

March 13, 2023

Admiral Rachel L. Levine, MD
Assistant Secretary for Health
U.S. Department of Health and Human Services

Dear Admiral Levine:

The Endocrine Society appreciates the opportunity to provide feedback to the Office of the Assistant Secretary for Health (OASH) as it develops a report on promising practices for advancing health equity for intersex individuals. Founded in 1916, the Endocrine Society is the world's oldest and largest organization of scientists devoted to hormone research and physicians who care for people with hormone-related conditions. Among our 18,000 members are experts in the research and care of intersex individuals, individuals with disorders of sex development (DSD), and transgender individuals, and we advocate to improve, expand, and protect access to care for these patient populations. The Endocrine Society applauds OASH for taking steps to ensure access to affirming, high-quality care for intersex people who live in America.

Below, we identify specific clinical, research, and policy gaps that we hope this report addresses as well as ongoing research, innovative clinical approaches, and policy actions of which OASH should be aware.

What do you see as the current clinical, research, or policy gaps that you are hoping this report addresses?

- Understanding of the educational needs for general practitioners and other health care professionals to enable broader access to evidence-based care for intersex individuals, including evaluating medical school curriculums and continuing medical education credits.
- Insurance coverage for preventive healthcare services for intersex patients.
- Use of telemedicine to increase patient access to specialized health centers or physicians who specialize in treating intersex individuals.
- Research to help determine optimal approaches for discussing DSD conditions with young patients and their parents.
- Understanding of the unique needs of elderly intersex individuals and guidance on hormone replacement across the lifespan.
- Inclusion of racial and ethnic minorities in studies on the impact of hormone replacement therapy and other medical interventions for intersex individuals with the aim of understanding and minimizing health disparities.
- Intersex individuals often experience other health issues. Longitudinal research on the impacts of the medical interventions for intersex individuals is needed, specifically on physiological and mental health, including skeletal health, neurocognitive function, and fertility.
- Because DSD can be described as orphan disorders, randomized trials are extremely challenging to address needs for DSD patients. Pragmatic, patient-centered trials are necessary to determine the effectiveness of multimodality treatment approaches that integrate pharmacological, psychological, and surgical modalities.
- Intersex and DSD variations are highly heterogeneous. Comprehensive studies are needed to inform the management of all intersex individuals. For example, for patients with partial



androgen insensitivity disorders, efficacy trials of treatment strategies using rational, mutation-specific, selection of androgens are also needed.

- Comparative effectiveness research is needed to inform clinical decisions on androgen therapy for specific groups of AR mutations, as well as those cases without a proven genetic cause.
- Studies on gender neutral trajectories and hormonal treatment options are needed.

What recent or ongoing research, innovative clinical approaches or policy actions do you think is important for us to know about as we begin this work?

- It is important to consider what is being done outside of the US to better understand the long-term health outcomes for intersex individuals. Some countries, such as Germany, legally recognize a neutral sex. It is generally assumed, both socially and within the pediatric endocrinology community, that a child cannot be brought up with a neutral sex; consequently, sex assignment must be done soon after birth. There is little scientific evidence supporting this assumption, since randomized controlled studies cannot be done. The outcomes of cases in these countries where parents elect to raise children without declaring a sex should be systematically studied.
- There are now 29 states with legislation or pending legislation that would ban care and/or penalize health professionals who provide gender-affirming care to minors. We are concerned about the unintended consequences that this legislation could have on the care of intersex individuals, particularly those who received medical intervention at a young age and go on to experience gender dysphoria as adolescents.

The Endocrine Society appreciates this opportunity to share our expertise in this field with OASH to inform its report on promising practices for advancing health equity for intersex individuals. We are encouraged by OASH's thoughtful approach and consideration of the unique needs of patients as it develops programs to improve intersex individuals' health. We look forward to the outcomes of OASH's report and other initiatives to support the research and care of intersex individuals.

Thank you for considering our comments. If we can be of further assistance, please contact Judith Gertzog, Manager, Health Policy and Advocacy at jgertzog@endocrine.org.

Sincerely,

Ursula Kaiser, MD
President
Endocrine Society