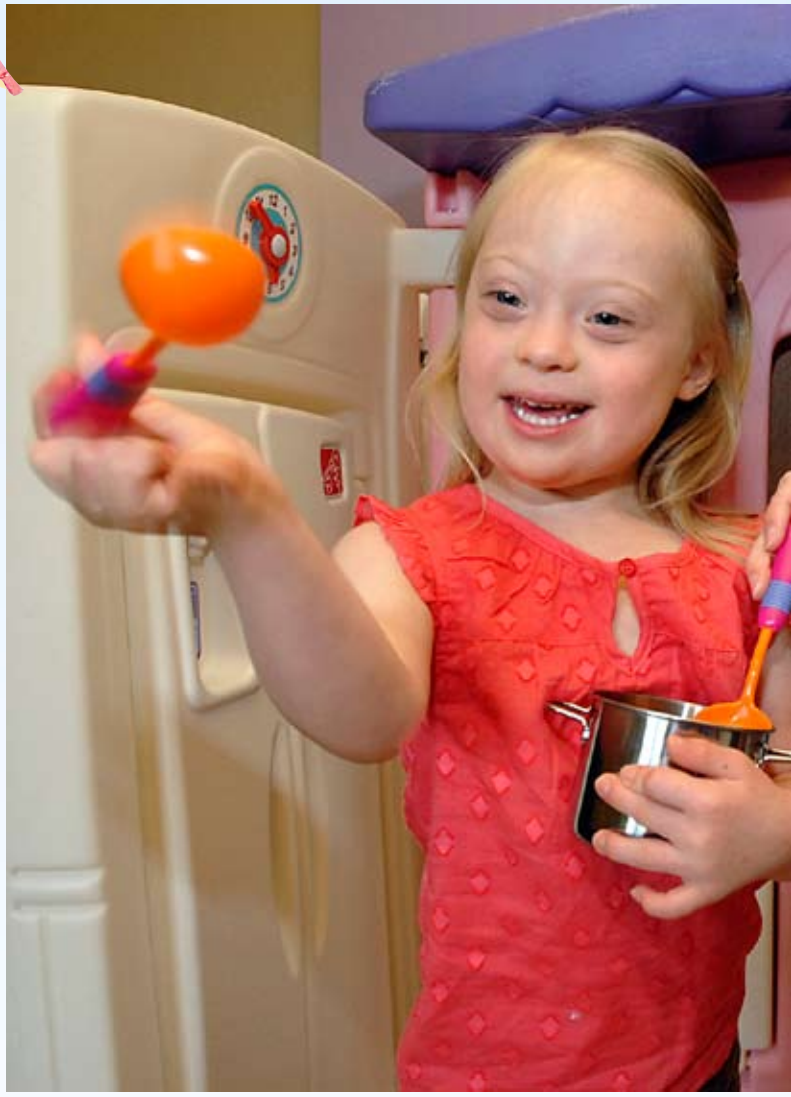
Partnering with Families of Children

Julie A. Ray, Julia Pewitt-Kinder, and Suzanne George



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"There's no good way to tell you. Your baby has Down syndrome," said the pediatrician. My world instantly stopped, and I felt a black fog closing in. I couldn't move or breathe or speak. The only sound I heard was my husband sobbing. My first thoughts were "No, I can't do this. How do we go from expecting a perfectly healthy baby to receiving a stranger?" Finding out that our daughter Ella had Down syndrome was like being told that the baby we dreamed of had died and now we had a child we knew absolutely nothing about.

—Baby Ella's Mother (One of the Authors)

FAMILIES MAY LEARN THEIR CHILD HAS A DISABILITY during pregnancy, at birth (as baby Ella's parents did), or even later, when their child enters a child care program in a home or classroom setting. Although a family's reaction to the news that their child has a special need may depend upon the child's age, the severity of the disability, and the family's cultural view of disabilities (Muscott 2002), researchers liken the experience to the grieving process that Kubler-Ross (1969) describes in her classic book, *On Death and Dying*. Reactions move from denial of the disability to anger at the diagnosis, to bargaining with the experts involved in the diagnosis, depression, and to acceptance of the disability. Acceptance of the diagnosis can take years, as frequent reminders of the disability cause families to reexperience the grief. For example, one parent said, "Grief may hit you when you least expect it—during a Christmas shopping trip . . . when you buy baby toys for a 9-year-old" (Naseef 2001, 207).

Stages of adjustment

Some parents criticize this "grief" view of adjustment to a disability as being patronizing and not fitting their experiences. Ulrich and Bauer (2003) propose instead that the adjustment experience occurs in four levels as parents gradually become aware of the impact of their child's disability. These levels include the following:

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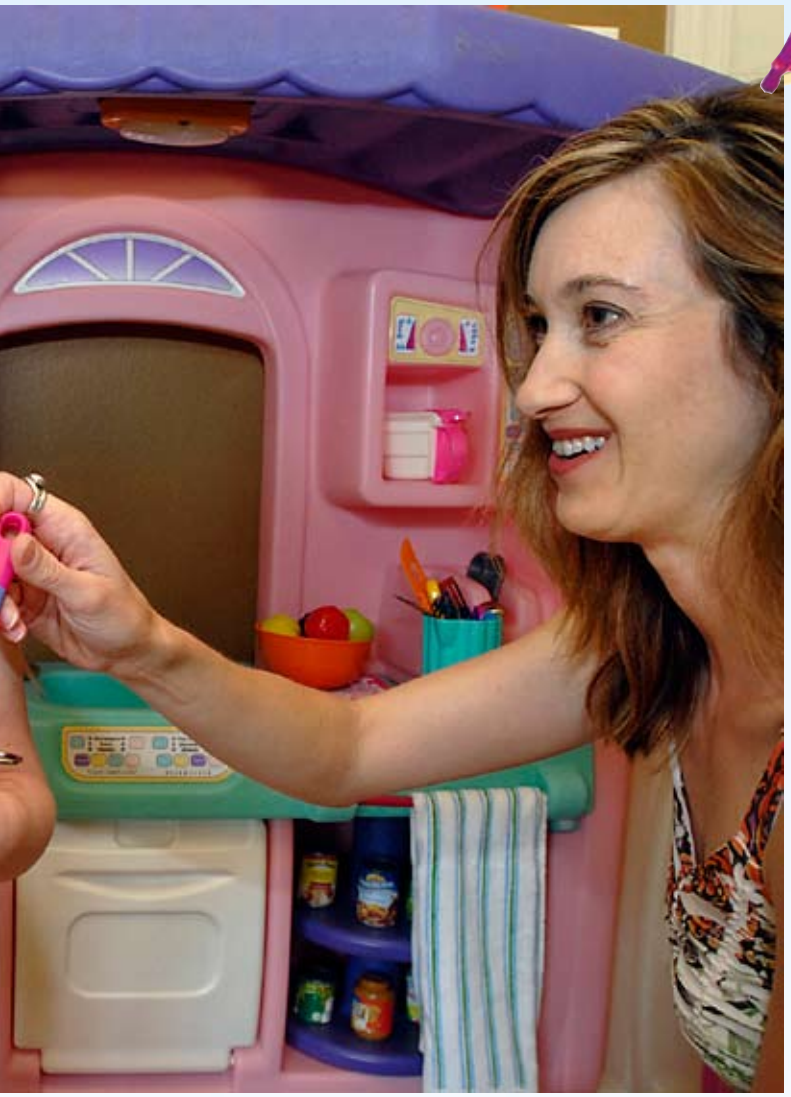

1. **The ostrich phase.** Parents do not deny a disability but do not fully realize its impact. For example, a parent may say, "He's all boy. He just doesn't like to sit still and read a book."

2. **Special designation.** Parents begin to realize that their child has a special need and seek help or ask for special services.

3. **Normalization.** Parents try to make the differences between their child and children without disabilities less apparent and may actually request a decrease in services and more regular classroom time.

4. **Self-actualization.** Parents do not view being different as better or worse, just different. They support their child in learning about his or her disability, including how to be a self-advocate.

As an educator, you may find that it is not as important to classify families by stages of adjustment to the child's disability as it is to understand that families have varied reactions and may work through their feelings in a different way and pace. It is helpful to realize that you and the family may not be operating at the same level or stage of understanding about the child rather than to make comments like "That family is so demanding" or "If the dad would get over his anger, we would be able to work together better" (Ulrich & Bauer 2003, 20). Listening to families is key in working with them as partners in supporting the learning and development of their child with special needs. Unless you have a child with a disability, you cannot fully understand the experience.

As you get to know the child and family, it is also important to learn about and participate in the development of the child's Individualized Family Service Plan (IFSP) or Individualized Education Program (IEP).

IFSP and IEP services

Some early childhood teachers may feel overwhelmed and unprepared to have a child with special needs in their care. However, it is imperative that they learn about the special education process so they can support families in the myriad decisions they will face about their child's education. The Individuals with Disabilities Education Act (IDEA) of 2004 ensures early intervention, special education, and related services for more than 6.5 million infants, toddlers, children, and youths with special needs (U.S. Department of Education 2009). A child younger than age 3 can receive early intervention services in the home or child care setting through an Individualized Family Service Plan developed specifically for the child by a team that may include therapists, early intervention specialists, teachers, caregivers, and parents. For children with special needs age 3 or older, the local school system develops and administers an Individualized Education Program.

Both the IFSP and the IEP state the goals and objectives for the child's

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IFSP and IEP Key Differences

Individualized Family Service Plan (IFSP) *Birth through age 2*	Individualized Education Program (IEP) *Ages 3 through 21 years*
Focuses on the family and parents' role in supporting the child's learning and development	Focuses on the child
Outcomes focus not only on the child, but on the family	Outcomes focus on the child
Includes the concept of natural environments as places where learning occurs, such as at home, in child care, outdoors in parks, and so on (services may be provided in the home)	Focuses on school and classroom environments, with services provided in the school setting
Involves many agencies in providing services because of the child's age; the IFSP integrates the services	Assigns the local school district to manage the child's services
Names a service coordinator, who assists the family in carrying out the plan	Authorizes the local school district to coordinate the program
Involves an initial meeting with the family to offer information and resources and to define the various agencies' roles and financial responsibility	Involves a meeting with the family to develop long-term and short-term goals for the child, accommodations and modifications, services, and child placement
Typically includes a meeting with the family every six months	Typically includes a meeting once a year

Sources: Bruder 2000; PACER Center 2000; Concord Special Education Parent Advisory Committee 2001; United Cerebral Palsy 2009.

developmental and educational progress. This plan or program also specifies who delivers the services, such as speech or occupational therapists, how the child's progress is assessed, and if any special classroom placements are needed. The parents' agreement with all the plans in an IFSP or IEP is required.

Educators and families both benefit in understanding the key differences between an IFSP and an IEP (see "ISFP and IEP Key Differences"). Although there are some common themes between the IFSP and the IEP, the differences focus on two main areas. In an IFSP, the concept of providing services in natural environments, such as the home or child care setting, is an important component. In an IEP, the school setting is typically where services are provided. Another major difference is the focus in an IFSP on the needs of not only the child, but also the family.

IDEA legislation requires the coordination of services from various agencies to avoid fragmented delivery of these services. In the child's first three years, a service coordinator assumes this responsibility, which may include any help needed for the family to function more effectively, such as food, shelter, health care, and education. When the child turns 3 and leaves the early intervention program, the service coordinator's role concludes. From age 3 through age 21, the local school district acts as coordinator.

Families should be a part of the IFSP and IEP planning processes; educators can make sure this happens.

Teachers and caregivers are important partners with families in the implementation of an IFSP or IEP. Families should be a part of the IFSP and IEP planning processes; educators can make sure this happens. For example, Ella's parents and all of Ella's caregivers and specialists attended and shared information during IFSP and IEP meetings, which gave a view of her development from several different perspectives. Educators facilitate the day–to-day environment in which the child participates, so it is essential to communicate with the family and other service providers, such as physical or developmental therapists, to know about and understand their recommendations for appropriate activities and materials to use with the child. For example, Ella's occupational therapist showed her preschool teacher how to help Ella hold pouring utensils so she didn't soak herself at the classroom water table.

As an educator, helping to implement objectives and obtain outcomes for the child with special needs is a major role for you, as well as reporting child outcomes to the IFSP and IEP teams. Also, asking family members questions to learn what you can about their child's specific abilities and needs is appropriate and helpful throughout the process.

Transition from the IFSP to the IEP

At age 3, children leave their state's early intervention program and move into the public school system's early childhood special education program. This transition from the natural home or infant/toddler child care setting to the typically more institutional classroom environment can be difficult and overwhelming for families, who must now learn about the IEP process and education laws, attend lengthy meetings, get acquainted with new therapists and school staff, and subject their child to new testing and evaluations.

As Ella's parents, we experienced a range of new emotions in this transition from the IFSP to the IEP. We felt sad, tired, concerned, angry, and surprised—

"Overnight, our child went from a baby to a school girl!"

"The complexity of our schedule increased with meetings, paperwork, and travel to numerous therapy locations."

"Our daughter would be exposed to illnesses in the classroom setting that she was protected from when receiving services at home."

"Strangers were telling us what they thought was best for our daughter based on a test score and a single meeting."

"We did not know we would have to fight for our daughter's rights."

Supportive caregivers and teachers can ease the stress of the transition from an IFSP to an IEP. Explaining families' rights and the procedures in the special education process and encouraging families to learn about the process is one way to provide support. Preparing families for an IEP meeting, typically once a year, by informing them of who will be there, what each person's role is, and what will happen in the meeting is also helpful. Let families know that they can bring advocates with them to this meeting.

Emphasize beforehand to the families their importance in the IEP meeting, and suggest they prepare and bring a list of their goals for their child. If needed, help them identify their concerns, family strengths, and priorities for their child. Encourage families to raise questions at the meeting about things they don't understand to make sure they agree with the IEP before they sign it (North Bay Regional Center 2008; PACER Center n.d.).

Strategies for working with families of children with disabilities

Families of children with special needs often have ideas from their perspective as parents about other ways educators can show support. Some collected suggestions focus on understanding family life, learning about disabilities, communicating frequently, and working through challenges with families.

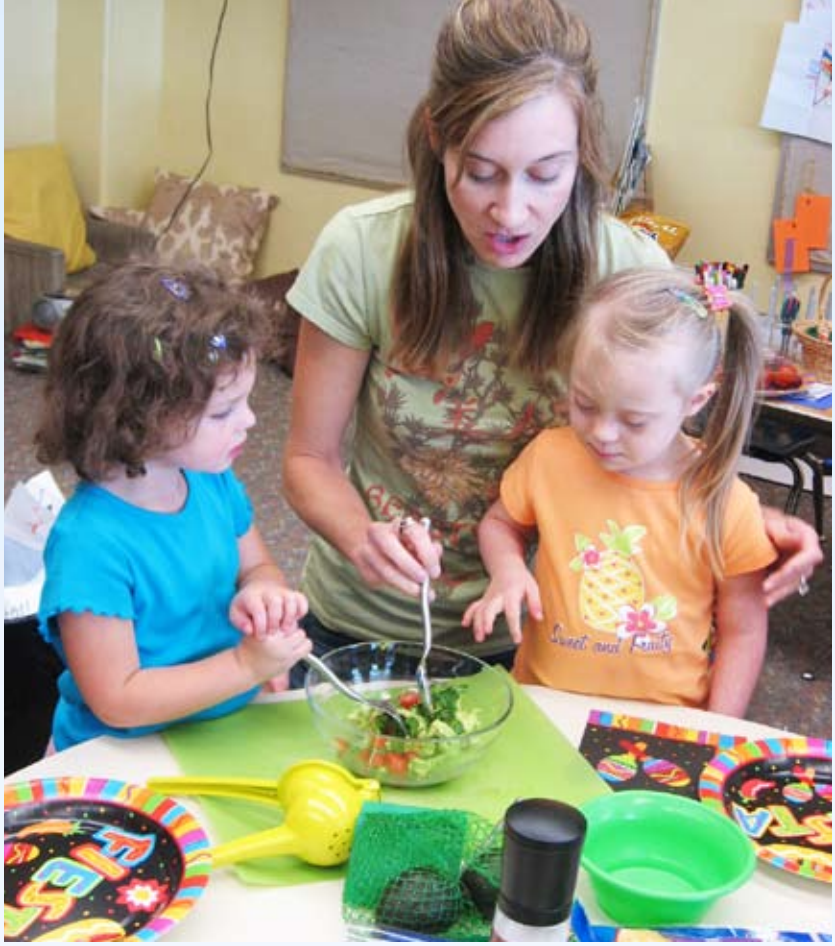
Understand family life

Appreciating and respecting the extra work it takes for families to care for and educate children with special needs is important. At the age of 3 months, Ella began a weekly schedule of six hours of physical, speech, developmental, music, and occupational therapies. She engaged in oral-motor exercises three times daily.

Courtesy of Julia Pewitt-Kinder

We taught all of Ella's caregivers how to feed, carry, and play with her. To accomplish the innumerable daily therapy goals, we kept lengthy, detailed checklists for separate caregivers. We asked caregivers to work on occupational therapy tasks such as having Ella pick up objects with clothespins and tongs or blow bubbles or suck drinks through thin straws to work on oral-motor (speech) therapy. All play activities were tailored to meet therapy objectives, as were the toys and books we purchased. Ella is now 5 years old, and our lives revolve around her therapies.

Our family's life is not unique in the strain that a child with special needs can place upon family time. Whether it is a therapy session, exercises, medical treatment done at home, or an unexpected hospital stay, there are extra demands for families of children with special needs. For working parents who cannot rearrange their daily schedule to fit therapies or doctors' appointments, difficult choices between their child's care and workplace requirements cause additional stress.



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Supportive teachers and caregivers help ease parents' stress, whether it is implementing daily therapies or offering a sympathetic listener's ear. Some parents may not be aware of all the services needed to meet their child's needs or be able to afford them. Thus, informing families about resources in the community and how to access them is an important teacher contribution. For example, because of a mother's limited literacy abilities, one early childhood teacher helped her fill out the paperwork necessary to get home medical equipment for her preschool child with severe disabilities.

Learn about the disability

As an educator, you may be familiar with a particular disability diagnosis, such as Down syndrome, but there is wide variation in its manifestations among children. Therefore, it is crucial to learn as much as you can about the individual child. The child's family may be the best resource for information, as well as the child's other teachers, caregivers, pediatricians, and therapists.

Borrow books and familiarize yourself with resources and free newsletters from national organizations. For example, the Council for Exceptional Children (CEC) Division of Early Childhood (DEC) offers several publications and professional development opportunities on the education and development of children with disabilities (www.dec-sped.org/About_DEC/Whats_New). Understanding a disability can help you better plan for the child's learning. Some of the families you work with may not have resources or knowledge about their child's disability, beyond their personal experience. Providing information that you've learned about the disability helps to support them.

Informing families about resources in the community and how to access them is an important teacher contribution.

Communicate frequently with families

As is true with families of all children, ongoing two-way communication between teachers and families is key in working successfully with families of children with disabilities. You can arrange a meeting with the child's parents prior to the child's start in your program or school. To get to know each other, find out as much as possible about the child and the family's goals for their child's learning and development, and tell parents how you design your program to meet individual children's needs. Provide a simple questionnaire for the family to specify important information about the child's likes, dislikes, personality traits, skills, special health needs or medications, and emergency contacts. As one father advised, "The first thing is to listen to us . . . because we know our kids better than anybody" (Blue-Banning et al. 2004, 175).

Continue to stay in regular contact through formal and informal conferences, phone calls, notes, and e-mails. Keep a record of all communication with family members, including dates and the content of the communication. Do not hesitate to ask the parents questions or request advice about learning or behavior issues that arise during the day and if they have experienced similar incidents at home. For example, after working cooperatively with a family, a kindergarten teacher determined that the reason their daughter refused to come inside at the end of recess was because the ringing bell on the school wall was painful to hear, due to her sensory integration disorder. After the class lined up in a different location away from the bell, the child willingly joined her class in line.

In your communications as an educator, include positive comments about the child's successes and express your respect for the parents' efforts in helping their child

develop as fully as possible. For non-English-speaking families, obtain translation services through your school, other family members, or the community. Use graphics or icons to convey information in your written communication (Al-Hassan & Gardner 2002).

By using accurate terminology, educators gain the family's trust. When you convey your knowledge, compassion, and respect, such as by saying "a child who is deaf" instead of "a deaf child," you place *the child as first and most important* over the secondary concern, the disability. Avoid categorizing children in negative ways. Describing Marcus as a child who "has blue eyes, likes music, and has autism" frames the wholeness of the child in contrast to categorizing him as "an autistic kid."

It is disrespectful and trivializing to shorten the name of a disability by saying "a Downs child," for example. Even "a child with Downs" sounds as absurd as "a child with Cerebral." Educators should avoid making such references as "normal child" or "normal development" in discussions with families as well in professional dialogue. Such uses imply that children with special needs are abnormal; the correct terminology is *a child with disabilities* or *a child with special needs* and *a child without disabilities*.

As an educator, you need to avoid making generalizations about children with disabilities. Saying that all children with Down syndrome "are developmentally delayed" or "mentally retarded" is not accurate. Due to individual differences, improved health care, early intervention, and new methods of teaching, children with Down syndrome can meet the same developmental guidelines as children without disabilities. Although Ella has special needs in fine and gross motor development, she does not have a cognitive disability and at age 5 is ahead of her peers in some developmental areas. It is important to learn about each child as an individual, beyond the label of "disability."

Children with disabilities may have a variety of teachers, from their daily child care provider or classroom teacher to a special educator, personal aide, or a speech, physical, or occupational therapist. Families may need help understanding how team teaching works (Salend 2006), being confused possibly about who is their child's real teacher. Educators' communication efforts can help families learn about the different services their child receives.

When explaining early intervention and special education services, avoid educational jargon and acronyms like LD (learning disabled), BD (behavior disorder), EMH (educably mentally handicapped), OT (occupational therapy), and

In your communications as an educator, include positive comments about the child's successes and express your respect for the parents' efforts in helping their child develop as fully as possible.

PT (physical therapy), or the names of tests like DIAL-3 (Developmental Indicators for the Assessment of Learning) or WISC-R (Wechsler Intelligence Scale for Children–Revised). These can be confusing to families and need to be fully explained.

Working with challenging situations

When working with families of children with special needs, you may encounter parents who appear angry, confrontational, mistrustful, or questioning about your teaching methods. Do not take this personally! Historically, families have had to be their own advocates for an appropriate education for their children with disabilities, and some families you are working with may have had negative experiences with the system in the past. They may have had to fight their medical insurance company for needed therapies or may have disagreed with school professionals about testing results or the best classroom placement for their child.

Strive to listen to families, understand their point of view, and be patient. Avoid creating another adversarial experience for them, and work toward building a positive, collaborative relationship.

Conclusion

In your efforts to partner with families in their child's learning and development, you are the expert in child development and education, but they are the experts in their child and the child's disability. Be a teammate with families, and do not try to work alone in educating their child. Together, you and the family can help their child reach his or her full potential.

Finally, don't fear or worry about having a child with special needs in your classroom, center, or school. See the whole child, not just the hearing impairment, the cerebral palsy, or the autism. Remember, they are just kids!

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Who may be eligible for FluMist®?

FluMist is a vaccine approved for the prevention of certain types of influenza disease in children, adolescents and adults 2-49 years of age. FluMist may not protect everyone who gets it. FluMist is for intranasal administration only.

Who may not be able to get FluMist?

FluMist is not right for everyone. FluMist must not be given to: people with history of hypersensitivity to eggs, egg proteins, gentamicin, gelatin or arginine; people with life-threatening reactions to previous influenza vaccinations; and children and adolescents receiving aspirin or aspirin-containing therapy.

Children less than 24 months of age are not eligible for FluMist.

The following people may not be able to get FluMist or may be able to get it only in certain situations: people with asthma or active wheezing, or children less than 5 years of age with recurrent wheezing; people with a history of Guillain-Barré syndrome; people with a weakened immune system; people with long-term medical conditions including heart disease, kidney disease, and metabolic diseases, such as diabetes; and pregnant women.

If your child falls into one of these groups, **be sure to tell your healthcare provider**. They will decide if FluMist is right for your child.

What are the most common side effects of FluMist?

Most common side effects included runny nose or nasal congestion, sore throat, and fever. For a full list of side effects, please see section 6.1 in the product information.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see accompanying brief summary of complete product information or visit www.FluMist.com.

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FluMist is a vaccine indicated for the active immunization of individuals 2-49 years of age against influenza disease caused by influenza virus subtypes A and type B contained in the vaccine.

DOSAGE AND ADMINISTRATION

FOR INTRANASAL ADMINISTRATION BY A HEALTH CARE PROVIDER.

Dosing Information

FluMist should be administered according to the following schedule:

Age Group	Vaccination Status	Dosage Schedule
Children age 2 years through 8 years	Not previously vaccinated with influenza vaccine	2 doses (0.2 mL* each, at least 1 month apart)
Children age 2 years through 8 years	Previously vaccinated with influenza vaccine	1 dose (0.2 mL*)
Children, adolescents and adults age 9 through 49 years	Not applicable	1 dose (0.2 mL*)

* Administer as 0.1 mL per nostril.

For children age 2 years through 8 years who have not previously received influenza vaccine, the recommended dosage schedule for nasal administration is one 0.2 mL dose (0.1 mL per nostril) followed by a second 0.2 mL dose (0.1 mL per nostril) given at least 1 month later.

For all other individuals, including children age 2-8 years who have previously received influenza vaccine, the recommended schedule is one 0.2 mL dose (0.1 mL per nostril).

FluMist should be administered prior to exposure to influenza. Annual revaccination with influenza vaccine is recommended.

CONTRAINDICATIONS

Hypersensitivity

FluMist is contraindicated in individuals with a history of hypersensitivity, especially anaphylactic reactions, to eggs, egg proteins, gentamicin, gelatin, or arginine or with life-threatening reactions to previous influenza vaccinations.

Concomitant Pediatric and Adolescent Aspirin Therapy and Reye's Syndrome

FluMist is contraindicated in children and adolescents (2-17 years of age) receiving aspirin therapy or aspirin-containing therapy, because of the association of Reye's syndrome with aspirin and wild-type influenza infection.

WARNINGS AND PRECAUTIONS

Risks in Children <24 Months of Age

Do not administer FluMist to children <24 months of age. In clinical trials, an increased risk of wheezing post-vaccination was observed in FluMist recipients <24 months of age. An increase in hospitalizations was observed in children <24 months of age after vaccination with FluMist.

Asthma/Recurrent Wheezing

FluMist should not be administered to any individuals with asthma or children < 5 years of age with recurrent wheezing because of the potential for increased risk of wheezing post vaccination unless the potential benefit outweighs the potential risk.

Do not administer FluMist to individuals with severe asthma or active wheezing because these individuals have not been studied in clinical trials.

Guillain-Barré Syndrome

If Guillain-Barré syndrome has occurred within 6 weeks of any prior influenza vaccination, the decision to give FluMist should be based on careful consideration of the potential benefits and potential risks.

Altered Immunocompetence

Administration of FluMist, a live virus vaccine, to immunocompromised persons should be based on careful consideration of potential benefits and risks. Although FluMist was studied in 57 asymptomatic or mildly symptomatic adults with HIV infection, data supporting the safety and effectiveness of FluMist administration in immunocompromised individuals are limited.

Medical Conditions Predisposing to Influenza Complications

The safety of FluMist in individuals with underlying medical conditions that may predispose them to complications following wild-type influenza infection has not been established. FluMist should not be administered unless the potential benefit outweighs the potential risk.

Management of Acute Allergic Reactions

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

Limitations of Vaccine Effectiveness

FluMist may not protect all individuals receiving the vaccine.

ADVERSE REACTIONS

FluMist is not indicated in children <24 months of age. In a clinical trial, among children 6-23 months of age, wheezing requiring bronchodilator therapy or with significant respiratory symptoms occurred in 5.9% of FluMist recipients compared to 3.8% of active control (injectable influenza vaccine made by Sanofi Pasteur Inc.) recipients (Relative Risk 1.5, 95% CI: 1.2, 2.1). Wheezing was not increased in children ≥24 months of age.

Hypersensitivity, including anaphylactic reaction, has been reported post-marketing.

Adverse Reactions in Clinical Trials

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

A total of 9537 children and adolescents 1-17 years of age and 3041 adults 18-64 years of age received FluMist in randomized, placebo-controlled Studies D153-P501, AV006, D153-P526, AV019 and AV009 described below. In addition, 4179 children 6-59 months of age received FluMist in Study MI-CP111, a randomized, active-controlled trial. Among pediatric FluMist recipients 6 months-17 years of age, 50% were female; in the study of adults, 55% were female. In MI-CP111, AV006, D153-P526, AV019 and AV009, subjects were White (71%), Hispanic (11%), Asian (7%), Black (6%), and Other (5%), while in D153-P501, 99% of subjects were Asian.

Adverse Reactions in Children and Adolescents

In a placebo-controlled safety study (AV019) conducted in a large Health Maintenance Organization (HMO) in children 1-17 years of age (n = 9689), an increase in asthma events, captured by review of diagnostic codes, was observed in children <5 years of age (Relative Risk 3.53, 90% CI: 1.1, 15.7). This observation was prospectively evaluated in Study MI-CP111.

In MI-CP111, an active-controlled study, increases in wheezing and hospitalization (for any cause) were observed in children <24 months of age, as shown in Table 1.

Table 1
Percentages of Children with Hospitalizations and Wheezing from MI-CP111

Adverse Reaction	Age Group	FluMist	Active Control[a]
Hospitalizations[b]	6-23 months (n = 3967)	4.2 %	3.2 %
	24-59 months (n = 4385)	2.1 %	2.5 %
Wheezing[c]	6-23 months (n = 3967)	5.9 %	3.8 %
	24-59 months (n = 4385)	2.1 %	2.5 %

[a] Injectable influenza vaccine made by Sanofi Pasteur Inc.
[b] From randomization through 180 days post last vaccination.
[c] Wheezing requiring bronchodilator therapy or with significant respiratory symptoms evaluated from randomization through 42 days post last vaccination.

Most hospitalizations observed were gastrointestinal and respiratory tract infections and occurred more than 6 weeks post vaccination. In post hoc analysis, rates of hospitalization in children 6-11 months of age (n = 1376) were 6.1% in FluMist recipients and 2.6% in active control recipients.

Table 2 shows an analysis of pooled solicited events, occurring in at least 1% of FluMist recipients and at a higher rate compared to placebo, post Dose 1 for Study D153-P501 and AV006 and solicited events post Dose 1 for Study MI-CP111. Solicited events were those about which parents/guardians were specifically queried after vaccination with FluMist. In these studies, solicited events were documented for 10 days post vaccination. Solicited events post Dose 2 for FluMist were similar to those post Dose 1 and were generally observed at a lower frequency.

Table 2
Summary of Solicited Events Observed within 10 Days after Dose 1 for Vaccine[a] and either Placebo or Active Control Recipients; Children 2-6 Years of Age

	D153-P501 & AV006		MI-CP111	
	FluMist N=876-1759[c]	Placebo N=424-1034[c]	FluMist N=2170[c]	Active Control[b] N=2165[c]
Event	%	%	%	%
Runny Nose/ Nasal Congestion	58	50	51	42
Decreased Appetite	21	17	13	12
Irritability	21	19	12	11
Decreased Activity (Lethargy)	14	11	7	6
Sore Throat	11	9	5	6
Headache	9	7	3	3
Muscle Aches	6	3	2	2
Chills	4	3	2	2
Fever				
100-101°F Oral	9	6	6	4
101-102°F Oral	4	3	4	3

[a] Frozen formulation used in AV006; Refrigerated formulation used in D153-P501 and MI-CP111.
[b] Injectable influenza vaccine made by Sanofi Pasteur Inc.
[c] Number of evaluable subjects (those who returned diary cards) for each event. Range reflects differences in data collection between the 2 pooled studies.

In clinical studies D153-P501 and AV006, other adverse reactions in children occurring in at least 1% of FluMist recipients and at a higher rate compared to placebo were: abdominal pain (2% FluMist vs. 0% placebo) and otitis media (3% FluMist vs. 1% placebo).

An additional adverse reaction identified in the active-controlled trial, MI-CP111, occurring in at least 1% of FluMist recipients and at a higher rate compared to active control was sneezing (2% FluMist vs. 1% active control).

In a separate trial (MI-CP112) that compared the refrigerated and frozen formulations of FluMist in children and adults 5-49 years of age, the solicited events and other adverse events were consistent with observations from previous trials. Fever of >103°F was observed in 1 to 2% of children 5-8 years of age.

In a separate placebo-controlled trial (D153-P526) using the refrigerated formulation in a subset of older children and adolescents 9-17 years of age who received one dose of FluMist, the solicited events and other adverse events were generally consistent with observations from previous trials. Abdominal pain was reported in 12% of FluMist recipients compared to 4% of placebo recipients and decreased activity was reported in 6% of FluMist recipients compared to 0% of placebo recipients.

Adverse Reactions in Adults

In adults 18-49 years of age in Study AV009, summary of solicited adverse events occurring in at least 1% of FluMist recipients and at a higher rate compared to placebo include runny nose (44% FluMist vs. 27% placebo), headache (40% FluMist vs. 38% placebo), sore throat (28% FluMist vs. 17% placebo), tiredness/weakness (26% FluMist vs. 22% placebo), muscle aches (17% FluMist vs. 15% placebo), cough (14% FluMist vs. 11% placebo), and chills (9% FluMist vs. 6% placebo).

In addition to the solicited events, other adverse reactions from Study AV009 occurring in at least 1% of FluMist recipients and at a higher rate compared to placebo were: nasal congestion (9% FluMist vs. 2% placebo) and sinusitis (4% FluMist vs. 2% placebo).

Postmarketing Experience

The following adverse reactions have been identified during postapproval use of FluMist. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to vaccine exposure.

Congenital, familial and genetic disorder: Exacerbation of symptoms of mitochondrial encephalomyopathy (Leigh syndrome).

Gastrointestinal disorders: Nausea, vomiting, diarrhea

Immune system disorders: Hypersensitivity reactions (including anaphylactic reaction, facial edema and urticaria)

Nervous system disorders: Guillain-Barré syndrome, Bell's Palsy

Respiratory, thoracic and mediastinal disorders: Epistaxis

Skin and subcutaneous tissue disorders: Rash

DRUG INTERACTIONS

Aspirin Therapy
Do not administer FluMist to children or adolescents who are receiving aspirin therapy or aspirin-containing therapy.

Antiviral Agents Against Influenza A and/or B
The concurrent use of FluMist with antiviral agents that are active against influenza A and/or B viruses has not been evaluated. However, based upon the potential for antiviral agents to reduce the effectiveness of FluMist, do not administer FluMist until 48 hours after the cessation of antiviral therapy and antiviral agents should not be administered until two weeks after administration of FluMist unless medically indicated. If antiviral agents and FluMist are administered concomitantly, revaccination should be considered when appropriate.

Concomitant Inactivated Vaccines
The safety and immunogenicity of FluMist when administered concurrently with inactivated vaccines have not been determined. Studies of FluMist excluded subjects who received any inactivated or subunit vaccine within two weeks of enrollment. Therefore, healthcare providers should consider the risks and benefits of concurrent administration of FluMist with inactivated vaccines.

Concomitant Live Vaccines
Concurrent administration of FluMist with the measles, mumps and rubella vaccine and the varicella vaccine was studied in 1245 children 12-15 months of age. Adverse events were similar to those seen in other clinical trials with FluMist. No evidence of interference with immune responses to measles, mumps, rubella, varicella and FluMist vaccines was observed. The safety and immunogenicity in children >15 months of age have not been studied.

Intranasal Products
There are no data regarding co-administration of FluMist with other intranasal preparations.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Category C
Animal reproduction studies have not been conducted with FluMist. It is not known whether FluMist can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. FluMist should be given to a pregnant woman only if clearly needed.

The effect of the vaccine on embryo-fetal and pre-weaning development was evaluated in a developmental toxicity study using pregnant rats receiving the frozen formulation. Groups of animals were administered the vaccine either once (during the period of organogenesis on gestation day 6) or twice (prior to gestation and during the period of organogenesis on gestation day 6), 250 microliter/rat/occasion (approximately 110-140 human dose equivalents), by intranasal instillation. No adverse effects on pregnancy, parturition, lactation, embryo-fetal or pre-weaning development were observed. There were no vaccine related fetal malformations or other evidence of teratogenesis noted in this study.

Nursing Mothers
It is not known whether FluMist is excreted in human milk. Therefore, as some viruses are excreted in human milk and additionally, because of the possibility of shedding of vaccine virus and the close proximity of a nursing infant and mother, caution should be exercised if FluMist is administered to nursing mothers.

Pediatric Use
Safety and effectiveness of the vaccine has been demonstrated for children 2 years of age and older with reduction in culture-confirmed influenza rates compared to active control (injectable influenza vaccine made by Sanofi Pasteur Inc.) and placebo. FluMist is not indicated for use in children <24 months of age. FluMist use in children <24 months has been associated with increased risk of hospitalization and wheezing in clinical trials.

Geriatric Use
FluMist is not indicated for use in individuals ≥65 years of age. Subjects with underlying high-risk medical conditions (n=200) were studied for safety. Compared to controls, FluMist recipients had a higher rate of sore throat.

Use in Individuals 50-64 Years of Age
FluMist is not indicated for use in individuals 50-64 years of age. In Study AV009, effectiveness was not demonstrated in individuals 50-64 years of age (n=641). Solicited adverse events were similar in type and frequency to those reported in younger adults.

PATIENT COUNSELING INFORMATION
Vaccine recipients or their parents/guardians should be informed by the health care provider of the potential benefits and risks of FluMist, and the need for two doses at least 1 month apart in children 2-8 years old who have not previously received influenza vaccine.

Asthma and Recurrent Wheezing
Ask the vaccinee or their parent/guardian if the vaccinee has asthma. For children <5 years of age, also ask if the vaccinee has recurrent wheezing since this may be an asthma equivalent in this age group.

Vaccination with a Live Virus Vaccine
Vaccine recipients or their parents/guardians should be informed by the health care provider that FluMist is an attenuated live virus vaccine and has the potential for transmission to immunocompromised household contacts.

Adverse Event Reporting
The vaccine recipient or the parent/guardian accompanying the vaccine recipient should be told to report any suspected adverse events to the physician or clinic where the vaccine was administered.

MedImmune

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NAEYC's Work to Connect Early Childhood Programs with Families and Communities

In 2008, NAEYC created the Office of Family and Community Initiatives to

1. provide leadership to the early childhood field on the importance of families and communities as crucial components of high-quality early childhood education and

2. to prepare early childhood professionals to effectively engage families and communities. The work of this office aligns with NAEYC's Early Childhood Program Standards 7 (Families) and 8 (Community Relationships) and the accreditation criteria related to them and provides a framework for NAEYC's efforts in these areas.

The office provides resources to help ensure that early childhood programs and professionals are competent and effective in

- knowing, understanding, and communicating with families;
- nurturing families as advocates for their children;
- promoting the social and emotional health of the whole family;
- linking with and accessing community resources; and
- acting as responsible participants in the neighborhood and the early childhood community.

Engaging Diverse Families (EDF), a current project of the Office of Family and Community Initiatives, is helping early childhood education programs effectively engage families with diverse cultures, languages, structures, and abilities in meaningful ways. EDF is identifying high-quality early childhood education programs that show strong evidence of effectively engaging diverse families and positive child outcomes. Profiles of the exemplary programs, a review of the literature on family engagement, and other materials developed through this project will provide the basis for a tool kit to help all early childhood education programs more effectively engage diverse families.

Visit **www.naeyc.org/ecp/trainings** for more information about EDF and other NAEYC efforts related to families and communities.