The Beat Goes On: Weighing Clinical Benefits, Patient Selection, and Healthcare Economics of MRI-Compatible Cardiac Rhythm Devices
Summary

The recent decision by the Centers for Medicare and Medicaid Services (CMS) to reimburse providers for magnetic resonance imaging (MRI) studies in patients who have non-MRI-compatible devices has added further complexity to physician decisions at time of device implant. Is this change by CMS at odds with the value proposition of these premium devices? There are certainly patients who can benefit from these devices, but understanding the data and trends can help ensure appropriate patient selection while managing overall device spend.

Pacemakers and implantable cardioverter defibrillators (ICD’s) are collectively referred to as cardiac rhythm management (CRM) devices. Non-MRI-compatible devices have been the standard of care since inception of CRM devices, but unfortunately many publications have documented device malfunctions occurring in these devices during MRI procedures, which can lead to adverse outcomes. In 2011, MRI-compatible CRM devices were introduced. These devices were approved by the FDA after rigorous testing to ensure reliable performance during MRI procedures.

While MRI-compatible CRM devices have gained significant market share in recent months, these devices are more expensive and Medicare continues to reimburse at the established standard rates which do not factor in device features. With Medicare patients representing 70-75 percent of all CRM device recipients\(^1\), this increase in device cost is forcing hospitals to absorb the cost difference themselves. The result is an increase in total spend for CRM devices of 8 percent, based on current adoption rates, which translates to greater than $400 million estimated cost increase for U.S. hospitals annually.

Considering this added burden, it is important to ask the question: are MRI-compatible CRM devices required for everyone?

Multiple publications estimate that 25 to 50 percent of patients with CRM devices will not require an MRI study during their lifetime\(^2\). For those who do, recent studies, including one published from the Mayo Clinic\(^3\), have shown that a 1.5T MRI can be safely performed in patients with standard CRM devices if appropriate precautions and protocols are followed. Moreover, a review of 2017 total annual MRI procedures versus total annual CRM device implants by age from the Vizient Clinical Data Base\(^\circledR\) reveals interesting trend lines. The data show MRI usage appears to peak in patients around age 60 and then declines quickly as patients enter their mid-70s. Pacemaker and defibrillator implantation, on the other hand, peaks at age 79.

While there is clear clinical benefit to MRI-compatible devices, utilization data suggests that appropriate patient selection will be an important factor in effectively managing overall CRM device spend.

Background

Millions of individuals in the U.S. have an implanted pacemaker or defibrillator\(^4-5\). Each year, an estimated 600,000 pacemakers and defibrillators are implanted in patients in the U.S.\(^6\) (see Chart 1). These devices monitor and/or correct a patient’s heart rate when the heart goes too slow, too fast, or does not beat in a rhythmic, coordinated manner and are required to maintain activities of daily life.

Historically, these devices were thought to be contraindicated for MRIs due to the potential for device failure, tissue injury from lead-tip heating or movement caused by the electromagnetic fields used to obtain MRI images. Yet, an MRI is the best diagnostic tool that offers the most sensitive non-invasive method for imaging the brain, spinal cord or other areas of the body. It is the preferred imaging approach to help establish a diagnosis of multiple sclerosis, acoustic neuroma or low-grade astrocytomas and to monitor the course of a disease.

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Chart 1: 2018 CRM Device Procedure Location/Status Mix

- **Hospital Outpatient**: 70%
- **Inpatient**: 28%
- **Ambulatory Surgery Center**: 4%

Source: Impact of Change\(^\circledR\), Sg2 ©2018
The market

The pacemaker and defibrillator market has seen both revolutionary and evolutionary advancements in technology. Revolutionary technologies include the release of the leadless pacemaker introduced in 2016 (Medtronic), and the subcutaneous defibrillator (Boston Scientific), which received FDA approval in 2012. Other device innovation has been far more evolutionary over the past 15 years, with improvements in device size, battery life and heart failure diagnostics, as well as the introduction of MRI compatibility.

The Sg2 Impact of Change® forecast, the health care industry’s go-to tool to understand future utilization trends, projects the CRM device market to grow roughly 2 percent each year over the next decade. This is mostly due to the rising prevalence of cardiovascular disorders, technological innovations and the growing population of individuals over the age of 70. It is important to note that the majority of implantations are performed as hospital outpatient cases (see Chart 1). This requires greater focus on margin management, as these cases are reimbursed at less than the equivalent inpatient cases.

“While this is still a modest growth area for the industry, the shift of cases to hospital outpatient and ambulatory care settings will challenge provider margins under the current reimbursement model. As a result, the additional cost for the MRI-compatible devices adds another layer of complexity to margin management.”

Chad Giese
Senior director, cardiovascular service line research, Sg2

Magnetic resonance-compatible devices

The first MRI-compatible pacemaker was approved in the U.S. in 2011. In its first four years of availability, uptake was limited, never exceeding 10 percent total pacemaker market penetration. However, the use of MRI-compatible devices has exploded over the past 18 months (see Chart 2) and they are now on track to become the standard of care. Vizient SpendLINK® data show utilization of MRI-compatible pacemakers increased from 12.3 percent in 2016 to 73.6 percent in 2018 (see Table 1). Other MRI-compatible devices, such as implantable cardioverter defibrillators and resynchronization therapy pacemakers, have also experienced significant increases in the last 18 months.

“The rapid growth in the use of MRI-compatible devices by physicians reflects their focus on providing enhanced patient care both short and long term. It also demonstrates a potential lack of understanding of the difference in device costs and the financial impact to the health care system.”

Doug Beinborn
Senior director, contract services, Vizient

Chart 2: MRI-Compatible CRM Device Growth

Table 1: MRI-Compatible CRM Device Utilization

<table>
<thead>
<tr>
<th></th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implantable Pacemaker</td>
<td>12.3%</td>
<td>57.2%</td>
<td>69.9%</td>
</tr>
<tr>
<td>Implantable Cardiac Defibrillator</td>
<td>2.1%</td>
<td>22.8%</td>
<td>48.5%</td>
</tr>
<tr>
<td>Resynchronization Therapy</td>
<td>18.4%</td>
<td>25.1%</td>
<td>30.0%</td>
</tr>
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</table>

Source: Vizient SpendLINK, 2018
**Financial impact to hospitals**

Based on an analysis by Vizient, CRM device expenses are expected to increase for most hospitals in 2018 due to expanded MRI-compatible device adoption. While standard and MRI-compatible CRM device prices are expected to continue their multiyear downward trend (see Chart 3), the rapid adoption of more costly MRI-compatible devices at an increased cost is offsetting the downward price trend.

Chart 3: Total CRM Device 5-Year Price Trend

<table>
<thead>
<tr>
<th>Year</th>
<th>Pacemaker</th>
<th>Defibrillator</th>
<th>Resynchronization</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>$20,000</td>
<td>$15,000</td>
<td>$10,000</td>
</tr>
<tr>
<td>2014</td>
<td>$15,000</td>
<td>$10,000</td>
<td>$5,000</td>
</tr>
<tr>
<td>2015</td>
<td>$10,000</td>
<td>$5,000</td>
<td>$0</td>
</tr>
<tr>
<td>2016</td>
<td>$5,000</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>2017</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
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Source: Vizient SpendLINK, 2018

The premium price for MRI-compatible CRM devices is 17.7 percent, 17.0 percent and 18.6 percent for pacemakers, implantable defibrillators and resynchronization therapy devices as compared to standard devices, respectively (see Chart 4). While these devices are more expensive, Medicare reimburses providers at the same rate as it does for standard devices. With Medicare patients representing 70 percent to 75 percent of all CRM device recipients9, hospitals are being forced to pay the difference themselves.

Chart 4: MRI-Compatible CRM Device Price Difference

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Non-MRI</th>
<th>MRI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pacemakers</td>
<td>$20,000</td>
<td>$15,000</td>
</tr>
<tr>
<td>Defibrillators</td>
<td>$15,000</td>
<td>$10,000</td>
</tr>
<tr>
<td>Resynchronization</td>
<td>$10,000</td>
<td>$5,000</td>
</tr>
</tbody>
</table>

Source: Vizient SpendLINK, 2018

“As margin management becomes top of mind for providers, value analysis, supply chain and clinical teams must collaborate to ensure the premium dollars are appropriately spent. Additionally, hospitals need to accelerate pressure on their suppliers to lower overall CRM device spend.”

Craig Lukowski
Director, contract services, Vizient

**Clinical impact and value proposition of MRI-compatible devices**

The clinical benefits of the MRI-compatible CRM devices seems intuitive. A device that provides a patient with the option to have an MRI safely performed is a clear benefit. But are these devices necessary in all patients?

Recent studies have shown that MRIs can be safely performed in patients with standard CRM devices10-12. These studies led the Heart Rhythm Society to update its guidelines in 2017 to provide MRI-scanning protocols for patients with standard CRM devices who are not pacemaker dependent. As a result, in July 2018 CMS 2018 began reimbursing for MRIs in this patient population.

Moreover, a Vizient review of 2017 MRI procedures by age (see Chart 5) shows a declining use of MRIs in the older population. Usage of MRIs appears to peak in patients at 60 years of age and declines rapidly as patients enter their mid-70s. Many factors affect this, including reduced population size and a higher number of patients with other implantable devices that contain ferrous metals which contraindicates the procedure.

At the same time, Vizient data shows CRM implantation peaks at 79 years of age. The apparent data mismatch highlights the need for clinicians to consider future MRI needs in patient selection for these types of devices.

“"The data is unclear as to whether the declining number of MRI procedures in the older population is due to lack of necessity, limitations created from implanted CRM devices or other implanted medical devices, limitations created by non-MRI labeling and/or limitations on MRI reimbursement. However, given the cost impact being experienced by providers, further research is needed to better understand this decline."

Doug Beinborn
Senior director, contract services, Vizient
It seems to make clinical sense to implant a CRM device that provides greater future options for patients. But if it is a feature that will not be used or needed, is it a real clinical benefit? Additional research is needed into the clinical value and economic impact of MRI-compatible CRM devices.

**Conclusion**

The use of the MRI-compatible CRM devices will likely continue to expand. The sudden and dramatic increase in the use of these devices over the last 18 months has caused a significant increase in cost for healthcare providers, which estimates suggest could be greater than $400 million annually.

While there is clinical benefit to these devices, the data from Vizient suggest more research must be done and hospital value analysis teams need to collaborate with physicians to determine the true need for these devices for their patients. In the long run, the ability for vendors to maintain their premium pricing for MRI-compatible devices may not be sustainable, as the technology will likely shift to become a standard feature in the next two to four years.

Currently, no clear clinical decision-making model exists to reliably predict individuals who will need a future MRI. As such, health care providers need to be aware of the increased costs and work with their suppliers to minimize the impact to hospital margins.
References


8. Vizient SpendLINK, Vizient, July 2018


About the authors

Doug Beinborn

Doug is a senior director, contract services at Vizient. He leads the strategic cardiovascular initiatives and strategic supplier programs with Vizient members across the U.S. Doug has over 30 years of cardiovascular experience including clinical, administrative, reimbursement and new product innovation. Prior to joining Vizient, Doug manage the electrophysiology department at the Mayo Clinic for 26 years where he was responsible for the electrophysiology/implant device laboratory, heart rhythm center, arrhythmia consultative services, cardiac implantable device consultative service EP outreach and heart rhythm management research, CV monitoring and the ECG laboratory. He has authored over 40 publications and book chapters as well as having served on three different cardiovascular editorial boards including the Heart Rhythm Society.

Chad Giese

Chad is the senior director for cardiovascular service line research at Sg2. Giese develops Sg2’s cardiovascular intelligence and strategic insights to help members navigate the current landscape and future projections for CV services. With more than 15 years of medical device research experience, Giese’s extensive background in cardiovascular provides a unique perspective of the market.

Craig Lukowski

Craig serves as director, contract services for Vizient. Lukowski leads the team’s strategic support, innovative program development and new technology assessment and education programs. With more than 25 years of experience in cardiology and orthopedic healthcare industry, he has an extensive background working with both domestic and international medical devices suppliers, healthcare providers and markets providing a unique insight.
As the nation’s largest member-driven health care performance improvement company, Vizient provides network-powered insights in the critical areas of clinical, operational, and supply chain performance and empowers members to deliver exceptional, cost-effective care.