Enabling Improved Patient Outcomes and Reduced Costs: TYRX Outcomes Protection Program

James Mullin, MD; Laurie Niemet; Kristin Doster; Ruben Weber; Eric E. Johnson, MD

The continuous effort to provide high value healthcare involves the pursuit of three linked goals, according to the Triple Aim: (1) improving the experience of care, (2) improving the health of populations, and (3) reducing per capita costs of healthcare.[1] New programs that align incentives between healthcare industry manufacturers and healthcare providers, known as value-based healthcare (VBHC) programs, have the potential to both improve the experience of care and reduce healthcare costs. The increasing focus on VBHC programs is a potential paradigm shift, encouraging medical device manufacturers to consider the cost of care if adverse clinical outcomes occur despite the use of such products. As a result, related initiatives have been adopted by device manufacturers over the last several years and presented to end users, although narratives on the results of such initiatives are sparse.

Infections related to cardiac implantable electronic devices (CIEDs) represent one such opportunity for improving value in healthcare. Although CIED infections are rare (1%-4% of cases), the impact on the patient is substantial[2-4] and can result in device extraction, disruption of CIED therapy, prolonged hospitalization, re-intervention, reduced quality of life, and an increased risk of mortality.[5,6] The added burden on the healthcare system is implicit and it is estimated that U.S. hospitals spend, on average, $56,000 to $83,000 to care for each patient with an infection.[6-8] Often, reimbursement provided for these hospitalizations does not fully cover the costs incurred by the providers, leading to average hospital margin loss ranging from $6,000 to $31,000.[6]

The TYRX™ absorbable antibacterial envelope (Medtronic) represents a technology innovation meant to address the problem of CIED stabilization and infections. With nearly 7000 patients enrolled, the Worldwide Randomized Antibiotic Envelope Infection Prevention Trial (WRAP-IT) was the largest randomized, controlled, global CIED trial to demonstrate a 40% reduction in major CIED infection and a 61% reduction in device pocket infection[9], with no increase in complications out to three years of follow-up[10] in patients undergoing CIED replacements, revisions, upgrades or initial CRT-D implants. Economic analyses have also shown cost-effectiveness of the use of TYRX compared to standard-of-care infection prevention strategies in both the U.S.[11] and European[12] healthcare systems. The 2019 European Heart Rhythm Association (EHRA) Consensus document, endorsed by a number of professional societies and associations comprised of experts in cardiology, recommends the use of the TYRX in patients at high-risk for CIED infection.[13]

The TYRX Outcomes Protection Program (OPP) between Medtronic and participating hospital providers allows the device manufacturer to play an active role in striving for the Triple Aim. This VBHC program, developed by Medtronic, helps protect participating sites by taking into consideration the economic burden associated with unexpected outcomes.

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TYRX Outcomes Protection Program Overview

While the TYRX OPP is offered in several countries across the world with small deviations in program structure, the U.S. program is the largest. In the U.S. program, if a participating site implants a Medtronic CIED and reports a CIED infection despite use of a TYRX absorbable antibacterial envelope during the device implant procedure, Medtronic will pay a fixed rebate against the site's purchases of cardiac rhythm and heart failure products. The rebated amount is based on evidence demonstrating the average negative margin U.S. hospitals realize when caring for patients with a CIED infection.[6] Initially, infections were covered for up to six months post implant. After the WRAP-IT results were published[9], the post-implant infection coverage was extended to one year. Once a report is approved by Medtronic, the site receives a rebate payment of $10,000.

Program Results

Since the inception of the program in January 2017 to August 2021, 1568 sites participated in the U.S. TYRX OPP, with an estimated 92,044 CIED patients (Table 1) receiving the TYRX envelope at implant. A total of 144 infection reports were submitted of which 141 rebates were paid, resulting in $1,410,000 in rebate payments to the affected sites. The three denied rebate payments were due to duplicate report submissions.

The proportion of CIED infection reports to TYRX implants was 0.15%. Using the difference in infection rates reported at 12 months in the randomized, controlled WRAP-IT trial between control (1.2%) and TYRX (0.7%) patients[9], an estimated 425 infections were prevented across all patients implanted during the program. Treating those estimated additional infections that may have occurred without the use of TYRX would have incurred approximately $23.6M in additional costs to the sites in the program.

Discussion

The TYRX OPP is the largest program of its kind and serves as a blueprint for successful value-based programs between device manufacturers and healthcare providers, with more than 90,000 patients covered across over 1500 U.S. hospitals, which represents a significant portion of U.S. hospitals.[14] The program has had substantial impact on participating sites, with 141 paid reports totaling $1.41 million in fixed rebate payments designed to mitigate the hospitals' negative margin impact of treating CIED infections. Additional healthcare system benefits related to the use of TYRX under the program are estimated at $23.6 million in cost avoidance to participating sites related to infections prevented. In relation to the Triple Aim, the value of TYRX use is demonstrated by infection report rates as low as 0.15%.

The TYRX OPP addresses a critical need in the healthcare ecosystem, as the economic burden on providers is significant and patient demand continues to place pressure on hospital budgets. Such constraints may lead to delays in the introduction of innovative products, despite their potential to reduce complications and save overall treatment costs. At the same time, device manufacturers are currently paid at the point of sale and have only indirect incentives related to the outcomes for specific individual patients. Skepticism about the abilities of new healthcare technologies to

Table 1. Program Results.

Metric	Calculation/Description	Value
Total number of participating sites	Number of unique participating sites with a signed contract at a point in time	1,568
Estimated total number of patients implanted during the program	Total lesser of Medtronic CIED implants or TYRX sales per site, over time during the program	92,044[a]
Total number of rebates paid	Net total that excludes denied reports	141
Proportion of TYRX implants to CIED infection reports	Average rate of patients associated with an infection report over the lifetime of the program	0.15%
WRAP-IT trial infection rate difference	Difference in 12-month infection rates between control arm and TYRX patients[9]	0.5%
Estimated infections prevented	Infection rate differences applied to number of patients[a]	425
Report payments made by Medtronic	Total rebate payments to sites under program	$1,410,000
Cost avoidance for participating sites[a]	Total cost avoidance estimate based on average hospital cost per infection[6]	$23.6M[b]

[a]Adjusted for patient coverage timeframes under 6- and 12-month program; [b]Rounded to the nearest $100,000

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deliver on their promises further disincentivizes the adoption of new technologies. However, programs such as the one described here can help overcome these challenges.

While most providers are interested in value-based agreements with manufacturers to ease some of the cost burden, formal programs seem to be rare.[15] One reason is because such programs must be based on metrics that are measurable, meaningful, and ably influenced. The TYRX OPP meets these conditions: CIED infections have a significant impact on patients and provider economics, and have been proven, through randomized controlled evidence, to be reduced using TYRX envelopes. A key to VBHC program success is the ability to longitudinally track patient outcomes. The TYRX OPP is successful, as CIED infections are easily identifiable as intense, acute events and can be linked with ICD-10 diagnosis codes. A final key driver for the success of such programs is long-term commitment from both the providers and manufacturers. With the TYRX OPP, this commitment is secured with a 2-year contract that provides coverage for infections that occur up to a full year after the CIED procedure.

The TYRX OPP is also offered to providers in countries outside of the U.S., including Canada, Western Europe*, and India. The largest comparable program exists in the United Kingdom. As of mid-2021, across 114 participating sites, 3314 TYRX envelopes were used, and 16 reports have been submitted. This translates to just under 0.5% of patients with infection-related reports, which corroborates infection rates reported in WRAP-IT.[9]

United Kingdom, Italy, Spain, Sweden, Denmark, Norway, Finland, the Netherlands, Switzerland

While maintaining a similar structure and aiming to consider the economic burden put on healthcare providers in different countries, local constraints may necessitate changes in program structure, mostly related to the payment mechanisms.

As authors, we have had a significant experience with the TYRX OPP at The Ohio State University (459 patients implanted since November 2017), Prairie Health (993 covered patients since May 2018), and HSHS St. John's (916 covered patients since May 2019). We choose patients for TYRX that have increased risk for infection, matching the inclusion criteria of the WRAP-IT trial, including initial CRT-D implants, as well as all generator change-out procedures and lead revision/upgrade procedures. Between the sites, there have been 8 reports paid, totaling $80,000 in rebate payments, mitigating the negative margin impact of treating CIED infection, and with the use of TYRX, provided an estimated cost avoidance of $700,000, based on infections prevented. We see the program as valuable, as the reports paid are based on infections rather than simple volume of TYRX used, and as such, the TYRX OPP is the only value-based program our sites are currently involved in.

The TYRX OPP has demonstrated the benefits of a unique program between device manufacturers and providers, specifically at The Ohio State University, Prairie Health, and Baptist Memorial Hospital - Memphis. Thus, we recommend this program to other providers due to its clear benefits, which support the use of TYRX to further reduce CIED infection in patient populations with increased risk and consider the cost of care for infections that do occur. With over $1.41 million in rebate payments and a significant estimated cost avoidance of over $23.6M due to infections prevented, TYRX use in conjunction with the program is delivering on its aims.

As in most cases, there are limitations inherent to these types of analyses that should be acknowledged. First, the results reported here are among sites that were motivated to participate in a VBHC program and may not be representative of all providers. Additionally, it is possible that some CIED infections were not detected or reported, despite CIED infections being highly visible events. It is also possible that some patients received CIED implants at a site participating in the program, but had their infection treated in a separate site. However, if the implant occurred at a separate site, but was treated at a participating site, the report would be paid to the latter. Finally, only devices from a single manufacturer were considered eligible for the program.

Conclusion

The use of TYRX in conjunction with the OPP met its aims as demonstrated by the prevention of an estimated 425 CIED infections, payment of

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$1.41 million in rebates, and significant estimated cost avoidance of $23.6 million to participating sites, demonstrating both value and scale. The TYRX OPP was successful seemingly through its simple design, trackability of outcomes, and consideration of CIED infection costs. Achieving better patient outcomes while reducing costs can be achieved through close collaboration between industry and providers. ■

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In the Literature: *CLD* Editor's Picks

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Quantitative Flow Ratio Analysis by Paramedical Compared With Medical Users

Farhang Aminfar, MD; Benjamin Honton, MD; Pierre Meyer, MD, et al

When used prior to angioplasty, quantitative flow ratio (QFR) is a useful alternative to guidewire-based fractional flow reserve (FFR), which is the gold standard to assess the hemodynamic relevance of an intermediate coronary lesion. Unlike FFR, QFR is only based on the coronary angiogram and does not require a pressure wire or vasodilator administration. However, QFR analysis requires prior training and the ability to correctly interpret the angiographic frames. Therefore, the present study sought to evaluate QFR performed by physician and non-physician certified users.

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Shockwave Intravascular Lithoplasty as the Last Option to Restore Flow in a Nonagenarian With an Acute Coronary Syndrome

Qais Radaideh, MD, MS; Nagarjuna Gujjula, MD; Ann E. Narmi, MD, et al

Frequently, coronary angiography underestimates the presence of severe calcium within a plaque, which renders it non-dilatable with balloon angioplasty.[1,2] Intravascular lithotripsy (IVL) has emerged as an effective technique to modify severely calcified plaque. However, most clinical trials of IVL, including the recently published DISRUPT CAD III, did not include ST-elevation myocardial infarction (STEMI), acute thrombotic lesions, or coronary dissections. We present a case of coronary lithotripsy as a bailout strategy in the setting of acute dissection in a patient with STEMI and a non-dilatable severely calcified lesion.[3]

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