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Medical Devices and Adolescents:

Points to Consider

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Use of medical devices in adolescents presents many challenges. The Center for Devices and Radiological Health of the US Food and Drug Administration (FDA) defines the pediatric population as birth through age 21 years, with the adolescent age group defined as ages 12 through 21 years.[1] Following the Food and Drug Administration Amendments Act of 2007, the FDA implemented a requirement that medical device manufacturers provide readily available information in certain premarket applications on pediatric patients who have the disease or condition that the device is intended to treat, diagnose, or cure, even if the device is intended for adult use.[2] It is imperative to ensure appropriate focus on adolescents. The adolescent population is not monolithic. It has unique subgroups spanning different age groups with various stages of development, and it includes gender-specific variations—all important factors for manufacturers, investigators, and clinicians to consider. In many cases adolescents are treated as young adults, and the fact that they are still part of the pediatric population is often lost. There are special issues that should be considered in any treatment plan for adolescents that involves medical devices.

Medical Device Study Considerations for Adolescents

There are many challenges with respect to engineering and design of devices that will be used in the adolescent population. There is no one approach for evaluating all devices. Some devices are relatively simple in terms of design and use, whereas other devices may present greater risks. Compared with drugs, evaluation of medical devices presents additional challenges owing to the wide range of technological applications.[1] Adolescents may often be included in adult studies as young adults, or they may be included with young children in some pediatric studies. In certain premarket studies, safety and effectiveness of medical devices used in adolescents have been extrapolated from adult data. Hwang et al[3] found that most of the recently approved pediatric devices have been approved on the basis of adult

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studies. There are unique issues that should be considered in device use for adolescents. For example, the onset of puberty and the hormonal effects on growth and development differ significantly from those of other stages of pediatric development. Depending on the device type and level of risk, the FDA may require a staged approach to safety and effectiveness in the pediatric population, enrolling adolescents first, before younger pediatric participants.[1] However, in addition to the general considerations for all clinical studies, medical device studies involving adolescents should consider potential differences in level of maturity, growth, and development across the entire adolescent age range.

Depending on the target population, device study protocols should reflect plans to recruit and enroll a sufficient number of participants to ensure uniform distribution across the adolescent age spectrum. Much will depend on the intended use[1] and whether a device is being used to diagnose, manage a temporary disease state, treat an injury, or correct a condition. Data may be gathered for not only age, puberty, and psychological development but also cognition, aptitude, and comprehension. Adolescents may interact directly with their devices and may or may not follow the instructions for use.

Adolescent-Specific Medical Device Issues

Growth is an important aspect of development during adolescence and varies by sex. Use of medical devices in adolescents must consider the dynamic changes related to the growth plate and stages of epiphyseal closure, since most adolescents do not achieve complete skeletal maturity until ages 18 to 20 years. In determining future growth, bone age is more important than chronological age. Treatment of adolescents with neurologic devices, such as the vagus nerve stimulator, should also take into consideration different rates of physical growth, which may affect implanted devices in terms of appropriate duration and physiological fit.[4] Therefore, it is important to consider the effects of somatic growth on device design and engineering—one size may not fit all.

Medical device treatment for adolescents must also consider the physical nature of their daily activities, sports participation and possible risks to health, and potential interference with device therapies. The most common musculoskeletal conditions in the adolescent age group relate to injuries from sports, overuse, trauma, or accidents resulting in fractures. The FDA reported that the most common medical device adverse events for emergency department visits among adolescents involved orthopedic fixation devices.[5] Clinicians who treat adolescents with medical devices should be especially vigilant to ensure that the various activities of patients do not compromise the safety and effectiveness of medical devices.

Weight is also an important factor. Unlike adults, adolescent growth and development are not static: growth velocity is more complex. Adolescents often grow 2 to 3 inches in height and 1.8 to 2.3 kg in weight per year. Adolescents may require special attention to ensure that medical devices are safe and effective, particularly those based on algorithms with varying weight limits. It is important that algorithms used to derive treatment for adolescents are robust enough to support safety and effectiveness across the entire adolescent age spectrum. This may affect medical devices that use weight-based computations or body mass indices to

identify the intended population or to determine the model or treatment mode for certain adolescent patients. For example, insulin pumps with adult-based algorithms may lead to hypoglycemia in adolescents.[6]

Behavior and compliance are crucial factors in ensuring success of medical devices, and appropriate design of devices for adolescents will help in this endeavor. Some adolescents may have little or no parental supervision or oversight; they may be in school most of the day, or away at college. To ensure development of medical devices with robust user interfaces and to capture adolescent-specific data, human factors[1] evaluation across the adolescent spectrum is recommended. This will capture unique patient characteristics for labeling and not assume that they will be the same for all adolescents. Device design and size may vary depending on the adolescent's age, cognition, aptitude, and behavioral factors.

An FDA review of pediatric medical device adverse events for US pediatric emergency department visits[5] found that almost one-third of the total pediatric medical device adverse events involved ophthalmic devices, and more than one-fifth of the cases primarily involved contact lenses. More than 40% of all reported cases were adolescents with corneal contusions, abrasions, conjunctivitis, and hemorrhage. Contributing patient factors were noncompliant behaviors, such as wearing soft contact lenses while sleeping and while in the shower.

Adolescents with congenital conditions or chronic disease may present special challenges. Adolescents with cardiac anomalies interface with a wide range of cardiovascular devices—many implanted during infancy or early childhood. The cardiovascular anatomy changes significantly from birth to adolescence. Therefore, a wide range of anatomical sizes will be encountered throughout adolescence, requiring different device sizes. For instance, cardiac valve diameters increase 3-fold from birth to adulthood. A semilunar or atrioventricular valve prosthesis implanted into a small child may become inadequate and hemodynamically obstructive as the child grows.[7] Owing to growth spurts throughout adolescence and the pace of technological advancement, many devices may need to be replaced or updated.

Conclusions

As demonstrated in the specific examples provided herein, the FDA faces special challenges when reviewing premarket submissions for devices used in adolescents. The adolescent age group vastly differs from other stages of pediatric development as well as from adults. While legislation permits extrapolation of adult data to support some pediatric indications,[2] it is important to consider potential differences in safety and effectiveness for adolescents.

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