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COMMENTARY
Wheelchair Standards: It's All About Quality Assurance and Evidence-based Practice

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INTRODUCTION

This issue features an interesting case report on preventable burns in an individual with tetraplegia (1). This injury was secondary to wheelchair malfunction and a lack of backup to the equipment failure. This case underscores the need to ensure that safety features are addressed as technology is applied to rehabilitation and clinical care. As wheelchairs proliferate and become more sophisticated, it is crucial that safety standards for design and use also evolve. Standards need to be comprehensive (ie, they must provide a framework to guide research and development, promote safe and efficient design, and ensure the compilation of data that supports evidence-based practice and quality assurance. The requirements announced in 2005 by the Centers for Medicare and Medicaid Services (CMS) are an important step in the development of comprehensive standards.

EVOLUTION OF STANDARDS

The history of wheelchair standards in the United States dates back to 1979. The foundation for this work actually goes back to the 1960s—to the Veterans Administration (VA) Prosthetics Devices Evaluation Center in Castle Point, New York (2). When the Rehabilitation Engineering and Assistive Technology Society of North America (RESNA) was formed in 1980, RESNA became the body organizing the development and distribution of the U.S. wheelchair standards (3).The first set of RESNA standards was published in 1991, and a revised set in 1998 (4). Within a few years of the publication of the first RESNA standards, both the VA and the US Food and Drug Administration (FDA) recommended that wheelchair manufacturers use the standards when applying for reimbursement from the VA or when seeking approval of a notification to market (510[k] application) in the case of the FDA. Unfortunately, neither the VA nor FDA, or any other US-based agency made the standards a requirement. This has resulted in a virtual flea market for testing, as manufacturers and distributors pick and choose which tests to apply, create their own tests, or even choose to ignore the issue altogether. In the end, wheelchair users, their families, and their caregivers pay the price. Furthermore, insurance premiums may be adversely affected by the lack of compliance with testing.

The CMS have looked at wheelchairs, specifically electric-powered wheelchairs, with increasing scrutiny. In 2005, CMS announced requirements for testing of electric-powered wheelchairs as part of efforts to modernize coding (5–7). In this century, CMS, in what might be classified by some as an uncharacteristic move, has provided leadership in evidence-based classification of wheelchairs.

THE GLOBAL PERSPECTIVE

Globally, the International Standards Organization (ISO) manages the wheelchair standards. ISO and the RESNA standards committee work collaboratively. ISO and RESNA have often been driven by outside sources to expedite their work and to address needs of consumers and other organizations. In the 1990s, the European Community Medical Device Directive provided impetus to make a number of changes to ISO standards and to create new standards in response to stricter regulation. The European Committee for Standardization (CEN) went its own direction for a while and over time, CEN and ISO standards have begun to merge. American National Standards Institute (ANSI)/RESNA was a driving force for a long time and often had different standards than ISO. However, this has dwindled in the past decade. Concomitantly, the wheelchair industry has exploded over the past 10 years, and the standards have simply not kept pace. There is a clear and present need for change in standards development and support in the United States.

Most of the participants in wheelchair standards development are employed by the wheelchair industry, an inherent conflict. Unfortunately, wheelchair users and clinicians have traditionally not had the financial support to participate in sufficient numbers. Interestingly, the same companies that participate in the standards committees develop internal tests not represented by ISO or RESNA as part of their product development programs to protect them against legal liability. Test laboratories do the same thing, creating a number of tests that differ from or improve on ISO or RESNA

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standards. None of the existing standards (ISO, CEN, or RESNA) is comprehensive enough to cover all areas of wheelchair evaluation.

THE CMS CHALLENGE

The new requirements set forth by CMS seem well considered in terms of requirements. They are not test methods, and as the RESNA and ISO procedures allow, the institutions submitting the results will need to have supporting documentation as to how the results were obtained. CMS has set a challenging but appropriate bar—one that protects their beneficiaries (ie, people with disabilities), one that will actually differentiate products without undue burden, and one that has been discussed at ISO and RESNA for years. Perhaps, manufacturers, suppliers, test laboratories, and government agencies will rise to the challenge and build on the targets set by CMS. The ruling presented by CMS provides a tremendous opportunity to improve wheelchair standards worldwide.

The CMS performance and safety requirements seem to be based on real user need and reflect actual use, although more scientific data would be helpful. The requirements certainly support coding (product differentiation), which is one of the fundamental purposes for developing wheelchair standards. Everyone who has been involved in developing wheelchair standards has some culpability for the changes imposed by CMS, because ISO, CEN, and RESNA should have been revising and updating their standards (both test methods and requirements) in a timely fashion. More people should have been contributing data, and manufacturers, distributors, government agencies, and insurance agencies should have provided support to conduct the continuing research and development in support of wheelchair standards. Maybe they will in the future.

Someone needs to represent the consumers, their families, and their care givers. CMS has fired the first volley, but clinicians and consumers need to follow through. Data have been presented to ISO, CEN, and RESNA raising safety concerns and performance issues and showing noncompliance of manufactured products with the existing standards. Much of that evidence is in peer-reviewed scientific literature and more comes out each year (8–12).

We need to work to improve the standards and make sure that they serve their purpose of assuring quality, providing a foundation for evidence-based data; promoting optimal matching of user and wheelchair; and ensuring safe and productive long-term use. Inadequate planning and enforcement will lead to greater risk of preventable injury among wheelchair users.

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