Research Report

The Early Care (0–3 Years) In Duchenne Muscular Dystrophy Meeting Report

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Abstract

Objective: This report summarizes the key discussions from the “Early Care (0–3 years) in Duchenne Muscular Dystrophy” meeting, which aimed to address the challenges and opportunities in the diagnosis and care of Duchenne muscular dystrophy (DMD) and female carriers within the 0–3-year age group.

Methods: The meeting brought together experts and healthcare providers who shared insights, discussed advancements in DMD care, and identified research needs. Presentations covered diagnostic challenges, approved therapies, clinical trials, identification of young female carriers, and the importance of clinical care and support for families.

Results: The meeting highlighted the importance of timely diagnosis and the lack of evidence-based guidelines for the care of children with DMD aged 0–3 years. Diagnostic challenges were discussed, including delays in receiving a DMD diagnosis and disparities based on ethnicity. The potential benefits and process of newborn screening were addressed.

Approved therapeutic interventions, such as corticosteroids and exon-skipping drugs, were explored, with studies indicating the potential benefits of early initiation of corticosteroid therapy and the safety of exon-skipping drugs in DMD. Clinical trials involving infants and young boys were discussed, focusing on drugs like ataluren, vamorolone, and gene therapies.

The meeting emphasized the importance of clinical care and support for families, including comprehensive information provision, early intervention services, and individualized support. The identification and care of young female carriers were also addressed.

Conclusion: The meeting provided a platform for experts and healthcare providers to discuss and identify key aspects of early care for children with DMD aged 0–3 years. The meeting emphasized the need for early diagnosis, evidence-based guidelines, and comprehensive care and support for affected children and their families. Further research, collaboration, and the development of consensus guidelines are needed to improve early diagnosis, treatment, and outcomes in this population.

Keywords: Duchenne muscular dystrophy, newborn screening, neurodevelopmental disorders, therapeutics, genetic counseling, genetic testing, neuromuscular diseases – diagnosis, genetic carrier screening, patient care management

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The “Early Care (0–3 years) in Duchenne Muscular Dystrophy” (DMD) meeting brought together experts and healthcare providers to address the importance of early diagnosis and the best ways to care for children with DMD and female carriers of DMD variants within the 0–3-year age group. Presenters and invited attendees are listed in Appendix 1. The meeting provided an opportunity for the attendees to share insights, discuss the latest advancements in DMD care and treatment, and identify opportunities for further research. This paper explores key aspects of early care for children with DMD aged 0–3 years, including diagnostic challenges, the use of approved therapies, clinical trials, identification of young female carriers, and the importance of clinical care and support for families.

Whether due to newborn screening (NBS), incidental findings or family history, a diagnosis of a dystrophinopathy in the first three years presents valuable opportunities for families and healthcare providers to improve their child’s health and well-being, although there is a need to provide evidence-based guidance [1]. Currently, there are no evidence-based guidelines for the care of children with DMD aged 0–3 years.

Dr. Mena Scavina presented on early care practices, emphasizing the importance of developing “anticipatory guidance” for diagnostic referrals to primary care providers and specialty clinics and of providing schedules for follow-up and specialist care for infants referred with DMD variants [2]. Dr. Scavina described the findings of a survey of physicians from the Certified Duchenne Care Center network likely to be responsible for follow-up of infants identified through NBS. The survey highlighted key recommendations such as early intervention services, carrier testing for the mother, genetic counseling, clinical trial discussions, screening of siblings, exonskipping therapies, discussion of corticosteroids, and assessment of social and language development [3]. Dr. Scavina also discussed an algorithm for screening, diagnosis, and follow-up care of female carriers based on the New York State NBS pilot study, which concluded that identification of carriers can benefit the family and the individual child [4].

In the absence of NBS, the diagnostic journey for families remains challenging, with long delays in receiving a DMD diagnosis. Dr. Emma Ciafalon shared insights on the diagnostic delay for children with DMD, despite the presence of motor and non-motor signs that should prompt an evaluation of creatine kinase (CK) and suspicion for muscle disease [5–7]. Data from the Muscular Dystrophy Surveillance, Tracking, and Research Network (MD STARnet) showed no change in the mean age of diagnosis over the last 15–20 years (at 4.9 years), highlighting a persistent delay in the US, and only slightly reduced delay in a UK cohort (from 4 years and 10 months to 4 years and 3 months) [8–10]. Disparities in the diagnostic process were also observed, with studies indicating that Black and Hispanic ethnicity predict older ages at evaluation, CK measurement, and DNA testing [11, 12]. In addition, in a later panel discussion, it was noted that children with other identified neurodevelopmental disabilities such as autism, intellectual disability or speech/language delays can also have diagnostic delays [13]. However, countries with routine CK screening in young children or a lower threshold to include a CK as part of any work up for common pediatric illnesses have shown earlier age at diagnosis [14].

Niki Armstrong provided an update on the process of adding DMD/BMD to the Recommended Uniform Screening Panel (RUSP), which remains under review. The addition of DMD to NBS programs in various locations will provide valuable guidance for implementation [4, 15–17].

THE USE OF APPROVED THERAPIES IN INFANTS AND TODDLERS WITH DMD

Dr. Anne Connolly presented encouraging findings on the use of corticosteroids in infants and young boys with DMD. First, she described a natural history study that utilized the Bayley Scales of Infant and Toddler Development, Third Edition (Bayley-III) [5]. This assessment tool, consisting of five domains encompassing cognition, motor skills, language, socio-emotional abilities, and adaptive behavior, has been used to evaluate boys with DMD aged one month to 3.5 years. The study revealed noteworthy differences in developmental scores between boys with DMD and typically developing boys. Specifically, boys with DMD exhibited lower mean scores in motor composites, including both gross motor scale scores (GMSS) and fine motor function-scaled scores. Moreover, they displayed lower mean scores in cognitive comprehensive, receptive language, and expressive language assessments.

Tracking the developmental progress of boys with DMD over a period of 6 and 12 months, the study found a trend towards a further decline in GMSS among boys with DMD (though this did not reach...
statistical significance), while cognitive and language scores remained relatively stable and fine motor scores exhibited slight improvement compared to typically developing peers [6].

Building upon the natural history control arm, a subsequent study explored the effects of corticosteroid administration (5 mg/kg twice weekly) in a group of 24 boys (with a mean age of 1.7 years) diagnosed with DMD [18]. Despite the lower initial Bayley-III scores in these children, the treatment showed that over the course of one year, the treated group exhibited an improvement of 0.5 points on the gross motor scale, contrasting with a decline of 1.3 points observed in the control group (p = 0.03). These results indicate that early initiation of corticosteroid therapy may potentially contribute to the preservation of motor function in infants and young boys with DMD. Furthermore, the study reported no serious adverse events, although weight gain of more than 10%ile points was observed in 54% of boys.

In light of emerging data in animal models suggesting that once-weekly dosing of corticosteroids may have similar benefits with fewer long-term risks, [19]. Dr. Connolly is conducting another study evaluating whether a lower total dose (5 mg/kg) given once weekly is as effective in improving gross motor function in infants and young children.

Erin O’Rourke presented preliminary data on the use of eteplirsen, an exon-skipping drug, [20, 21] in boys aged 6–48 months with DMD amenable to exon-51 skipping [22]. The trial found that the drug was safe and well-tolerated in young boys with DMD, with no serious adverse events observed, although there were non-serious infusion-related reactions. There were no functional outcome measures in this study. Another study, EVOLVE, is evaluating the use of three approved exon-skipping drugs in routine clinical practice. With a total cohort of 144 patients at the time of the meeting, the study had enrolled 30 participants between the ages of 1 and 7 years.

Dr. Eric Camino presented data from PPMID’s Duchenne Registry comparing the outcomes of individuals diagnosed with DMD before one year of age versus those diagnosed at the average age (4-5 years) [23]. The registry data showed that earlier diagnosis was associated with earlier initiation of corticosteroid therapy and therapy services, as well as improved lower limb function scores on the Pediatric Outcomes Data Collection Instrument (PODCI).

During the session, a live poll among clinicians in the audience revealed diverse opinions on when to start corticosteroid therapy and dosing patterns. Of the respondents, 23% would initiate treatment within the first year of life if the child displayed symptoms, while 46% favored treatment initiation between 1 and 2 years of age. A further 23% suggested treatment between 2 and 4 years of age, with a small number opting to wait until the age of 4 years. Even if a child was not symptomatic, more than half would treat before 2 years of age, most of the remainder within the next 1-2 years, while 16% said they would wait for symptoms.

The vast majority (81%) of clinicians polled would start exon-skipping therapy in a symptomatic child diagnosed with a pathogenic variant amenable to such therapy in the first year of life. The proportion was not as high if the child was asymptomatic, but most indicated they would start as soon as symptoms appeared—and before the usual age of diagnosis.

During the discussion, participants discussed other issues to consider when treating infants and young boys with DMD, including how best to administer intravenous drugs in infants and the need for research to guide practice. Several specialists stressed the urgent need to leverage these emerging treatment modalities as soon as they become available to alter the disease trajectory and provide improved outcomes for affected children. Clinicians also discussed how to define symptoms in this young age group, with suggestions including hypotonia and developmental delays.

CLINICAL TRIALS AND OUTCOME MEASURES IN INFANTS AND YOUNG BOYS

Another session centered on clinical trials involving infants and boys under 4 years old. Ataluren, an approved drug in the European Union for children with BMD or DMD due to a nonsense mutation, is currently undergoing a 24-week safety and pharmacokinetic (PK) trial in children aged 6 months to less than 2 years old [24]. The trial aims to assess whether treatment leads to changes in CK levels from baseline. Additionally, vamorolone, a disassociative corticosteroid recently approved by the FDA, [25–28] is being investigated in a randomized controlled trial with steroid-naïve boys aged 2–4 years. The primary outcomes of this trial are PK and safety, with the Bayley-III serving as a secondary efficacy measure.
Dr. Megan Waldrop shared insights from a groundbreaking first-in-human clinical trial of a gene therapy (GT) product targeting individuals with DMD caused by a duplication of exon 2 [29]. The trial enrolled three participants aged 7 months, 9 years, and 14 years, with no serious adverse events reported. Notably, the study observed an age-dependent improvement in functional outcomes and increase in dystrophin expression post-treatment, with the infant participant displaying the most robust expression. Additionally, the infant has achieved all developmental milestones on time.

Dr. Craig McDonald discussed GT approaches and emphasized the potential of timely treatment in preventing irreversible loss of muscle fibers at a young age. Dr. McDonald presented ongoing GT trials focused on infants and young boys, including one in boys aged ≥2 and ≤3 years of age, and another in boys aged 2-3 years [30–32]. As safety data accrues, these studies are expected to expand to include younger boys. Finally, he highlighted outcome measures such as the Bayley-4, NSAA, developmental quotients, and functional tests like rising from the floor, which can be utilized to assess improvements in functional abilities within this age group [33, 34].

CLINICAL CARE OF THE FAMILY UNIT

The importance of care and support for families was highlighted. The panel acknowledged the emotional difficulties faced by parents upon receiving a devastating diagnosis for their infant and emphasized the need for clinical care to address both the medical and emotional needs of the family. Dr. Scavina shared a case from her practice, illustrating the immediate attention and support provided to a 3-month-old infant diagnosed with DMD. The family received comprehensive information and links to resources, along with encouragement to seek ongoing support from the care team.

Dr. Anne Wheeler introduced the model used by Early Check (see https://earlycheck.org), a research project in North Carolina, which offers additional screening for various conditions to all birthing parents. The follow-up program for families with a positive diagnosis focuses on providing four pillars of care: information, support, surveillance, and intervention. The program addresses specific areas of child development, such as feeding, sleeping, motor skills, and social-emotional development. The panelists acknowledged the importance of tailoring support to the unique needs of each child and their family.

The discussion moderator, Dr. Russ Butterfield emphasized the need for sensitive communication with families due to varied reactions to the diagnosis. He noted some families being in denial about their child’s diagnosis or the urgency of treatment, while other families are devastated and want to understand the diagnosis. However, this too can pose a dilemma if families turn to the internet where they could find difficult to understand or out-of-date information. There was consensus around the need for curated materials online to respond to families’ “first needs” after an infant’s diagnosis—to which patient advocacy groups such as PPMD are responding. Long-term support for families, resources for newborn diagnosis and intervention programs are also needed. The panelists also discussed the potential role of insurance coverage for more intense support and therapy programs similar to those offered by Early Check and the significance of providing families with hope and support.

NAVIGATING THERAPY AND EARLY INTERVENTIONS

The next panel discussion focused on physical, occupational and speech/language therapy for the young child with DMD. This included a discussion of the neurocognitive aspects of DMD, including autism spectrum and learning disorders. Individualized support and referrals to early intervention for speech, language, social communication, sensory processing difficulties, and motor delays were deemed essential in reducing disruptive behavior, facilitating participation in preschool classrooms, and supporting developmental transitions. The importance of a case manager to assist families in managing appointments and providing parenting support without overwhelming them was emphasized.

Additionally, the panelists underscored the importance of educating families about developmental stimulation and therapy at home and making environmental modifications to accommodate the needs of children with DMD. Building a community among early intervention therapists and empowering them to advocate for the child was also highlighted as valuable. Variability in access to and quality of therapy services was discussed as a potential barrier.
NEWBORN SCREENING AND IDENTIFICATION OF YOUNG FEMALE CARRIERS

Dr. Scavina provided insights into the identification of female carriers of DMD, highlighting the variability of symptoms and signs attributed to specific DMD variants, X-inactivation, tissue-specific expression, and other factors. Expanded carrier screening in the US has identified carriers at a prevalence of one in 813 girls and women [35]. Recent studies have demonstrated that carriers may develop weakness, myalgias, cramps, exercise intolerance, and reduced strength, with approximately 81% of adult carriers exhibiting reduced strength [36]. Cardiac involvement was observed in two-thirds of carriers, characterized by fibrosis, abnormal electrocardiogram, and changes in Holter and echocardiogram results [37].

Dr. Richard Parad, a neonatologist and genomics expert, presented a pilot study on DMD NBS at Brigham and Women’s Hospital, Boston. Their team developed a hospital-based CK-MM/next generation sequencing (NGS) screening algorithm which offered parents a free supplement to their newborns’ mandated state NBS. Eighty percent of parents consented to immediate (without repeat consenting) reflex to DMD NGS for elevated CK-MM levels. Initial follow-up for screen positive newborns of concern includes referral to a pediatric neuromuscular clinic associated with the hospital. A joint workgroup of supplemental DMD NBS program and neuromuscular clinic members developed a follow-up/surveillance program tailored to medical evaluation, counselling and monitoring of asymptomatic newborns with either repeat persistent CK elevation/normal DMD sequence or a DMD variant with or without persistent CK elevation.

As of the time of presentation, the hospital had screened 8,700 newborns, 224 of whom had CK-MM levels above the high-risk cutoff. Seven newborns were DMD variant-positive, 1 male and 6 females (incidence 1/713 female births). Two variants of uncertain significance (VUS) and four pathogenic or likely pathogenic variants were detected in females. The male infant had a VUS. Obtaining repeat CK levels to confirm return to normal presented challenges, with less than half willing to return for repeat CK testing, although nearly all who did had normalized levels.

Dr. Stanley Nelson addressed the genetics involved in identifying manifesting carriers and discussed the utility of CK screening. He emphasized that while X-inactivation plays a significant role in most manifesting carriers, routine blood X-inactivation tests are limited in diagnosing manifesting females due to weak predictability of X-inactivation skewing in muscle, which can also vary with age. CK screening, although it can identify carriers, has only modest predictive value for manifesting carriers. In addition, Nelson said that women and families of girls inadvertently identified as manifesting carriers should be warned that high alanine transaminase (ALT) and aspartate transaminase (AST) may be mistaken for a liver damage or liver pathology by clinicians when measured in isolation without also measuring CK. Manifesting carriers should have a gamma-glutamyl transferase test to avoid having an unnecessary liver work-up. Nelson also highlighted the significance of muscle biopsy for direct observation of dystrophin in diagnosing manifesting carriers and recommended comprehensive family workup at the time of diagnosis to ensure information is not lost within families.

During the subsequent discussion, participants explored the objectives of NBS in girls, focusing on the benefits of newborn diagnosis and improved care. They debated whether NBS should prioritize identifying carriers or diagnosing infant girls at high risk of clinical complications. The Boston study, originally not designed to detect carriers, unexpectedly identified a high number of carriers due to the use of a low CK cut-off followed by DMD genetic testing. However, excluding girls from testing would have been logistically challenging and raised ethical implications, as screening had the potential to identify symptomatic girls and even detect limb girdle muscular dystrophy.

Attendees raised various concerns, including the consent process, the importance of thorough follow-up and genetic testing in mothers, and the need for comprehensive medical evaluations and specialist referrals. The discussion also addressed the fluctuating nature of CK levels, which may limit its utility in monitoring carriers over time. Additionally, participants emphasized the broad definition of “symptomatic,” considering cognitive manifestations and learning difficulties in female carriers, reinforcing the importance of comprehensive evaluation and support.

FUTURE STUDIES AND NEXT STEPS

During the final session of the meeting, Dr. Jackie Glascock delivered a presentation focused on data
collection models developed for NBS and early care programs for spinal muscular atrophy (SMA). She emphasized the importance of collecting real-world data due to the diverse range of symptoms, onset, and progression of disease, and outlined key factors to consider when implementing NBS for a disease at the state level.

Following this, Armstrong summarized the important points of consensus that emerged throughout the day regarding care for children aged 0–3 with DMD. These points included:

- Most clinicians who responded to the live poll would begin corticosteroid treatment of boys with DMD before the typical age of diagnosis, symptomatic or not, and would primarily use twice-weekly dosing—though the numbers responding were small and may not have been representative.
- Access to early intervention services with programming targeted to this age group is critical.
- The Bayley Development Scales were recognized as useful tools for clinical evaluation and outcome measures in young boys with DMD.
- Long-term support for families, including repeated genetic counseling visits, is necessary.
- Empowering families and involving them as partners in medical decision-making is essential.

The meeting also raised many questions regarding care for DMD in 0–3-year-olds, including the appropriate timing for initiating steroids and exon skipping therapies, how to manage administration logistics such as ports for small children, and how to get insurance coverage for early intervention programs. Other questions included which outcome measures to use to show benefit in the short term and how best to support families through diagnosis and decision-making. The slow disease process of DMD makes demonstrating the benefits of treatment and therapy challenging within the space of a clinical trial. While more data is needed from studies to support the case for NBS, more NBS is needed to enroll those studies.

The meeting concluded with a rapid-fire discussion of next steps, resulting in a to-do list for the community:

COMMUNITY TO-DO LIST

- Gather case reports and neurodevelopmental data on early treated and untreated infants
- Reach consensus on core outcome measures
- Develop newborn-specific patient-facing materials
- Optimize conversations and counseling for newly diagnosed families
- Improve access to care for all populations
- Educate primary care providers on early care
- Streamline assessments for children to reduce burden
- Instill a sense of urgency regarding the irreversible loss of muscle fibers in early childhood
- Develop follow-up care programs for girls identified through NBS
- Conduct a Delphi analysis on care consensus guidelines for infants and children aged 0–3 years (this was identified as a key next step)

The meeting closed with a quote from a mother who expressed gratitude for her son’s early diagnosis, which spared the family from a lengthy diagnostic process and allowed for prompt treatment initiation.

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REFERENCES


## APPENDIX 1

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