What the Baby Formula and Medical Contrast Material Shortages Have in Common: Insights and Recommendations for Managing the Iodinated Contrast Media Shortage

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The impact of supply chain and supply chain logistics, including personnel directly and indirectly related to the movement of supplies, has come to light in a variety of industries since the global COVID-19 pandemic. Acutely, the experience with baby formula and iodinated contrast material exposes key vulnerabilities to supply chains. The rather sudden diminished availability of iodinated contrast material has forced health care systems to engage in more judicious use of product through catalyzing the adoption of behaviors that had been recommended and deemed reasonable prior to the shortage. The authors describe efforts at a large, academic safety net county health system to conserve iodinated contrast media by optimizing contrast media use in the CT department and changing ordering patterns of referring providers. Special attention is given to opportunities to conserve contrast material in cardiothoracic imaging, including low kV and dual-energy CT techniques. A values-based leadership philosophy and collaboration with key stakeholders facilitate effective response to the critical shortage and rapid deployment of iodinated contrast media conservation strategies. Last, while the single-supplier model is efficient and cost-effective, its application to critically necessary services such as health care must be questioned considering disruptions related to the COVID-19 pandemic.

The consequences of COVID-19–induced lockdowns, workforce decimation, and supply chain crises have substantially impacted a wide variety of business sectors. The most recent supply casualties for infant formula and iodinated contrast media (ICM) are eye-opening, and for both, the reasons are multifactorial.

Over 40% of infant formula is out of stock nationwide, leaving parents traveling large distances to obtain formula and paying price-gouged amounts on Internet marketplaces (1). Abbott Laboratories (Similac), which controls approximately 42% market share and is the sole supplier of formula for more than half of the Women, Infants, and Children agencies (2), temporarily halted production at their Michigan manufacturing plant due to a U.S. Food and Drug Administration–issued recall.

For ICM, iohexol (Omnipaque; General Electric) has a large market share in the United States. Additional agents include iopamidol (Isovue; Bracco) and iodixanol (Visipaque; General Electric), as well as other brands of ICM. Production of iohexol at the dominant manufacturing site in Shanghai, China, was drastically reduced following COVID-19–related lockdowns. The dominant factory has only recently reopened, and while production is ramping back up, delivery delays due to shipping are unfortunately expected. The ICM shortage has left hospitals with only their immediate stock on hand and has sent hospitals and health systems racing to buy remaining stock or attempt to obtain alternate agents.

For both formula and ICM, the availability of alternative brand products is limited. For the U.S. infant formula market, demand had been decreasing prior to the pandemic due to a decline in birth rate, and the market was unprepared for the combined effect of a pandemic-induced increase in formula. While ICM use was increasing before the pandemic, lack of market diversity and loss of a key supplier for both products have been catastrophic. For both ICM and formula, pandemic-induced global supply chain issues have limited precursor availability and distribution, and the dearth of both products has the potential to disproportionately affect our most vulnerable populations.

The impact of the ICM shortage at a given site has been influenced by the specific type of ICM primarily used and the amount in store prior to the shortage. Institutions that depend on iohexol have been hit the hardest, particularly those with a limited supply on hand prior to the shortage. This has forced many institutions to drastically change practices to conserve ICM (3–5). Meanwhile, those using a different brand of ICM have been less impacted.

Our radiology department services four facilities, each operated by distinct health systems; the largest two use iohexol as the primary ICM agent. For these two facilities, supply chain procurement has been variable, leaving one with a greater shortage. Parkland Health, the safety net hospital serving Dallas County, is facing the greatest shortage, with fewer than 4 weeks ICM on hand at the time of writing. This facility performs more than 2000 CT

Abbreviations

CECT = contrast-enhanced CT, CTA = CT angiography, ED = emergency department, ICM = iodinated contrast media, MECT = multienergy CT

Summary

This report discusses the COVID-19 pandemic–related shortages in supply of iodinated contrast media and other commodities and their effect on the health system's ability to deliver excellent patient care. Mitigation strategies to optimize delivery of health care while facing various stages of the shortage are discussed.

Keywords

CT, Intravenous Contrast Agents, CT-Spectral Imaging (Dual Energy)

examinations a week, nearly 60% of which use ICM. We describe strategies implemented at our safety net hospital to optimize use of ICM in the radiology department, with a focus on CT services. We also describe our methodology of the health system–wide response to limit use of contrast-enhanced CT (CECT) across a broad range of service lines.

Forming a Task Force

Upon identification of the problem with the iohexol supply, the radiology faculty and administration first sought to determine the scope and expected duration of the shortage, as well as alternative ICM options, and to ponder potential mitigation strategies. Within the radiology department, a task force was created to address the shortage. This task force included members of the CT Operations Committee, divisional radiologist representatives, radiology informaticists, and departmental leadership. Early engagement with health system leadership was vital to facilitate a coordinated response, and key stakeholders were engaged (Fig 1). We were initially enthusiastic for the quick purchase and delivery of large quantities of alternative ICMs and less frequently used vial sizes of iohexol, which had potential to substantially mitigate the shortage. Our enthusiasm was short-lived, however, as the deliveries soon halted, and we and other health systems had simply depleted the existing stores of ICM. We found there was only approximately half the ICM needed to last through the expected duration of the shortage.

Within 24 hours of identifying the severity of our ICM supply chain disruption, health system leadership and radiology administration formulated initial data analysis and projected interventions. Mitigation strategies to conserve ICM were quickly put into place, and involved a multipronged approach, focusing on two main tactical principles: *(a)* optimizing use of existing ICM supply and *(b)* encouraging strategic use of contrast-enhanced examinations. Under the condition of scarcity, time is limited, and effort was initially focused on interventions that would yield the most savings. As the vast majority of ICM is used in CT, we will focus on interventions related to CECT.

Optimizing Use of Existing Supply

A basic starting point is completing an inventory assessment that includes an account of vial size and concentration and modifying protocols to avoid waste. ICM vials come in single-use and multiuse vials. Multiuse vials can be applied to multiple patients when following proper procedures; while they must be used within a certain time frame, they can avoid waste. While protocols may be designed with a vial size in mind, inventory may change during the "mad dash" procurement process, and adjustments may be needed.

Our first efforts involved lead technologists working with radiologists to make minor changes that aligned our injection volumes with vial size (eg, contrast material dosing for a head CT angiography [CTA] was changed from 60 mL to 50 mL, allowing usage of a smaller vial and avoiding 40 mL waste). Next, after reviewing the existing inventory side-by-side with our CT protocols, we determined that we could save far more ICM if single-use vials were divided into aliquots of 25 mL, and existing protocols were modified to use ICM volumes in multiples of 25.

We quickly enlisted our pharmacy colleagues to create aliquots from the single-use vials. This is a massive undertaking and ramping up any new process during a supply chain disruption may cause other shortages. Nonetheless, collaboration with our pharmacy colleagues allowed the team to work through these challenges.

We also assessed our enteric contrast material supply. In our standard workflow, emergency department (ED) patients and inpatients undergoing unenhanced abdominopelvic CT drink water-soluble enteric contrast material to avoid giving a barium-based agent to a potential surgical patient. While barium-based agents were plentiful, our water-soluble enteric contrast material supply was limited. We eliminated enteric contrast material from all inpatient and ED abdominopelvic CT unless specified by the radiologist or ordering provider on a case-by-case basis. This both conserved water-soluble enteric contrast agents and helped further simplify our technologists' workflow.

In our practice, the top three examinations by case volume are CECT of the abdomen and pelvis, CECT of the chest, and pulmonary CTA. These were targeted first, as optimization for these examinations would yield the most savings. At the same time, care was taken to avoid overcomplicating the technologist workflow, with the premise that any changes during this time of rapid protocol modifications should ideally simplify the decision tree. For example, we moved from a weight-based dosing model to a fixed dosing model for abdominopelvic CT, reduced our ICM dose for multienergy abdominopelvic CT, and created a look-up table that technologists could easily reference for ICM dosing with single- and multienergy CT (MECT).

Technologists are vital stakeholders in these discussions, and communication with them is essential. Changes in ICM injection parameters are only useful if all technologists can implement them reliably and rapidly. If it does not already exist, a clear communication chain to every technologist

Figure 1: Gear diagram shows an example of the organization of interlocking components forming the institutional response to the acute iodinated contrast media shortage.

working any shift must be established. As the situation evolves, more changes will be necessary, and establishing this communication chain early on will allow technologists to pivot quickly.

CT Protocol Tactics for Contrast Material Dose Reduction in Cardiothoracic Imaging

The concept of reducing ICM dose has been studied predominantly in the context of impaired renal function, but these experiments can also provide data regarding image quality and be used as a foundation for ICM reduction with regard to the current ICM shortage. Such approaches make use of recent developments in power injection and CT scanner technology, including dual-energy, spectral, and photon-counting CT (collectively termed *MECT*); high-pitch helical scanning; and wide-detector CT. However, incorporation of several such techniques into mainstream practice, particularly for the goal of ICM dose reduction, has been slow due to many factors beyond the scope of this paper. The current crisis is also an opportunity to catalyze the shift to more rational, short-term use of ICM resources; therefore, we will summarize the technical principles and exemplify a few tactics to attain this goal.

CT attenuation is proportional to iodine concentration for a given kVp, and attenuation increases by lowering kVp for similar amounts of iodine (6). As a result, ICM reduction tactics can target ICM bolus dynamics, use of low kV imaging, or both. Wu et al (7) evaluated an alternative bolus tracking method for pulmonary CTA at the superior vena cava with threshold set at 75 HU. Using only 30 mL of ICM, the authors did not find attenuation differences at the segmental or subsegmental level or differences in the subjective image quality score when compared with the standard protocol. In another study, Schueller-Weidekamm et al (8) compared the effects of scanning pulmonary CTA with 100 kVp against 140 kVp. Low kVp imaging was associated with higher CT numbers in the central pulmonary arteries and improved visualization of subsegmental branches, without compromising the overall image quality or visualization of thoracic or upper abdominal structures. Small modifications in ICM injection protocols combined with kVp adjustments can have a substantial impact in reducing ICM utilization. Common ICM bolus tactics include reduction of ICM volume and injection rate or the use of a mixed injection protocol, consisting of the concurrent injection of different proportions of saline and ICM. The use of a saline chaser after the ICM bolus is also proven to improve blood pool opacification in cardiac and aortic CTA, allowing for reductions of the ICM bolus (9,10). A volume of 30 mL saline is recommended (11) using a similar injection rate to avoid it outrunning the ICM bolus.

MECT is particularly advantageous for exploring low kVp imaging, as low and high energy scans are obtained concurrently (12). Godoy et al (13) showed that 80-kVp images obtained in a low ICM dose pulmonary MECT angiography protocol improved the visualization of central and peripheral pulmonary arteries when compared with simultaneously obtained 140-kVp images. Newer MECT techniques include use of spectral CT data to derive virtual monoenergetic reconstructions, which simulate the CT numbers that would be obtained from a monochromatic beam of x-rays (14). Virtual monoenergetic reconstructions obtained with 40 to 70 keV are beneficial for improving contrast-to-noise ratio in CTA of the chest (Fig 2) (15–17). Yuan et al (18) used 50-keV images to enhance pulmonary artery visualization in an MECT angiography protocol with a 50% dilution of ICM in saline. Intravascular CT numbers in the pulmonary arteries

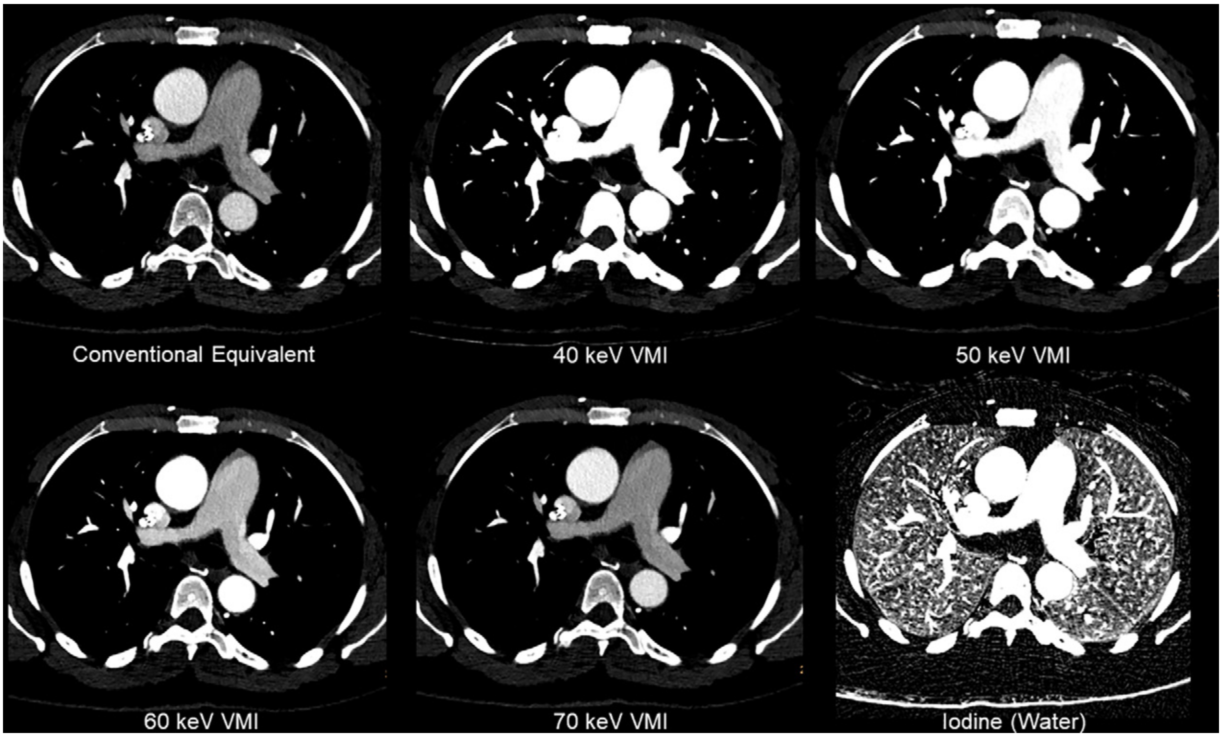

Figure 2: Effects of multienergy CT reconstruction on contrast media attenuation. Pulmonary CT angiogram obtained on a dual-layer spectral scanner shows suboptimal opacification of the pulmonary arteries on conventional-equivalent image reconstruction (window settings: center = 250 HU; width = 500 HU). Series of virtual monoenergetic images (VMI) reconstructed from 40 keV through 70 keV, displayed with similar window settings to the conventional-equivalent image, show increased signal of iodinated contrast material. Images reconstructed with 50 keV or less were deemed adequate for interpretation. Dual-material decomposition with iodine and water ["Iodine (Water)"] can be used to improve visualization of intravascular contrast and allow for visualization of lung perfusion.

were increased, with no compromise of signal-to-noise ratio, contrast-to-noise ratio, or rate of nondiagnostic studies when compared with standard ICM dose pulmonary CTA.

Multiple studies also confirm the feasibility of combining low kV imaging with ICM reduction in CTA of the heart and aorta (19–24). Strategies such as high-pitch helical scanning and whole-heart volumetric scanning have been successfully combined with low kV imaging and contrast material bolus optimization. For example, Felmly et al developed a protocol for planning transcatheter aortic valve replacement, which includes consecutive retrospective cardiac CT and high-pitch CTA from the aortic arch to the proximal femoral arteries, using only a 40-mL ICM bolus lengthened by a triphasic injection regimen (25). High-pitch helical scanning, usually defined as pitch factors between 1.0 and 3.4, is a powerful tool for ICM dose optimization. Not only can it decrease ICM dose, but it can also reduce radiation exposure and improve visualization of the cardiovascular structures (26–29). However, high-pitch scans with factors greater than 2.0 may have field-of-view restrictions, which limits the applicability in some clinical scenarios (30).

Wide-detector CT scanners are systems with extended z-axis coverage (ie, 160 mm) allowing for single-beat whole-heart imaging. Such scanners can concurrently reduce scanning time and radiation dose, potentially decreasing ICM dose when combined with low kV imaging (31,32). In a study with a 320-row detector scanner, Oda et al compared three different cardiac scanning protocols consisting of 120-kVp scanning with standard ICM dose, 80-kVp scanning with 25% ICM dose reduction, and 80-kVp with 50% ICM dose reduction (33). Quantitative and qualitative analyses demonstrated that either 25% or 50% ICM reduction could be used to achieve sufficient cardiovascular enhancement.

As a word of caution, there are many factors that can negatively influence the quality of CECT, even when imaging protocols are well planned and executed (6). These factors include patient size, cardiac output, age, sex, pre-existing diseases, and even breath-holding patterns (34). Many of the studies presented here intentionally included smaller patients. Photon starvation artifacts are of particular concern in larger patients, especially when low kV imaging is applied. Thus, thorough consideration and continued quality assurance must be exercised when translating such tactics to different populations or to applications dissimilar to those initially intended by the original protocol.

In our practice, efforts were initially focused on CECT of the chest, and the primary change involved decreasing ICM dose from 80 mL to 75 mL for single-energy CT and to 50 mL for MECT. These quantities were chosen to align with available vial sizes and the pharmacy aliquoting plan. ICM dose for MECT pulmonary angiography was also decreased from 90 mL to 75 mL injected at 5 mL/sec. Use of existing protocols using high-pitch scanning was encouraged. Other targets for ICM dose reduction will be prioritized depending on the volume of examinations and potential clinical impact.

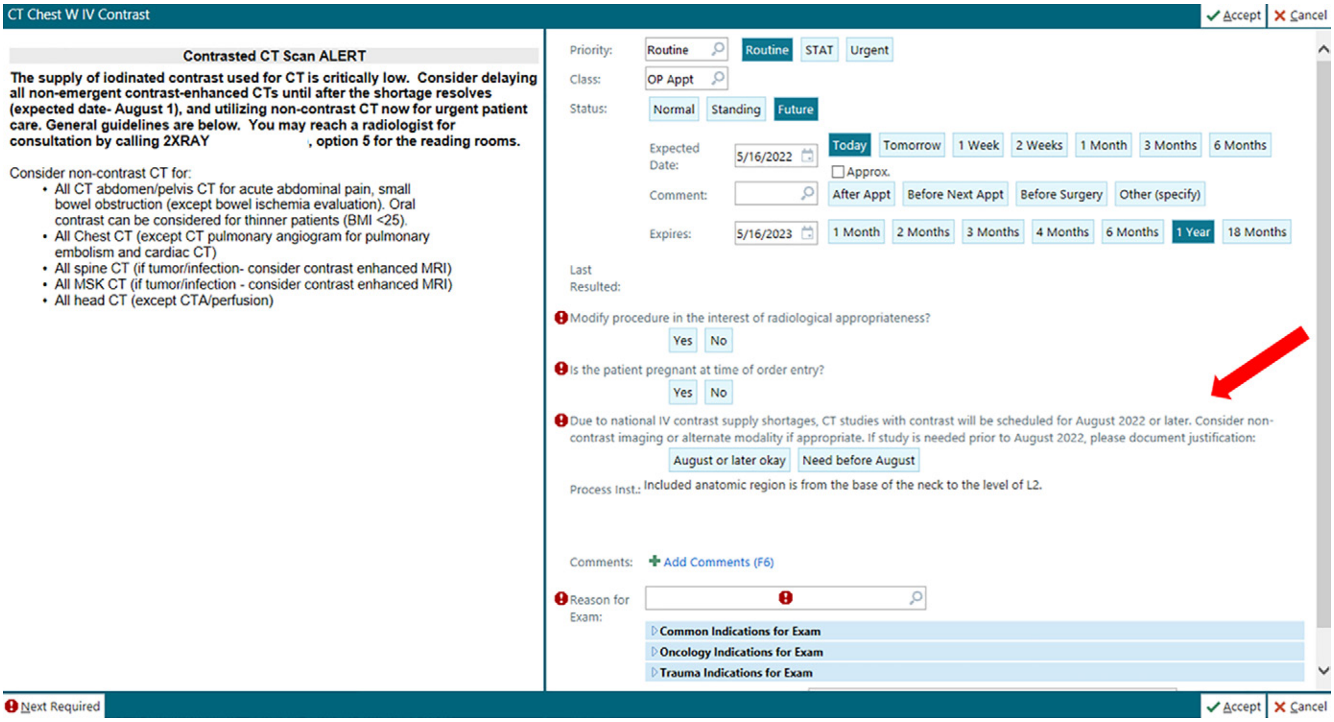

Figure 3: Decision support tools were created with the end user in mind. Rather than using a best-practice alert, which might be more disruptive to workflow, general guidance provided by the radiology department (left) was included in a sidebar panel for every contrast-enhanced CT order. Order entry questions (right) were used by ordering providers for scheduling purposes, both to indicate approval for a delay in scheduling new orders or to provide justification for why the examination is necessary during the shortage.

Influencing Behavior of Ordering Providers

While the above techniques were used to reduce waste of ICM for individual examinations, a health system–wide approach was needed to decrease ICM use to a set goal of 50%. At our safety net county hospital, approximately half of the CECT volume is in the outpatient setting and is mostly related to oncologic care; the other half is performed in the hospital, the vast majority of which are requested from the ED. Within 24 hours of identifying the severity of our ICM supply chain disruption, the health system leadership worked with radiology leadership to formulate initial data analysis and projected interventions. The stages of intervention included the following: stage 1: postponing outpatient CECT scheduled for the next 2 months, unless deemed necessary for patient care by the ordering provider; stage 2: use of unenhanced CT in lieu of CECT, with the exception of vascular and emergent conditions in ED patients or inpatients or as deemed necessary by the ordering provider (eg, trauma, stroke, concerns for ischemia); and stage 3: restriction of CECT for conditions that are not immediately life-threatening. Based on the similar contribution of outpatient and ED cases to the CECT volume, stages 1 and 2 were implemented simultaneously.

The ICM shortage incited the need for an emergent clinical and operational transformation. As in the initial stages of the COVID-19 crisis and transformation, we employed a values-based leadership construct to navigate the ICM shortage. Values-based leadership is the idea that leaders should draw on organizational values for direction and motivation (35). The health system medical leadership and radiology department agreed that those who know the patients best should decide on the acuity of their care needs. In the spirit of "doveryai no proveryai" ("trust but verify"), the senior medical leadership clarified that they too would monitor the volume of requested examinations and procedures requiring ICM to ensure that appropriate reductions were made to allow our ICM supply to cover the predicted duration of the shortage.

Rapid, authentic, and two-way communication of the crisis and the planned response was initiated. Communication vehicles to medical staff were multimodal, including dissemination through huddles from executive to unit, chain-of-command communications, system-wide emails, and an emergency virtual town hall of all medical staff and pertinent nursing and administrative leaders where health system leaders discussed the scope of the shortage and initial interventions planned. A round robin of the key service chiefs in internal medicine, emergency medicine, and surgery spoke to the planned response of their areas, sharing personal anecdotes and perspectives on where ICM conservation measures could be made. Medical staff leadership verbalized a shared vision of confidence, community, communication, as well as trust between services, staff, administration, faculty, and providers with the overarching goal of balancing patient safety and quality of care during a critical resource shortage.

To rapidly deploy this plan, engagement of several teams was necessary. Radiology schedulers developed a plan to auto-postpone CECT examinations using procedures developed early in the COVID-19 pandemic. Ordering providers were informed of the critical shortage and were given autonomy in their decision-making: their options included unenhanced CT, use of a different imaging modality (while acknowledging that other modalities had limited capacity to absorb a large volume increase), or performing the CECT now if justified, with the understanding that these would be audited by medical leadership. To address new CECT orders, Information Technology deployed decision support tools to allow ordering providers to provide justification for any new CECT orders that needed to be performed despite the shortage (Fig 3).

Throughout this process, stakeholders provided insights to maximize impact and minimize burden on proposed process changes. One simple example is the difference between requiring a faculty referrer to place an order for a CECT (operationally challenging) versus requiring the faculty referrer to cosign the trainee's order (easier to operationalize). The latter derived from a collaborative approach that achieves the desired goal of faculty review of ICM necessity, while both minimizing workflow disruption and offering educational opportunities. Another example includes selecting a method of notification of the ICM shortage that is informative but not overly disruptive for the end user. For this reason, rather than sending a best-practice alert to inform providers of the shortage, general guidelines provided by the radiology department were instead displayed in a side panel for every CECT order (Fig 3) to be available for quick reference. ED leadership took simple actions such as removing commonly ordered CECT examinations from order preference lists and replacing them with unenhanced CT examinations.

Our initial monitoring indicated that our clinicians had become rapidly adept and compliant with our collaborative ICM rationing plan. Three days after implementation of the plan, ICM usage by volume decreased by 69% compared with the prior week.

Contrast Material Shortage and the Staffing Shortages

The ICM shortage comes during a perfect storm—clinical and radiologic volumes are at an all-time high. Even before the pandemic, technologist shortages were at an all-time high, with 10.7% of CT, 8.7% of MRI, 5.2% of nuclear medicine, and 9.0% of US technologist positions unfilled in 2019 (36). In our system, the ability to divert certain CECT examinations to alternative modalities has been limited by capacity-throughput limitations due to the technologist shortage and the inability to absorb more cases based on existing backlogs and access issues. However, the ICM shortage is also an opportunity for other modalities; for instance, departments may develop abbreviated MRI protocols and heighten awareness and use of contrast-enhanced US for certain scenarios.

Changing Radiologist Behavior

The rapid changes in image acquisition and ICM injection parameters needed in response to this crisis require an acceptance by the radiologists that images will look different and may contain less information compared with routine practice. There are legitimate concerns for the potential for misdiagnoses when unenhanced CT scanning is used in scenarios where CECT would have been preferred. Furthermore, doubts arising from interpretation of less familiar imaging may create the potential for increased hedging in reports. These concerns must be framed in the context of the ICM shortage reality, and radiologists may need to recalibrate interpretations accordingly. Radiology departments may choose to insert standardized language into reporting templates to specifically note that practice changes have been employed to address the ICM shortage. In our practice, the phrase "This exam was performed during a global contrast shortage" is temporarily added to all unenhanced CT reports. Regardless of the language chosen, radiologists can strive to provide interpretations that are actionable for the referring providers.

Radiologists need to be aware of the scope of the contrast material shortage (both ICM and availability of enteric contrast material options), as well as the capacity (or lack thereof) of other modalities to absorb additional case volume. Care must be taken to avoid overusing follow-up imaging recommendations in reports during this time, as overuse may lead to unintended downstream effects such as increasing orders for US, MRI, and PET/CT that may already be at limited capacity.

The sudden change in practice is particularly relevant at our county hospital, which is a level 1 trauma center and the primary training site for our residents and fellows. Radiology trainees must also be kept fully informed. Program directors and chief residents can provide feedback regarding resident comfort in interpreting unenhanced CT images, and early compilation of challenging unenhanced CT cases by educational leaders can be used for teaching purposes during the recalibration time. Simultaneously, interactions between trainees and all subspecialities can provide critical feedback of how individual services are interpreting the request to conserve ICM.

This shortage is also a unique opportunity for radiologists to take ownership of their role as consultants and showcase their role as essential members of the clinical care and hospital leadership teams. Radiologists can provide enabling education and guidance to referring providers regarding appropriate use of imaging. Each interaction with referrers at all levels (trainees, advanced practice providers, faculty) and in all settings (phone calls, reading room consultations, multidisciplinary conferences, tumor boards) can be used as an educational opportunity.

Just-In-Time Inventory Management

The unexpected disruption in ICM has exposed vulnerability in cost-savings approaches to health care products. The cost savings achieved with group purchasing from a limited number of suppliers takes advantage of economies of scale. Further savings can be achieved with just-in-time inventory management by limiting on-site storage expenses.

An early experience in the COVID-19 pandemic is the inability to meet the accelerated demand of personal protective equipment with a dearth of local suppliers. The satisfaction of having achieved a focused solution may have precluded a broader view toward predicting vulnerabilities.

The economic imperatives that drive diminished supplier redundancy and abundant local warehousing may make sense for nonessential goods. While this strategy is efficient and cost-effective, its application to critically necessary supplies such as health care consumables must be questioned given substantial risks and consequences when disruptions and subsequent shortages occur. Indeed, the financial impact and lessons learned from this ICM shortage will be revealing. Meanwhile, focused tactics to conserve the constrained supply of ICM, now a scarce and essential element in health care diagnostics, will potentially lead to proactive adjustments in supply chain management.

Conclusion

Radiology departments may use technical and operational strategies that can be rapidly deployed to optimize ICM savings during this pandemic-related ICM shortage. These include strategic use of product to avoid waste, protocol changes, and use of advanced technology such as MECT, low kVp imaging, and high-pitch acquisitions. Simultaneously, institution-wide efforts and buy-in are needed to change ordering patterns and decrease CECT use. When considering employing alternative studies such as MRI, US, and nuclear medicine, local capacities must be assessed so that the messaging to and expectations of referring providers are realistic and well-calibrated. The values-based leadership model and effective communication methods described may help implement expedient and effective change management. At the time of writing, these changes have resulted in a projected ICM depletion from 26 days to 85 days.

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