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Examining the Need to Standardize Implanted Stimulator Connectors: NANS Survey Results

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ABSTRACT

Introduction: Connectors between implanted stimulator electrodes and pulse generators allow revisions, including battery changes or generator upgrades, to proceed without disturbing uninvolved components, such as the electrode. As new devices are introduced, however, connector incompatibility, even with updated hardware from the same manufacturer, can lead to additional procedures, expense, and morbidity.

Materials and Methods: Following the example of the cardiac pacemaker/defibrillator industry, the Institute of Neuromodulation (IoN) met to explore the possibility of creating connector standards for implanted neurostimulation devices. At a subsequent meeting of the Association for the Advancement of Medical Instrumentation, which coordinates the development of such standards, industry representatives asked for data defining the need for a new standard. Accordingly, IoN prepared an online survey to be sent to the North American Neuromodulation Society mailing list regarding experience with the connectivity of spinal cord stimulation (SCS) generators and electrodes.

Results: The 87 respondents of 9657 surveyed included 77 clinicians, who reported a total of 42,572 SCS implants and revisions. More than a quarter of revisions (2741 of 9935) required the interconnection of devices made by separate manufacturers, in most cases (n = 1528) to take advantage of a new feature (e.g., rechargeability, new waveform) or because an original component could not be replaced (n = 642). Connector adapters provided by manufacturers were used in less than half (n = 1246) of these cases. Nearly all (94%) of the clinicians agreed that standardized connectors should be developed for SCS, and 86% opined that standardized connectors should be developed for other neurostimulation therapies.

Conclusion: Those who responded to our survey support the development of standard connectors for implanted stimulators, with voluntary compliance by manufacturers, to mitigate the need for adapters and facilitate interchanging components when appropriate. Other advantages to patients and manufacturers might accrue from the adoption of standards, as technology evolves and diversifies.

Keywords: Adapter, connector, patient care, spinal cord stimulation, standards, technology

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INTRODUCTION

The first implanted neurostimulators, like the first cardiac pacemakers, were unitary devices implanted in a single surgical procedure (1). Subassemblies with connectors were soon developed to allow staged implantation and to facilitate revision or replacement of one component with minimal disturbance to the other (2). As the numbers of both neuromodulation devices and manufacturers have grown, many connector designs have come and gone (3). In addition, when a manufacturer is acquired or goes out of business, patients with existing implants must rely on successors for compatible replacement parts. The resulting incompatibilities can compromise revision and replacement, leading to the potential need for additional procedures with attendant expense and morbidity. This applies to routine maintenance, as when internally powered, implanted pulse generators (IPGs) used in spinal cord stimulation (SCS) require replacement because of battery depletion, and also to efforts to improve SCS effectiveness by offering patients access to new or different components. In such cases, the absence of a connector-compatible replacement or of a suitable adapter can necessitate replacement of an entire system, incurring additional expense and increasing surgical and therapeutic risk of SCS revision, which is a common procedure (4–6). For spinal cord, peripheral nerve, or deep brain stimulation electrodes, the position of which is often critical, normal postsurgical scarring can interfere with successful replacement (7, 8).

Complications and adverse events are routinely reported in the literature on SCS, and some papers have addressed them in detail, but the compatibility problems described above have not been described previously (4–6). Since the 1980s, some manufacturers have offered an adaptor to connect their particular IPG with a specific electrode made by another company. This can occur only after a delay, for example, when one manufacturer releases a new product and a competitor must then build and obtain United States Food and Drug Administration (FDA) approval for an adaptor. Although this solves a problem for a limited number of cases of cross compatibility, it does not provide a long-term or general solution that would allow all manufacturers to have cross-compatible electrodes and IPGs. Issues of cross-compatibility led to significant medical complications during the expansion of cardiac pacing technology before adoption of more universal standard connectors (9, 10).

An additional problem is that most connectors are so similar in appearance and dimension across manufacturers that they might appear to have been designed to interconnect, when in fact they were not. This situation has arisen largely because as shown in Figs. 1 and 2, (1) the male component of the generic inline connector in use for the past 40 years has been designed for insertion through a standard gauge needle, and (2) at any given time, the most commonly used number of contacts per electrode has been the same across manufacturers (originally four in the 1980s and 90s, and eight since then). Connecting components that are similar but were not designed to connect admits the risk of electromechanical failure from current leakage or open circuits.

Today, only a few SCS components or subassemblies are built independently; nearly all are instead part of a complete system from a single manufacturer. Connector standards foreseeably would encourage growth of expertise among small manufacturers of subassemblies and components, such as electrodes, pulse generators, power sources, and user interfaces.

Beginning in 2017, the newly established Institute of Neuromodulation (IoN) (2) convened a series of meetings to explore and identify the needs, opportunities, and challenges associated with developing connector standards for implanted neurostimulation devices. Following the example of the cardiac pacemaker/defibrillator industry, which developed connector standards that were first published in 1992-1993 and then updated to accommodate newer technology (11), IoN convened an April 2018 meeting with the Association for the Advancement of Medical Instrumentation (AAMI), which coordinates the development of standards, and invited representatives of all United States neuromodulation equipment manufacturers (12). At this meeting, industry representatives asked for data defining the need for a new standard.

MATERIALS AND METHODS

We prepared an online survey for distribution to the North American Neuromodulation Society (NANS) mailing list that solicited information on the use of SCS devices and opinions regarding the connectivity of pulse generators and electrodes (Appendix A1). This list included not only NANS members but also neuromodulation practitioners and technical and supporting staff worldwide; we wanted to capture as many as possible of those involved in SCS revisions, not just implanting physicians and surgeons.

RESULTS

Of 9657 people who received the email invitation, 2433 opened the message, 149 clicked the link, and 87 completed the survey. Of these, 89% were clinicians. As shown in Fig. 3, most of these

Figure 1 The most common SCS connector accommodates multiple inline contacts, similar to the electrode contacts at the distal end of a "lead" assembly that can be inserted percutaneously through a needle, which can then be withdrawn. The female component of the connector commonly has seals between contacts to prevent current leakage and one or more setscrews to secure the connection; these may vary among manufacturers and are not shown. Pulse generators may incorporate multiple connectors in a single header.

Figure 2 These IPGs from four major manufacturers all have two inline eight-contact connectors, and it appears on inspection that they all have the same contact diameter and intercontact spacing, although in fact they do not. [Color figure can be viewed at wileyonlinelibrary.com]

were anesthesiology/pain medicine specialists (51%) or neurosurgeons (25%).

The respondents reported their experience with 42,572 SCS implant and revision procedures, of which 9935 (23%) were revisions (Table 1). Of the latter, 2741 (28% of revisions, 6% of the total) involved interconnecting devices made by two different manufacturers, thus creating a hybrid system. Of these, 1528 (15% of revisions) were done to take advantage of a new feature available from a different manufacturer, 642 (6%) because a component was unavailable (out of stock, no longer made, etc.), and 571 (6%) for other reasons (Table 2). Adapters provided by manufacturers were used in 1246 (45%) of the hybrid cases (13% of revisions).

The great majority of respondents (94% of clinicians and 70% of non-clinicians) opined that standardized connector designs should be developed for SCS. In addition, 86% of clinicians and 70% of non-clinicians responded that standardized connectors should be developed for other neuromodulation therapies.

DISCUSSION

Proposing a Novel SCS Connector Standard

With the goal of understanding end-user views of the need for a standard connector for neuromodulation devices, we conducted a survey to be distributed via the NANS mailing list. The strong preference for standardized connector designs expressed in the results of our survey is a compelling reason to move forward with the development of such standards. Cases in which standardized connector designs would be clinically important are commonplace: our survey results indicate that interconnection of devices made by different manufacturers, thereby creating a hybrid system, already occurs in 28% of SCS revisions. Revisions represented 23% of SCS procedures reported in our survey, a rate consistent with, albeit slightly lower than the 33%-50% rates previously reported (4–6). Therefore, our survey results might underestimate the incidence of hybrid system creation.

In our survey, most of the hybrid systems were created to provide a new feature (e.g., rechargeability, new waveform) to patients to improve their health outcomes. The benefits of such hybrid systems will be facilitated if connector compatibility is effectively addressed by standardization.

Adapters provided by manufacturers were used in 45% of the hybrid cases. As the number of manufacturers and systems continues to grow, the number of adapters needed can be expected to grow at an even higher (nonlinear, combinatorial) rate. Thus, a strategy that relies upon post-market identification and development of adaptors among competing companies will be inadequate

to keep up with the problem. To the extent that adapters remain in use even with the adoption of connector standards, the standards can facilitate the design and construction of the adapters.

The new standards envisioned by the authors would not be intended to apply retroactively to existing components but rather to be phased in as new systems are designed and introduced. Furthermore, the authors propose that adhering to the new connector standards should be voluntary (although their advantages could be compelling). This has been true in the case of cardiac devices, for which analogous standards have been developed. A review of this experience is instructive.

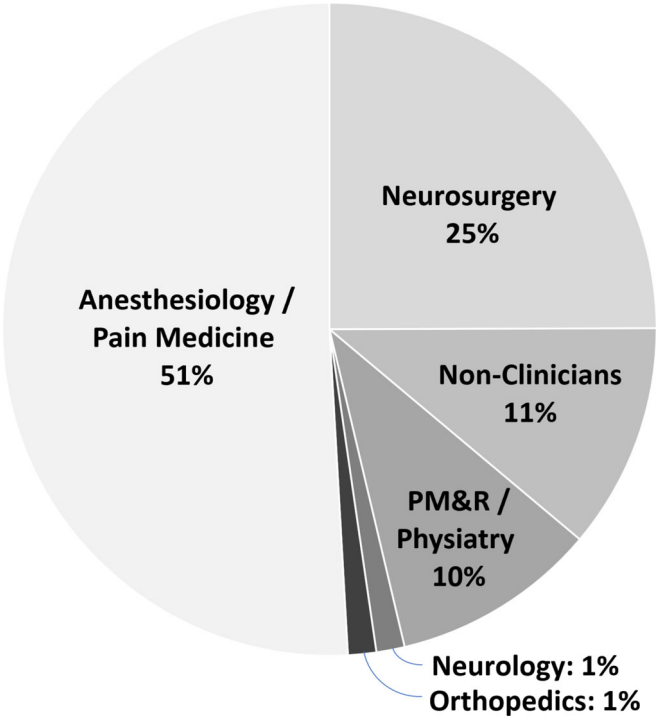

Figure 3 Specialties of the clinical respondents to the survey. [Color figure can be viewed at wileyonlinelibrary.com]

Development of Cardiac Pacemaker Connector Standards

Implanted neuromodulation devices evolved alongside cardiac pacemakers and defibrillators, with which they share many design elements. The first neuromodulation and cardiac devices were unitary devices implanted as an assembly in a single operation (1); but, the technology soon incorporated connectors to facilitate staged procedures and revisions (13). The evolution of each type of implant increased connector complexity as well as incompatibility among products. The problem escalated when cardiac pacing devices added sensing functions, which became unreliable in the event of lead-IPG connector problems, leading to failed arrhythmia detection and potential life-threatening conditions (9, 14, 15). The same dilemma arises when discussing lead and IPG compatibility issues with neural devices destined for dependency on sensing to improve therapy output.

As cardiac rhythm management provides critical life support, and therefore cannot be interrupted, connector incompatibility became an important problem. Accordingly, in the 1980s, a plea from the physician community, supported by the medical device engineering community, led to the first implanted connector standards in the 1990's (10, 16, 17). The AAMI, a North American organization that develops and maintains medical-device standards, was enlisted by the International Standardization Organization (ISO) and other groups to develop the first bi-polar pacing connector standard, known as IS-1, which was released in 1992 (18). This was followed in 1993 by DF-1, a connector standard for use with unipolar high-voltage defibrillators. In 1998, in response to the need for a standard for a combined connector that would reduce pocket bulk and address the complexity of connecting with multiple ports, while safely isolating high voltages from low-voltage pacing and sensing functions and retaining flexibility, a Connector Task Force began discussions that resulted in new IS4 and DF4 standards, which AAMI issued in 2010 (11, 19, 20).

Today virtually all new implants incorporate some combination of the above standards (20). The benefits of standardizing cardiac device connections to facilitate prompt, safe, and effective

Table 1 Experience of Respondents, Mean ± SD (Range).

	Years of experience	Number of manufacturers represented	Of total 45,572, implants and revisions experienced	Of total 9935, revisions experienced
Clinical n = 77	13.7 ± 9.6 (1 to 40)	3.6 ± 1.2 (1 to 8)	560 ± 678 (5 to 3000)	136 ± 224 (5 to 1500)
Non-clinical n = 10	7.3 ± 9.2 (0 to 21)	1.3 ± 1.6 (0 to 4)	106 ± 262 (0 to 750)	17 ± 26 (0 to 50)
Total n = 87	13.0 ± 9.7 (0 to 40)	3.4 ± 1.5 (0 to 8)	517 ± 633 (0 to 3000)	127 ± 218 (0 to 1500)

Table 2 Creation of hybrid systems during 9,935 revisions.

	N of hybrid systems	% of revisions	% of hybrid systems
Take advantage of new feature from a different manufacturer	1,528	15.4	56
Component unavailable	642	6.4	23
Other reason	571	5.7	21
Total	2,741	27.6	100
Use of adapters provided by manufacturers	1,246	12.5	45

treatment are difficult to quantify and require ongoing study (21, 22). The standards are limited to the interface between electrodes and generator; establishing the most appropriate system configuration for a given patient is beyond their scope and remains the responsibility of the implanting physician. This is true for cardiac as well as neuromodulation devices.

The Case for Neuromodulation Connector Standards

Existing regulatory practice in neuromodulation involves FDA approval of each manufacturer's entire product portfolio before market release. Once a portfolio is approved for a new line of products, however, two implicit assumptions are clinically problematic: that replacement components will always be available for the patient and/or that future upgrades of the device will ensure continuity of optimal therapy, even in the face of competitive developments. Many neuromodulation devices implanted in patients, however, are no longer supported or manufactured (i.e., they are "orphan" devices and product lines). Prominent examples are:

Functional Electrical Stimulation

A device called "Freehand," formerly manufactured by NeuroControl, allowed quadriplegic patients to regain basic use of arm and hand function through functional electrical stimulation with implanted muscle-based electrodes. The device went through clinical trials and received FDA approval in 1987. More than 250 patients underwent the surgical procedure to receive the electrodes and generators and gained clinical benefit where none was previously possible. Despite having Centers for Medicare and Medicaid Services and third-party-payer payments in place for not only the components but also the rehabilitation and therapy billing codes necessary to ensure the long-term success of the implant, the company closed several years later (2001) and stopped manufacturing all components of the device. As the IPG batteries eventually expired, patients returned to their previous state of upper extremity dysfunction due to spinal-cord injury. A number of these patients consequently underwent surgery to remove the components. This unfortunate outcome for both patients and the industry might have been avoided had interchangeable electrodes and pulse generators existed (23).

Cerebral Cortical Stimulation

A system for cerebral cortical stimulation developed by Northstar for the treatment of stroke, depression, and tinnitus underwent clinical trials with encouraging initial results; however, a pivotal FDA trial in stroke was disappointing (24, 25). The company went on to declare bankruptcy, and the devices that remained in patients, some of whom continued to benefit, were explanted, as replacements could no longer be provided.

Spinal Cord Stimulation

An SCS system with both paddle and percutaneous electrodes, developed by Nuvectra, had been implanted in more than 5000 patients, with unique 12-contact connectors in most cases, by the time the company declared bankruptcy in 2019. As of this writing, a substantial portion of Nuvectra's assets have been acquired by a medical device contract manufacturer, Cirtec Medical Corporation, which is exploring the possibility of making compatible components and parts available to original equipment manufacturers going forward. Unsupported "orphan" systems and components are a problem not only for patients immediately affected but also for the field of neuromodulation—practitioners and manufacturers alike. This problem goes beyond instances of company failure, as above: when a new product line is introduced, unless its components are compatible with older product lines, patients with the latter can find their system orphaned until and unless the manufacturer (or a competitor) develops an adapter. In general, in the absence of adapters and/or connector standards, patients are effectively captive, unable to avail themselves of new technology.

Additional Advantages

Another advantage of interchangeable components would be reduced time for improvements to be available to patients. For example, rechargeable technology introduced 15 years ago offered major cost savings and reduced morbidity to patients needing frequent replacement of depleted primary cells. This advantage was not made available to all patients, however, until all manufacturers had introduced rechargeable IPGs compatible with all of their electrodes. In at least one case, a manufacturer offered no compatible IPG pocket connector for a large population of its patients until several years after introducing its own rechargeable IPG, leading to continued replacements with primary cell IPGs in this captive population. Standardization of connectors would have facilitated substitution of rechargeable IPGs from other manufacturers, allowing patients to benefit from this important technical advance promptly.

Manufacturers of implantable cardiac pacemakers and defibrillators use electrode ("lead") and generator components that are similar to neuromodulation devices; in fact, many manufacture both. Due to the existence of ISO/AAMI standards for cardiac lead interchangeability (11), patients with implanted components manufactured by one company can be "rescued" should the manufacturer discontinue the product line or no longer remain in business. Furthermore, cardiac patients benefit from an industry whose manufacturers might in some cases specialize in lead design and in others in generator design. Clinicians and healthcare facilities might not need to stock several manufacturing product systems but rather can choose a given manufacturer whose components fit with others. This is useful not only when manufacturers discontinue products or cease operations but also when patients move from one region to another where a component needed for repair or replacement is not available. Cardiac lead replacement is expensive and potentially morbid, and unnecessary replacement creates a risk of failure to reproduce a satisfactory result. Interchangeable components can eliminate the need for lead replacement and benefit both the patient and the healthcare economy.

In general, the advantages of component interchangeability among manufacturers can be seen in the explosion of computer and electronic technology that consumers benefit from on a daily basis. Multiple layers of industry growth have enabled the interchangeability of components used in computers and electronic systems to yield quicker product development, greater product variety, and lower costs. Rather than impose proprietary control over a complete set or system of components, most large manufacturers choose existing and compatible component formats that offer more features, options, upgradability, and lower manufacturing costs once the standard is defined.

A good example is the Universal Serial Bus (USB) connector used by peripheral devices to interface with computers. With Intel Corporation as its initial champion, a USB Implementers Forum (USB-IF) was established in partnership with other companies to

create the initial USB standard in 1996 (26). The result was the immediate and spectacular growth of USB-connected consumer components produced by manufacturers that did not make computers (27). Before the USB standard, a typical connection might use a serial-port connector, a parallel-port connector, an RCA jack, a mini-phone plug, or other custom or hybrid connector that interfaced with a limited number of peripheral devices. The growth in number and diversity of peripheral devices and resources controlled by computers was therefore limited. After the adoption of the USB standard by industry, the increase in both peripheral devices and computers benefited industry, consumers, and the economy. Foreseeably, a connector standard for the neuromodulation market will also produce positive results in terms of technology advancement, sustainability of effective therapies, and safety for patients.

Why do neuromodulation systems lack standards for component interchangeability despite the obvious need? Several reasons likely explain the inertia of adoption:

1. To date, standardization has not been advocated by influential clinician or patient organizations.
2. Neuromodulation devices are rapidly evolving in terms of complexity of channels and features.
3. The field has only recently expanded to include a large number of manufacturers and multiple new stimulation targets and applications.

Challenges and Trade-Offs

Although a standard connector will enable a physical connection between components from different manufacturers, this alone will not guarantee that the system will be safe or that it will operate as intended. Pulse generators, electrodes, and programming software are generally designed together, to work safely as a system and provide optimal therapy. Off-label mixing of components by an uninformed user might introduce safety hazards or reduce performance. As has been the case for cardiac devices, development of a standard will require assessment of associated testing and labeling requirements for the following:

- Excessive charge density might occur when mixing components from different manufacturers. To guarantee that an electrode can function safely with a pulse generator, the generator output must be adjusted based on waveform and surface area of electrode contacts, so that charge density is limited to a safe level.
- Magnetic resonance imaging (MRI) compatibility is another significant issue for standards that allow the interconnection of implanted devices from different manufacturers. The FDA will designate the MRI safety of implant systems as "conditional" only for specific combinations of electrodes, extension cables (if any), and pulse generators and not for the electrode or generator individually. Manufacturers might or might not include their older components when they apply for this designation. Adapters potentially can mitigate the above challenges if they are tested for safety and approved by regulators for specific combinations of components from different manufacturers. The numbers of patients in need of specific combinations might be insufficient, however, to justify the associated costs of such testing. Were connectors standardized, however, there would be no need for an intervening adapter, and the cost would be limited to testing combinations.

The cost to design a neurostimulation system is in the tens of millions of US dollars for each manufacturer. Redesigning a connector so that an existing system or component would meet a new standard would add to that cost, competing for funds that might better be used to advance neuromodulation therapies, develop new products, or perform clinical research. Once a standard is established, however, incorporating the design into a new product line might reduce costs. We intend that a new standard would be voluntary, in any event, and that rather than pose a burdensome obligation, it would provide an opportunity not only to build to the standard to facilitate interconnection but also to build away from it, should a manufacturer wish to discourage the practice.

Finally, a standard connector might limit innovation by locking in a standard to today's state of the art. Smaller implants, increased electrode count, and improved sensing capabilities might render a connector standard obsolete. Indeed, the history of medical devices and device standards indicates that this is inevitable, and the useful life of any standard is finite.

Study Limitations

Our survey was sent to the entire NANS mailing list, which includes not only NANS members but also members of the international neuromodulation community. It was returned by fewer than 1%; thus, the results cannot be assumed to represent this sample as a whole. Had we limited the mailing to NANS members, of whom there were 1552 at the time (16% of the multispecialty, international mailing list), the yield might have been higher as a percentage; however, it might also have been lower in absolute terms and perhaps unacceptably small. We believe that our results represent the subset most interested and involved in SCS implantation and revision.

Notwithstanding its sampling limitations, our survey has filled a gap in the literature; the underlying issues of connector incompatibility have not been described previously. We have learned that at a minimum thousands of hybrid SCS systems have been implanted over the years, most of them (at least in our sample) without the benefit of adapters. Although we cannot infer the full magnitude of the issue, because of statistical limitations, we conclude that this is an additional reason (above and beyond the opinions expressed in the survey) to pursue development of standards.

We recognize the limited scalability of existing connector designs to future implants with more channels, but these have been in routine and ever growing use since the 1980s and predominate in current clinical practice.

Next Steps

Having demonstrated the need for connector standards, as defined by user opinions and experiences, we look forward to continued collaboration to address technical issues, which include function as well as form. Standards include not only dimensions (e.g., diameter and spacing of contacts and seals) and materials but also mechanical (e.g., insertion force) and electrical (e.g., current density, MRI compatibility) performance measures. These are beyond the scope of the present report.

CONCLUSIONS

Neuromodulation compares favorably with many other procedures in that it is reversible and minimally invasive; it should also be sustainable. Clinical data and the opinions of our survey respondents support the development of standards for connectors that enable interchangeability between implanted electrodes and pulse generators, mitigating the need for adapters to facilitate interchanging components when appropriate.

This strategy has been successful in cardiac pacemakers and defibrillators and more broadly in the computer and consumer-electronics industry. The arguments against development of such standards, even assuming that compliance by manufacturers is voluntary, are offset by potential benefits to patients, to our field, and to society.

Authorship Statement

Drs. North, Judy, and Konrad identified the need for the study and contributed to its design. Dr. North supervised the data collection. All authors analyzed the data and the significance of the outcomes. Dr. North prepared the manuscript, with his co-authors providing important intellectual input and a thorough critical review.

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COMMENTS

Dr. North and colleagues have provided a thought provoking manuscript highlighting a solution to a relatively common problem in the field of neuromodulation. Device interchangeability, particularly with the ever-changing landscape of available manufacturers, is increasingly important. Physicians and patients alike should feel confident that a device implanted today will be compatible with offerings touting improved innovation and outcomes in the future. The authors have provided one possible solution to this clinical conundrum, and I applaud their efforts to improve the neuromodulation experience for all of us involved.

Jonathan Hagedorn, MD
Rochester, NY USA

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In this article, the authors make a compelling argument for the adoption of a connector standard for spinal cord stimulation. The authors come from a wide range of backgrounds including industry, clinical and academic settings to survey the neuromodulation

community about the necessity of creation and adoption of this standard. The results of the survey indicate that both clinicians and non-clinicians believe that a standard connector design should be developed for spinal cord stimulators, and that many clinicians have previously created hybrid systems by connecting components from one manufacturer to those of another. The development and adoption of this standard is critical to provide optimal clinical benefit for patients as new therapies and technologies emerge and to prevent orphan devices that are no longer supported or manufactured. Additionally, this publication comes at a critical juncture in time due to emerging interest in a range of different clinical applications across multiple neuromodulation technologies. As spinal cord stimulation makes up the majority of neuromodulation procedures, the neuromodulation field as a whole may adapt to standard connectors if they are developed and adopted by spinal cord stimulator manufacturers. Therefore, this message is vital and should be communicated swiftly to the neuromodulation community.

Jonathan Calvert, BS
Rochester, MN USA

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This is an extremely timely and important survey and sharing results are critical for the community of neuromodulators. The only flaw noted in this article is that a very small number of individuals actually responded to the survey. (<1% of the 9657 (87 people) responded.)

Nevertheless, in that group, the number of revisions, 42,572, and interchange of device components are reflected. Like suspected, this is reflective of taking advantage of new features or because the original device components were discontinued.

Cameron (1) described large complications related to device migration (13%) and lead breakage (9%) 15 years ago. Given the rapid evolution of the devices, it is interesting to note that these problems still exist and now there are additional reasons for revisions.

It is really surprising that we are, in sorts, parallel of the cardiac pacer market but have not adopted device interchangeability standards. Would be curious to hear what the authors believe are the reasons for the slow migration in neuromodulation. And be creating standardization, if revision rates would decrease, then is it not in everyone interest to get this done!

Ashwini Sharan, MD
Philadelphia, PA USA

(1) Cameron T. Safety and efficacy of spinal cord stimulation for the treatment of chronic pain: a 20-year literature review. *J Neurosurg*. 2004;100(3 Suppl Spine):254-267. doi:10.3171/spi.2004.100.3.0254

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The topic covered in the article is extremely interesting for physicians who use neurostimulation devices. The problems often encountered by physicians related to technological evolution or to devices no longer supported or manufactured are of paramount importance. The standardization of connectors would allow patients to benefit from the most suitable therapies. Physicians could guarantee hybrid implants much more than they can do today. Unfortunately, the only surprising drawback is the low number of participants who completed the survey. Congratulations to the authors who have addressed this critical topic of neurostimulation devices.

Gianni Colini-Baldeschi, MD
Rome, Italy

APPENDIX A1: QUESTIONNAIRE

COVER MESSAGE

Following the example of the cardiac pacemaker/defibrillator industry, IoN has convened a series of meetings to develop connector standards for implanted stimulation devices, to address common clinical issues. We are beginning with the 1 × 8 inline connector in common use with percutaneous (and paddle) spinal cord stimulation (SCS) electrodes. We ask that you make your needs and opinions known by completing the following questionnaire (estimated time 5-10 min)

For how many years have you been doing SCS implants?_____

Approximately how many systems have you implanted, revised or replaced?_____

How many different manufacturers' devices have been included in the above experience?_____

Approximately how many of the above cases were revisions or replacements?_____

How many of your revisions or replacements have involved interconnecting components made by one company with components made by another (e.g., lead by company A, pulse generator by company B), for each of the following reasons:

- component unavailable (out of stock, no longer made, etc.)_____
- new feature (e.g., rechargeability, new waveform) available from different manufacturer____
- other reason(s)_____Please elaborate__

In how many of the above revisions or replacements did you use an adapter made by one company to connect to components made by another?_____

In your opinion should standard connector designs be developed, for voluntary compliance by manufacturers, to mitigate the need for adapters and facilitate interchanging components when appropriate? (Y/N)_____

Do you feel that a standard connector design is needed for future neuromodulation therapies outside SCS? (Y/N)_____ (if yes, please elaborate_____)

Thank you! If you would like to share an illustrative or interesting case with us, please feel free to attach a file or contact us by E-mail.

