

The Value of Generic Contrast Utilization in Imaging

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Acknowledgement

This article highlights the knowledge and experience of the following professionals from University of California, San Diego health system with transitioning their radiology department to generic iodinated and gadolinium-based contrast agents: Cynthia Santillan, MD, Clinical Professor of Radiology, Vice Chair of Clinical Operations, Department of Radiology; Irina Kalyan, Radiology Manager, Quality, Safety & Performance Improvement; Jeannie Cruz, MRI Manager, Lead Technologist; Laura Israel, CT Manager, Lead Technologist; Joseph Savoie, Senior Director of Radiology.

Executive Summary

This white paper explores the clinical, operational, and financial rationale for adopting US Food and Drug Administration (FDA)-approved generic contrast agents in magnetic resonance imaging (MRI) and computed tomography (CT) imaging. It demonstrates that generic contrast media provide a reliable means to manage rising imaging costs and supply challenges while maintaining diagnostic quality and patient safety. Held to the same safety and efficacy standards as their proprietary counterparts under the FDA's Abbreviated New Drug Application (ANDA) pathway, generic agents present a cost-conscious alternative that aligns with value-based care objectives.

The primary considerations for adopting generic contrast agents discussed include:

- **Therapeutic equivalence:** FDA-approved generics are required to meet identical quality, safety, and performance standards as their proprietary counterparts.
- **Economic impact:** Generic agents reduce per-unit cost and enable significant long-term savings across imaging departments.
- **Operational continuity:** Diversification of contrast suppliers mitigates risk during shortages and supports sustainable, efficient workflows.
- **Clinical validation:** Pilot evaluation and ongoing monitoring of quality and safety can help confirm diagnostic equivalence and maintain clinician confidence.
- **Stakeholder collaboration:** Success requires early engagement across radiology, pharmacy, procurement, information technology (IT), and finance teams.
- **Phased implementation:** A gradual rollout, accompanied by staff education and data-driven periodic reviews ensures a seamless transition and patient safety oversight.

By sharing insights gained from the successful transition to Fresenius Kabi's generic gadolinium-based and iodinated contrast agents at the University of California San Diego (UCSD), this paper further demonstrates how other healthcare organizations can employ similar strategies to enhance supply chain stability while maintaining quality patient care.

Introduction

The burden of an aging population and more people living with chronic diseases has led to a rise in the number of diagnostic imaging examinations performed in the US, a significant portion of which utilize contrast agents to enable accurate diagnoses.^{1,2} Nevertheless, imaging exams are associated with a high-cost burden, and proprietary

contrast agents often account for a sizable portion of imaging expenses.

In the broader healthcare landscape, healthcare organizations and insurers have long been leveraging generic pharmaceuticals to contain costs and manage operational budgets without compromising patient care.^{3,4} With the enactment of the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act,

the US has seen a steady rise in the uptake of generic pharmaceuticals.⁵ This legislation created a framework for manufacturers to market generic medicines more efficiently by basing approval on therapeutic equivalence to their proprietary counterparts. The impact of this law is clear: according to the Association for Accessible Medicines, the use of FDA-approved generic and biosimilar pharmaceuticals accounted for 90%

of all prescriptions filled in 2024, but only represented 12% of the total prescription costs, yielding \$467 billion in savings for patients and the US healthcare system.⁶

The same cost-savings pressures are now affecting radiology departments, and having the option to switch to generic contrast agents can help alleviate the financial burden of imaging examinations. With generic agents subject to the same strict regulatory standards as proprietary contrast media, there is a unique opportunity for radiology departments and healthcare organizations to save costs without compromising diagnostic quality or patient safety. Moreover, stocking generic options promotes supplier diversification, eliminates vulnerabilities to contrast media shortages, and ensures supply chain stability.⁷

This paper examines the rationale for using generic contrast agents, highlights their economic, clinical, and operational benefits, and provides an overview of key implementation considerations to support the successful integration of these agents into practice.

Generic Contrast Influences and Drivers

The acceptance of generic contrast media by healthcare organizations is largely driven by financial, operational, and clinical factors that aim to provide value-based care. Rising healthcare costs, reimbursement pressures, and budgetary cuts are among the most immediate motivators. Generic pharmaceuticals offer a practical solution to help address these motivators and stabilize product supply.

The global iodinated contrast media supply shortage in 2022 underscored the need to diversify contrast media sourcing to mitigate risks to patient care and ensure

consistent product availability.⁷ Organizations responded by re-evaluating the need for contrast in many exams, minimizing individual doses to reduce waste, exploring the feasibility of other imaging modalities, and, in some cases, delaying non-critical procedures.⁷⁻⁹

Following the shortage, the University of California, San Diego (UCSD) health system switched some of their agents to generic iodinated and gadolinium-based contrast agents supplied by Fresenius Kabi.^{10,11} “The iodinated contrast media shortage significantly impacted us, and with the pharmacy’s recommendations, we had an interest in diversifying supply across modalities,” says Joseph Savoie, senior director of radiology at UCSD.

Having alternative source options can help prevent the need to ration contrast media—a compelling consideration given that generic products meet the same standards for quality, strength, and efficacy as proprietary agents, as ensured through the FDA’s ANDA process ensures.¹²

Furthermore, healthcare organizations that have adopted generic contrast agents often report a generally smooth transition, as confirmed by the experience at UCSD. Cynthia Santillan, MD, who is a clinical professor of radiology and the vice chair of clinical operations in the department of radiology at UCSD, notes, “It was certainly a value to diversify the brands of contrast agents that we use in our institution because we did not want to restrict the utilization of contrast agents for patient care. Fresenius Kabi’s generic contrast agents are therapeutically equivalent to the branded agents as determined by the FDA. From the QA perspective, I was quite pleased with how the adoption went.”

Another major driver for the adoption of generic contrast is the standardization and sustainability

it brings to radiology workflows. Streamlining formularies to include generic options can simplify inventory management and reduce product waste, ultimately supporting environmental sustainability and operational workflow goals, particularly when a generic alternative replaces its proprietary counterpart. This alleviates the need for a comprehensive product evaluation, which is standard practice when considering changes to contrast agents that are not a one-for-one swap. With generic utilization, a one-for-one change promotes consistency in imaging protocols, workflow efficiency, and bypasses the need for in-depth staff training.

Generic contrast options can give organizations greater flexibility to balance cost, quality of care, and product supply. Rather than being locked into a single supplier or proprietary formulation, organizations can design a formulary that includes one or more agents to align with their clinical and financial objectives. This flexibility can enable organizations to make data-driven choices that enhance operational efficiency while maintaining quality patient care.

The Implementation of Generic Contrast Agents

Transitioning to a generic contrast agent requires careful planning, education, and stakeholder engagement to ensure smooth and successful adoption. A successful feasibility assessment, which includes multidisciplinary representation from administrative leadership, radiology, nursing, pharmacy leadership, procurement and supply chain, quality and safety, IT, and finance, is crucial to meeting the expected outcomes. Involving these stakeholders at the outset enables clear goal setting around cost savings and operational objectives, product training,

Key Takeaways

Best practices for the successful implementation of generic contrast media:

- Establish timelines and financial and operational goals, including those for potential cost savings, product training, tracking and review of safety, and implementation process.
- Determine and engage internal stakeholders early in the process, with representation from administrative leadership, radiologists, technologists, nurses, pharmacy, procurement, quality and safety, IT, and finance.
- Address stakeholder questions and provide supporting clinical data.
- Prepare a formulary kit to introduce the product into clinical practice, including NDC numbers, packaging presentations, pricing, and approved indications.
- Work with the IT team to build entries into the organization's systems with product information and proper billing and reimbursement coding.
- Collaborate with the generic supplier to stock products prior to phasing out proprietary contrast, and update reporting templates and the electronic health record system to list the generic name.
- Educate and train the imaging staff (ie, radiologists, technologists, nurses) on product handling and the importance of monitoring.
- Monitor conversion progress by performing a comparative or pilot evaluation before the complete transition from proprietary to generic contrast.
- Document outcomes post-implementation to ensure continued image quality, patient safety, and workflow efficiency.
- Reinforce the overall goal(s) for generic conversion through validation and effective communication among all stakeholders.
- Review cost savings associated with generic contrast implementation.

quality standards, and verification of clinical and safety equivalence. The product information and clinical data collected throughout the feasibility process not only inform stakeholders but can also be used to facilitate formulary decision-making by pharmacy and therapeutics committees, and support IT efforts to update systems with proper product entries and billing and reimbursement coding.

Jeannie Cruz, MRI manager, technical manager, and lead technologist at UCSD, notes that key steps to generic contrast rollout include educating the imaging staff, securing product from suppliers, and updating reporting templates and electronic health records before phasing out the currently stocked agent. “We did not start the switch until we had supplies on hand. And we made sure to use all the old contrast first. We rolled out communication and training to staff,

and when it was time to start using the generic contrast, the team made sure to monitor patients and report any adverse events immediately. We had overlap to ensure consistency of care, especially in the event of reactions or any other issue.” Using such a phased approach ensures proper documentation and continuity of patient care with minimal disruption to imaging operations.

Conduct a Pilot Evaluation

Although generic contrast agents must demonstrate therapeutic equivalency to their proprietary counterparts, it is important to consider conducting a pilot evaluation to validate contrast performance in the real-world setting. The FDA mandates that generic formulations provide the same active ingredient and strength.¹² However, a pilot evaluation or comparative review can help instill clinician confidence

through hands-on experience and address operational concerns before system-wide rollout.

Engage Early

Transparent and proactive communication during the transition process can help ease end-user hesitancy and skepticism. The longstanding familiarity with the currently used proprietary contrast agent may lead staff to question the quality or diagnostic performance of the generic contrast. Organizations can manage the transition effectively by engaging the entire team of radiologists, technologists, and pharmacy staff early in the process, explaining the stringent standards for generic products set forth by the FDA. Hands-on training via the pilot evaluation can ensure operational continuity and foster acceptance of the generic contrast by radiology staff.

Enact a Feedback Loop

Successful implementation also relies on an evaluation loop that supports continuous monitoring. Once a generic contrast agent is introduced, feedback from radiologists and technologists, along with data on image quality, patient safety, and workflow impact, should be reviewed by a multidisciplinary team to address any challenges promptly. This review ensures patient safety and fosters trust within the radiology department.

Moreover, sharing positive findings such as demonstrating equivalent image quality and the safety of the proprietary contrast agent further validates the decision to adopt a generic product. The safety monitoring performed at UCSD during the change to generic contrast serves as an example. Irina Kalyan, radiology quality manager for safety, quality, and performance improvement notes, “Standardization is key, but keeping patient safety and quality at the forefront is the most important aspect of a product rollout. We have a quality dashboard that allows us to track and trend events. Since switching to generic contrast, we have not observed any differences in patient care.”

Align Goals

Alignment between clinical requirements and financial goals can help determine the value of generic contrast. In addition to the clinical metrics discussed, financial and operational advantages should be quantified and benchmarked against the performance of the proprietary contrast. These include cost per unit, the amount wasted, supply predictability, and budget impact. Balancing financial analyses with clinical data can validate

return on investment, determine cost avoidance, and help justify the expansion of system-wide generic contrast use.

Evaluate, Re-Evaluate, Communicate

Finally, periodic data-driven re-evaluation can help healthcare organizations adapt to new product availability and updated regulatory guidance, while maintaining efficient and high-quality imaging standards. By combining structured evaluation, multidisciplinary collaboration, and financial oversight, organizations can sustain the use of generic contrast media with both clinical confidence and economic efficiency.

Proactively implementing a process in collaboration with radiologists to monitor patient safety trends is critical to the long-term success of the transition. Capturing and sharing safety-related metrics post-implementation can guide informed decision-making, build staff confidence, and justify expanding the use of additional generic products. Ultimately, one successful transition can serve as the blueprint and guide future transitions.

Conclusions

Generic contrast agents can help healthcare organizations address costs and streamline operational processes. With FDA oversight ensuring efficacy and patient safety through therapeutic equivalence standards, these agents are well-positioned to become more commonly used in imaging practices across the US. A carefully managed implementation process, guided by stakeholder engagement, hands-on experience, and ongoing clinical monitoring, can expand the use of

generic contrast agents and unlock significant value for healthcare organizations and patients alike.

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