of Interventional Radiology (SIR)- https://connect.sirweb.org/e-irq/participate/viewirqarticle?DocumentKey=fc58e500-f4e9-40fe-8034-b088b44c7b38
- Canadian Association of Radiology (CAR)- https://car.ca/news/contrast-agent-use-in-medical-imaging-a-roadmap-for-patients/?inf_contact_key=16f572b7dba74d873d1cc6918d9e0e1f680f8914173f9191b1c0223e68310bb1#more-14986
- Royal Australian & New Zealand College of Radiologists (RANZCR)https://www.ranzcr.com/doclink/ranzcr-statement-on-iodinated-contrast-media-

- shortage/eyJ0eXAiOiJKV1QiLCJhbGciOiJIUzI1NiJ9.eyJzdWIiOiJyYW56Y3Itc3RhdGVtZW50LW9uLWIvZGluYXRIZC1jb250cmFzdC1tZWRpYS1zaG9ydGFnZSIsImlhdCl6MTY1Mjc2NTM4MywiZXhwIjoxNjUyODUxNzgzfQ.ybIkoD4 pP9OVNCvxmZ44jOfp-Uu1W2ejWEAskIqyB8
- Australian and New Zealand Society for Vascular Surgery (ANZSVS)-https://www.anzsvs.org.au/wp-content/uploads/2022/05/STM-2022-05-13-lodinated-Contrast-Shortage.pdf
- American Journal of Roentgenology published best practices for Iodinated Contrast Media Shortage- https://www.ajronline.org/doi/abs/10.2214/AJR.22.27969
- Rapid Response to the Acute Iodinated CM Shortage Vanderbilt University Medical Centerhttps://els-jbs-prod-cdn.jbs.elsevierhealth.com/pbassets/Health%20Advance/journals/jacr/Contrast Media JACR 5868-1652368490753.pdf
- University of North Carolina-Chapel Hill, Short-Term Mitigation CM Shortage-https://els-jbs-prod-cdn.jbs.elsevierhealth.com/pb-assets/Health%20Advance/journals/jacr/Contrast_Media_JACR_5867-1652368481637.pdf
- Radiology: Cardiothoracic Imaging- Managing ICM Shortage Cardiothoracic Imaginghttps://pubs.rsna.org/doi/epdf/10.1148/ryct.220101
- An Empiric Medicare Claims-Based Utilization Approach to Mitigating the Iodinated Contrast Shortage- https://els-jbs-prod-cdn.jbs.elsevierhealth.com/pb-assets/Health%20Advance/journals/jacr/Contrast_Media_JACR_00266-1652884817293.pdf
- Diagnostic Imaging- Fifteen Recommendations for Addressing the Shortage-https://www.diagnosticimaging.com/view/iodinated-contrast-media-fifteen-recommendations-for-addressing-the-shortage

Interventional Cardiology Community

- American College of Cardiology (ACC)- What You Need to Know: Navigating the ICM shortagehttps://www.acc.org/latest-in-cardiology/articles/2022/05/19/19/23/what-you-need-to-know-navigating-the-iodinated-contrast-media-shortage
- Society for Cardiovascular Angiography & Intervention (SCAI)- SCAI Practical Techniques Reduce CM- https://scai.org/practical-techniques-reduce-contrast-volumes-cardiac-catheterization-laboratory
- CathLab Digest's Clinical Editor Corner- CM Shortage: What Should We Do About it?-https://www.hmpgloballearningnetwork.com/site/cathlab/clinical-editors-corner/contrast-media-shortage-what-should-we-do-about-it
- Cardiovascular Business- https://www.cardiovascularbusiness.com/topics/cardiac-imaging/cath-lab/video-how-iodine-contrast-shortage-impacting-interventional-cath

Emergency Medicine, Surgical Anesthesiology, Pain Management, EP Community, etc.

- EP Lab Digest- Strategies to Minimize Use of Iodinated Contrast in the Electrophysiology Labhttps://www.hmpgloballearningnetwork.com/site/eplab/letter-editor/strategies-minimize-useiodinated-contrast-electrophysiology-lab
- American College of Emergency Physician (ACEP)- https://www.acep.org/home-page-redirects/latest-news/clinical-alert-shortages-in-iodinated-contrast-media-baby-formula/
- The Spine Intervention Society (SIS) & American Academy of Pain Medicine (AAPM)-https://cdn.ymaws.com/www.spineintervention.org/resource/resmgr/patient_safety/22/contrast.advisory.pdf

Molecular Imaging Community

- Molecular Imaging community & SNMMIhttp://www.snmmi.org/IssuesAdvocacy/content.aspx?ItemNumber=29602&navItemNumber=2 9603&utm_source=Email&utm_medium=Informz&utm_campaign=Email%20Outreach&_zs=VFq_n91&_zl=bsEj6
- American Society of Nuclear Cardiology (ASNC)https://www.asnc.org/blog home.asp?Display=474

Appendices

Appendix A. Clinical Advisory Panel Membership

Name	Discipline	Role	Region	Hospital	
Chris Simpson	Executive Vice President, Medical	Co-Chair	East	Kingston Health Sciences Centre	
Julian Dobranowski	Provincial Health Cancer Imaging Program and Clinical Lead DI Information Program	Co-Chair	West	Niagara Health	
Narinder Paul	Chair/Chief Dept of Medical Imaging, Cardiothoracic Radiologist	Radiology	West	London Health Sciences Centre	
Omar Islam	Head, Dept of Medical Imaging, Neuroradiologist	Radiology	East	Kingston Health Sciences Centre	
Youssef Almalki	Diagnostic Imaging Medical Director, General Radiologist	Radiology	West	Bluewater Health	
Leanne Casaubon	Medical Director for Toronto West Stroke Network, UHN Stroke Program, and CorHealth Stroke Leadership Council Chair, Stroke Neurologist	Cardiac, Stroke and Vascular Physician	Toronto	University Health Network	
Sudhir Nagpal	Chief of Vascular and Endovascular Surgery	Cardiac, Stroke and Vascular Physician	East	The Ottawa Hospital	
Madhu Natarajan	Director, Hamilton-Niagara Integrated Heart Investigation Unit, Interventional Cardiologist	Cardiac, Stroke and Vascular Physician	West	Hamilton Health Sciences/Niagara Health System	
Aimee Langan	Director, Diagnostic Imaging and Laboratory Services	Healthcare Institution Administration	Central	William Osler Health System	
Rhoda Lordly	Director, Enterprise Risk Management and Radiation Safety	Healthcare Institution Administration	Toronto	Sunnybrook Health Sciences Centre	
Jim Andrews	CT Team Leader	Medical Radiation Technologist	North East	Timmins and District Hospital	
Pauline McColeman	Senior Technologist, CT	Medical Radiation Technologist	North East	Health Sciences North	

Appendix B. Institutional Inventory Management of Contrast Examples

HHS Item	Item Description	Total HHS Allocation	MUMC	JH	HGH	WLMH	HIU/EP	Estimated Total Inventory	Average Weekly Usage	Weeks of Inventory
501236	IOHEXOL 240MG/ML 20ML 10 VI/BX									
514893	IOHEXOL 240MG/ML 50ML 10 BO/BX									
033821	IOHEXOL 240MG/ML 100ML 10 BO/BX									
066064	IOHEXOL 240MG/ML 200ML 10 BO/BX									
501139	IOHEXOL 300MG/ML 20ML 10 VI/BX									
504441	IOHEXOL 300MG/ML 50ML 10 BO/BX									
504444	IOHEXOL 300MG/ML 100ML 10 BO/BX									
005314	IOHEXOL 300MG/ML 200ML 10 BO/BX									
069934	IOHEXOL 300MG/ML 500ML 6 BO/BX									
081290	IOHEXOL 350MG/ML 100ML 10 BO/BX									
504831	IOHEXOL 350MG/ML 200ML 10 BO/BX									
074844	IOHEXOL 350MG/ML 500ML 6 BO/BX									

Fig. 1 Hamilton Health Sciences

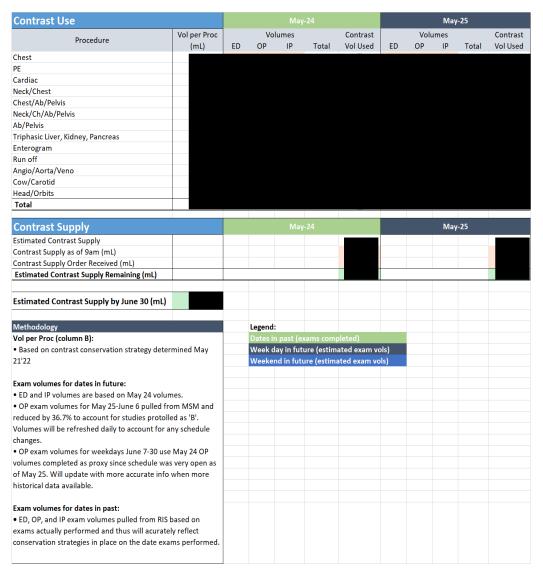


Fig. 2 William Osler Health System