Making the Case for Imaging Bulk Packages in MRI

Stephanie Allen, MBA, RT(R)(MR), CPPS

Stefanie Allen, MBA, RT(R)(MR), CJCP, is a Quality & Safety Healthcare Consultant whose career spans leadership in healthcare quality, patient safety, and regulatory readiness. Building on her radiologic science background, she partners with organizations to strengthen compliance, enhance performance, and promote a culture of safety.

Gadolinium-based contrast agents (GBCAs) are essential in MRI for high-quality imaging. Traditionally, these contrast agents have been supplied in single-dose vials, each intended for use in a single patient and discarded after use. While effective, this approach can often result in wasted contrast, workflow inefficiencies, and increased environmental burden.

A practical yet underutilized solution to these operational challenges is the imaging bulk packages (IBPs) which are approved for multi-patient use. By following the product's Indications and Important Safety Information (IISI), IBPs can be used for multi-patient dosing of gadolinium contrast media. Within the supporting quality, safety and regulatory frameworks, IBPs hold significant promise for improving many aspects of MRI practice.

What is an Imaging Bulk Package?

An imaging bulk package is an FDA-approved container of contrast media designed to be used across multiple patients in a single medical imaging procedure room. Introduced more than a decade ago in CT, their implementation reflected a broader push to streamline workflows in radiology while meeting safety and compliance standards.

IBPs were developed in response to the difficulties radiology departments had when implementing pharmacy bulk packages, which required pharmacy compounding in an ISO Class 5 environment to divide the contents into individual doses. They are multi-dose containers that provide immediate, customized dosing to multiple patients within the imaging suite. The transfer spike allows the technologist to transfer contrast from the IBP container to empty, sterile syringes within a 24-hour period, thus, improving contrast administration workflow.

IBPs in MRI

In 2020, Bayer's Gadavist® (gadobutrol) became the first IBP to be approved by the FDA for use in MRI. It is presented as a container of a sterile preparation for parenteral use that contains many single doses of gadobutrol for use with a medical imaging device. Gadavist IBP can be safely administered when paired with an FDA-approved transfer spike system or automated contrast injection system designed to create a closed system and maintain sterility.[1]

Still, today, most MRI departments continue to use single-dose vials. This means that each vial can only be punctured once and used for only one patient. Once the contrast is administered, any contrast remaining in the vial must be discarded, a costly, wasteful practice for high volume MRI departments.

Imaging bulk packages, on the other hand, reduce the amount of discarded contrast, supporting sustainable practices. Technologists can transfer the exact amount needed for each patient into a sterile syringe, leaving the remaining contrast safely stored in the IBP container for subsequent patients. A 65 mL IBP, for example, can conceivably carry a technologist through a full shift.

Clinical Applications and Flexibility

With respect to clinical usefulness, IBPs can be used across a wide range of MR indications depending on the contrast agent, including central

Tips for Integrating IBPs into Your Department

Following established best practice guidelines can help the process of implementation go more smoothly. It takes a team. Include all stakeholders right from the start of the process, including infection preventionists, pharmacy leaders, quality director or accreditation managers, radiologists, and technologists.

Assess contrast utilization

Review current contrast usage and waste patterns and compare that data with projections/estimates of how IBPs can help address them.

Conduct needs assessment

Contrast storage: Is your current storage cabinet large enough and secure (locked)? Is it convenient for staff to access?

Supplies: What tools will staff need to access and administer contrast using an IBP; e.g., approved transfer spikes, injectors, swabs, etc.?

Staff Training: Who will train and ensure the competency of technologists regarding aseptic technique and use of IBP/transfer spikes?

MRI Contrast Protocols: Will these need to be adjusted to customized dosing? Collaborate with radiologists to determine whether any changes in the amount of contrast being administered are required.

Ongoing Compliance: What tools and procedures should be established to monitor and to ensure regulatory compliance and produce the desired outcomes regarding contrast waste, trash volume, and room set-up time? Partner with the practice infection preventionist to ensure safe access to and labeling of the IBP.

nervous system, breast, cardiac, and angiographic imaging. Their flexibility supports adult and pediatric dosing, making them well-suited for hospitals and outpatient centers alike. High-volume outpatient settings are especially appropriate for IBPs; the more contrast-enhanced MRI exams a facility conducts in a day, the more savings and workflow improvements are appreciated.

Regulatory Compliance

On-site surveys conducted by CMS or accrediting bodies focus on patient safety and include both observation and staff interviews. Joint Commission accredited facilities often experience compliance deficiencies concerning infection control and medication management that could result in corrective action plans and return surveys. Using IBPs according to the preparation instructions (e.g., only in a room designated for radiological procedures, with their approved transfer spike or automated contrast injection system) is key to preventing cross contamination.

Training and competency-based assessments should be implemented before allowing technologists to use IBPs. Ongoing observation and monitoring is also essential. Infection preventionists can observe aseptic techniques and documentation practices during routine audits. Billing documentation requires close attention, as well: each dose must be recorded in the electronic medical record and linked to its corresponding IBP lot number. Regulators want to ensure the traceability of every milliliter of contrast. Accurate documentation, moreover, ensures efficiency gains translate into financial and operational value.

Implementing IBPs in MRI

Transitioning to IBPs requires thoughtful planning and input from multiple stakeholders. It's only natural that implementation works best when the people who will use and oversee the product every day are part of the decision-making process. Infection preventionists, pharmacy leaders, quality directors, accreditation managers, and MRI

Joint Commission Related Standards

Infection Prevention and Control

The hospital implements its infection prevention and control program through surveillance, prevention, and control activities (IC.06.01.01)

Medication Management

The hospital safely administers medications (MM.06.01.01)

Human Resources

Staff are competent to perform their responsibilities (HR.01.06.01)

technologists should all be involved throughout the entire implementation process.

Facilities can start by evaluating current contrast usage and waste and comparing the figures to projected savings using IBPs. Practical considerations include storage cabinet capacity; availability of transfer spikes, injectors, and other supplies; and staff training.

It's worth noting that change management skills are essential to getting staff buy-in. People tend to adhere to what they know in any environment, including the MRI department. Therefore, taking a layered approach to training and implementation–e.g., holding short in-service sessions led by infection prevention, pharmacy or quality and safety management, followed by peer-to-peer reinforcement among technologists—can be helpful.

Leadership modeling of best practices—using transfer spikes correctly, labeling consistently, discarding at 24 hours—also reinforces standards of care. Using ongoing observation and monitoring to provide real-time feedback reduces the likelihood of staff to drift or create workarounds. In addition, keeping laminated quick-reference guides, checklists and even copies of the product's IFUs readily available for staff is advised. Holding mock regulatory surveys can help ensure staff comfort and confidence using IBPs, especially in preparation for and during actual regulator agency visits. While the process entails multiple components, it is readily achievable through structured implementation and ongoing reinforcement of best practices.

MR IBPs Are Here to Stay

Considering the depth and breadth of their benefits, IBPs are poised to become the standard of care in MRI in high volume MRI departments. Vendors are developing larger-volume IBPs and new injector-compatible designs, and are providing detailed training videos on how to use associated supplies like the transfer spike.

At the end of the day, however, IBPs are not just about streamlining operations, strengthening regulatory compliance, saving money, or even saving the environment. They are about helping MRI clinicians deliver the best possible patient care.

That's a package worth opening!

References

1) https://bayer2019tf.q4web.com/news/news-details/2020/FDA-Approves-Gadavist-gadobutrol-Imaging-Bulk-Package/default.aspx.