

# Unmet Needs Associated with Attention-Deficit/Hyperactivity Disorder in Eight European Countries as Reported by Caregivers and Adolescents: Results from Qualitative Research

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## Abstract

**Introduction** Attention-deficit/hyperactivity disorder (ADHD) is a neurobehavioral disorder characterized by inattention, impulsivity, and hyperactivity, the levels of

which are inappropriately high for an individual's developmental age.

**Objective** The objective of this study was to explore the unmet needs of children/adolescents with ADHD and their caregivers in eight European countries.

**Methods** Semi-structured interviews with 38 caregivers of children/adolescents (aged 6–17 years) with ADHD and no or less serious comorbidities and 28 adolescents (aged 13–17 years) with ADHD and no or less serious comorbidities were conducted, audio-recorded, transcribed into English, and coded for analysis.

**Results** Caregivers reported their own ADHD-related issues, including making personal accommodations, such as limiting activities and spending extra time/effort caring for their child/adolescent, social impacts, and strained relationships. Medication was generally considered helpful; however, most children experience core ADHD symptoms while on medication (reported by 88 % of caregivers and 100 % of adolescents). Adolescents often reported schoolwork difficulties (96 %) and peer issues (75 %), while caregivers reported school issues (84 %) and peer difficulties (79 %). Caregivers reported minimal ADHD education and community support. Caregivers (29 %) and adolescents (54 %) desired medication that better controlled symptoms but had concerns about being oversubdued. Caregivers reported concerns about adverse effects (21 %).

**Conclusions** European caregivers of children/adolescents with ADHD identified multiple unmet needs, which persist despite treatment. Adolescents noted impacts on school and social interactions consistent with caregivers. Future research is needed to quantify the study findings, and, ultimately, ease the impact of ADHD on patients and their caregivers.

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### Key Points for Decision Makers

Unmet needs in children with attention-deficit/hyperactivity disorder (ADHD) with no or less serious comorbidities persist across Europe despite medical treatment; patients struggle with symptoms, school, and peer difficulties.

The burden of caring for a child with ADHD with no or less serious comorbidities is substantial, leading to strained relationships and various means of adjusting and coping, while receiving minimal community support.

Medication alleviates some symptoms and burden, but concerns about being overly subdued and adverse effects remain among both adolescents and caregivers.

## 1 Background

Attention-deficit/hyperactivity disorder (ADHD) is a neurobehavioral disorder characterized by the combination of three primary symptoms: inattention, impulsivity, and hyperactivity, the levels of which are inappropriately high for the individual's developmental age. Prevalence estimates for ADHD in Europe range from 1.5 to 8 %, as defined by the ICD-10 or by the DSM-IV, respectively [1–3].

Best practice guidelines for the diagnosis and treatment of ADHD in Europe have been provided by organizations such as The National Institute for Health and Care Excellence (NICE), the European Society for Child and Adolescent Psychiatry (ESCAP), the Deutsche Gesellschaft für Kinder- und Jugendpsychiatrie (DGKJP), and the Health Ministry of Spain [4–6]. Guidelines generally suggest the use of methylphenidate for initial pharmacologic treatment, if indicated. Other possible pharmacologic treatments, including the non-stimulant atomoxetine, are prescribed depending on factors such as the presence of comorbidities, experience of adverse effects, and parent/child preferences. NICE, ESCAP, and DGKJP recommend that pharmacologic treatment be part of a multi-disciplinary interventional approach that includes educational and psychological components.

A number of studies describe the burden of living with ADHD [7–11]. ADHD can impact many aspects of a child's life, including school performance, social interactions, family life, and emotional well-being [12]. Some studies note that ADHD not only affects the patient, but may have a substantial impact on the immediate family [13–15]. While behavioral and medical therapy may help

to reduce ADHD symptoms, it is not well understood to what degree unmet needs persist, despite current treatment options and the standard of care that children/adolescents with ADHD receive in Europe.

Qualitative research is a robust method of exploring complex issues in depth and comprehensively [16]. The open-ended nature of qualitative interviews allows for a rich data set to be generated in the words of those directly impacted. Qualitative data can be used not only to deepen the understanding of an issue, but also to develop a comprehensive quantitative survey instrument to gather additional insights on the frequency with which issues occur among a larger sample.

The objective of this study was to identify quantifiable concepts of unmet need affecting children/adolescents with ADHD and their caregivers in selected EU countries. Specifically, the study explored qualitatively, through open-ended interviews, the effects of ADHD and currently available treatments in the EU (including pharmacologic and non-pharmacologic) on the daily life of patients and caregivers in an attempt to identify unmet needs. This study aimed to generate concepts related to unmet need that would help inform the development of a patient-centered web-based caregiver survey to further validate and quantify those identified unmet needs for this population. This approach to survey development is consistent with the US Food and Drug Administration guidance on the development of patient-reported instruments [17].

## 2 Methods

This was a cross-sectional study involving one-time interviews both the caregivers of children/adolescents (aged 6–17 years) with ADHD and adolescents (aged 13–17 years) with ADHD. The study was reviewed and approved by a central institutional review board: MaGil IRB, Rockville, MD, USA; the study was performed in accordance with ethical standards laid down in the 1964 (and later amendments) Declaration of Helsinki. Study participants resided in France, Germany, Italy, the Netherlands, Norway, Spain, Sweden, and the UK.

Potentially eligible participants, recruited through online panels of patients who had signed up to receive information on studies for which they may qualify, were sent standardized email invitations with a link to an online screening form. To be eligible for the study, the child/adolescent with ADHD had to be diagnosed at least 6 months prior to screening. The adolescent participants had to be aged 13–17 years, and the caregivers had to have a child/adolescent with ADHD who was aged 6–17 years. Caregiver/adolescent dyads (i.e., where both the caregiver and his/her adolescent would participate in interviews)

were allowed but not required. All interviews occurred independently, including dyads. Identification of any comorbid condition in the child/adolescent with ADHD was a criterion for exclusion to minimize influencing factors of such conditions. However, because ADHD is highly comorbid, it became difficult to meet recruitment targets in a timely manner, so this criterion was removed prior to any interviews. Patients with few or no comorbid conditions and conditions that were deemed by the research team to be less severe and less related to the ADHD, such as learning, speech, sleep, or oppositional defiant disorder, were preferentially selected over patients with comorbidities where ADHD unmet need concepts could potentially be confused with other severe comorbidities, such as autism, bipolar disorder, or schizophrenia. Additionally, a diverse sample with respect to age, sex, and treatment experience was sought. As certain portions of the ADHD population are typically under-represented in studies of ADHD, we oversampled to ensure representation of adolescent female individuals and children/adolescents taking the non-stimulant atomoxetine hydrochloride (Strattera<sup>®</sup>, Eli Lilly and Company, Indianapolis, IN, USA). As such, if a caregiver had more than one eligible child with ADHD, priority was given to the child who would increase the representativeness of the sample with regard to age, sex, and treatment experience, and with no or fewer comorbidities.

One-on-one telephone interviews were conducted by experienced interviewers in the participant's native language. Participants in the UK were interviewed by members of the research team with extensive qualitative interview experience. Non-English interviews were conducted by interviewers experienced in market research who were native speakers of the language in which the interviews were conducted. To ensure standardization and harmonization of interviewers and techniques, a 1-day training seminar that included mock interviews was held with all interviewers. Each participant was asked to provide the appropriate informed verbal consent and/or assent approved for the study. Each interview followed a standardized semi-structured interview guide, which was designed based on previous ethnographic market research and feedback from three EU clinical experts in ADHD, to elicit caregiver and adolescent perspectives of ADHD impacts and treatment. The interview began with open-ended questions to avoid limiting input from patients and caregivers and to avoid researcher bias in identifying unmet need. Participants were asked questions about symptoms and behaviors, and asked to compare on and off treatment experiences. Caregivers were also asked about the impact of having a child with ADHD on their own life. Caregiver interviews lasted 60–90 min and adolescent interviews lasted 30–60 min. Interviews were audio-recorded and subsequently transcribed into English.

Both cohorts were remunerated the equivalent of £25 in local currency.

## 2.1 Analysis

All transcripts were translated into English and a content and thematic analysis was performed to identify key themes that emerged from the interviews [18]. Four researchers trained in qualitative analysis coded the data using MaxQDA 10 (VERBI GmbH, Germany), a qualitative software analysis program. A code system was developed, and the four coders met frequently to discuss the identified themes, come to a consensus on any variance in coding, and revise the code system as needed. The coding was cross-checked for consistency and accuracy in the application of codes. In addition, transcripts of caregiver/adolescent dyads were compared using the coding system to determine the general level of agreement with respect to elicited concepts between the caregiver and their adolescent. Specifically, codes applied to the transcripts of the caregiver and corresponding adolescent were compared to identify overlap in elicited concepts.

### 2.1.1 Assessment of Saturation

An examination of information saturation, or the point at which no new information is collected with additional interviews, was examined by reviewing the application of codes. Evidence that saturation was obtained and the sample size was sufficient was supported when no new codes were being applied to the transcripts. Saturation was attained in both sample groups. For the caregiver interviews ( $N = 38$ ), 85 % of codes were assigned by the end of the 15th interview, and 95 % by the end of the 27th interview. No new codes were applied in the last two interviews. For the adolescent interviews ( $N = 28$ ), 84 % of codes were assigned by the end of the 17th interview, and 96 % by the end of the 23rd interview. No new codes were applied in the last interview. The same process was followed for caregivers and patients, including dyads ( $N = 6$ ).

## 3 Results

Thirty-eight caregivers of children/adolescents with ADHD and 28 adolescents with ADHD originating from France, Germany, Italy, the Netherlands, Norway, Spain, Sweden, and the UK were interviewed. Of the caregivers, 74 % were female, 30 % reported sharing the caregiving role with a partner, and 26 % had earned a university degree. Fifty-two percent were employed full- or part-time.

The cohort of children/adolescents whose caregivers were interviewed is presented in Table 1. The mean (standard deviation [SD]) age of the cohort was 11.9 (3.7) years and 66 % were male. Thirty-four percent were currently attending behavioral therapy sessions. Twenty-five (66 %) children/adolescents were currently taking stimulant medication, four (11 %) were taking non-stimulant medication (atomoxetine), and four (11 %) were on combination therapy. Five (13 %) children/adolescents were not currently medicated.

Approximately half (53 %) of this cohort had no comorbid conditions.

The adolescent cohort had a mean (SD) age of 15.3 (1.5) years, 50 % were male, and all were currently on medication for ADHD (Table 2). Forty-three percent were currently attending behavioral therapy sessions. Nineteen (68 %) adolescents were currently taking stimulant medication, six (21 %) were taking non-stimulant medication, and three (11 %) were on combination therapy. Seventy-five percent of adolescents had no comorbid conditions.

**Table 1** Sample characteristics for children and adolescents of caregiver participants: total sample and by country

Children/adolescents with ADHD	Total ( <i>N</i> = 38)	UK ( <i>n</i> = 10)	Italy ( <i>n</i> = 6)	Germany ( <i>n</i> = 5)	Spain ( <i>n</i> = 5)	France ( <i>n</i> = 4)	Netherlands ( <i>n</i> = 4)	Nordic regions	
								Finland ( <i>n</i> = 2)	Sweden ( <i>n</i> = 2)
Age of child, mean [SD] (range), years	11.9 [3.7] (6–17)	12.5 [3.1] (7–17)	9.7 [3.4] (6–16)	12.4 [4.6] (7–17)	11.2 [2.4] (8–14)	11.8 [5.0] (8–17)	10.8 [4.9] (6–17)	16.5 [0.7] (16–17)	14.5 [2.1] (13–16)
Female sex	13 (34)	3 (30)	3 (50)	2 (40)	1 (20)	1 (25)	1 (25)	0	2 (100)
Currently in behavioral therapy	13 (34)	0	5 (83)	2 (40)	2 (40)	2 (50)	1 (25)	1 (50)	0
Current medication(s)									
Methylphenidate	25 (66)	7 (70)	2 (33)	5 (100)	3 (60)	4 (100)	1 (25)	2 (100)	1 (50)
Atomoxetine	4 (11)	2 (20)	1 (17)	0	0	0	0	0	1 (50)
Combination	4 (11)	0	0	0	2 (40) <sup>a</sup>	0	2 (50) <sup>b</sup>	0	0
Not currently medicated	5 (13)	1 (10) <sup>c</sup>	3 (50)	0	0	0	1 (25)	0	0
ADHD type									
Inattentive	10 (26)	2 (20)	2 (33)	2 (40)	0	0	2 (50)	1 (50)	1 (50)
Hyperactive/impulsive	12 (32)	4 (40)	3 (50)	1 (20)	2 (40)	1 (25)	0	1 (50)	0
Combined	6 (16)	1 (10)	0	1 (20)	0	2 (50)	1 (25)	0	1 (50)
Unknown	10 (26)	3 (30)	1 (17)	1 (20)	3 (60)	1 (25)	1 (25)	0	0
Comorbidity status									
Without comorbidities	20 (53)	5 (50)	3 (50)	4 (80)	2 (40)	0	3 (75)	1 (50)	2 (100)
With comorbidities	16 (42)	5 (50)	3 (50)	1 (20)	3 (60)	3 (75)	1 (25)	0	0
Reported comorbidity, <i>n</i>									
Aggression	4	1	0	0	0	2	1	0	0
Anxiety	6	3	1	0	1	1	0	0	0
Asperger syndrome	1	1	0	0	0	0	0	0	0
Conduct disorder	4	0	0	1	2	1	0	0	0
Depression	1	1	0	0	0	0	0	0	0
Learning disorder	7	1	3	0	1	2	0	0	0
Oppositional defiant disorder	1	0	0	0	0	1	0	0	0
Sleep disorder	3	1	0	0	0	2	0	0	0
Speech/language disorder	3	0	0	0	1	1	1	0	0
Missing data	2 (5)	0	0	0	0	1	0	1	0

Data are given as *n* (%) unless indicated otherwise

ADHD attention-deficit/hyperactivity disorder, SD standard deviation

<sup>a</sup> One participant on atomoxetine and methylphenidate, and another on atomoxetine and risperidone

<sup>b</sup> Immediate- and extended-release methylphenidate

<sup>c</sup> Previous experience with methylphenidate

**Table 2** Sample characteristics for adolescent participants: total sample and by country

Adolescents with ADHD	Total ( <i>N</i> = 28)	UK ( <i>n</i> = 5)	Italy ( <i>n</i> = 4)	Germany ( <i>n</i> = 4)	Spain ( <i>n</i> = 4)	France ( <i>n</i> = 4)	Netherlands ( <i>n</i> = 4)	Nordic regions	
								Finland ( <i>n</i> = 1)	Sweden ( <i>n</i> = 2)
Age of adolescent, mean [SD] (range), years	15.3 [1.5] (13–17)	14.6 [0.9] (14–16)	16.8 [0.5] (16–17)	15.5 [1.7] (14–17)	14.5 [1.3] (13–16)	15.5 [1.3] (14–17)	14.8 [2.1] (13–17)	16.5 [0.7] (16–17)	14.5 [2.1] (13–16)
Female sex	14 (50)	2 (40)	2 (50)	2 (50)	2 (50)	2 (50)	2 (50)	0	2 (100)
Currently in behavioral therapy	12 (43)	1 (20)	4 (100)	1 (25)	2 (50)	2 (50)	1 (25)	0	1 (50)
Current medication(s)									
Methylphenidate	19 (68)	5 (100)	0	4 (100)	1 (25)	4 (100)	3 (75)	1 (100)	1 (50)
Atomoxetine	6 (21)	0	4 (100)	0	1 (25)	0	0	0	1 (50)
Combination	3 (11)	0	0	0	2 (50) <sup>a</sup>	0	1 (25) <sup>b</sup>	0	0
ADHD type									
Inattentive	3 (11)	0	0	0	1 (25)	2 (50)	0	0	0
Hyperactive/impulsive	5 (18)	0	2 (50)	0	0	1 (25)	2 (50)	0	0
Combined	7 (25)	3 (60)	1 (25)	0	1 (25)	1 (25)	1 (25)	0	0
Unknown	13 (46)	2 (40)	1 (25)	4 (100)	2 (50)	0	1 (25)	1 (100)	2 (100)
Comorbidity status									
Without comorbidities	21 (75)	4 (80)	4 (100)	4 (100)	2 (50)	2 (50)	3 (75)	0	2 (100)
With comorbidities	6 (21)	1 (20)	0	0	2 (50)	2 (50)	1 (25)	0	0
Reported comorbidity, <i>n</i>									
Anxiety	3	0	0	0	1	2	0	0	0
Conduct disorder	3	0	0	0	1	2	0	0	0
Eating disorder	1	0	0	0	0	1	0	0	0
Learning disorder	4	1	0	0	0	1	0	0	0
Oppositional defiant disorder	0	0	0	0	0	1	0	0	0
Sleep disorder	1	0	0	0	0	1	1	0	0
Missing data	1 (4)	0	0	0	0	0	0	1 (100)	0

Data are given as *n* (%) unless indicated otherwise

ADHD attention-deficit/hyperactivity disorder, *SD* standard deviation

<sup>a</sup> One on atomoxetine and risperidone; another on extended- and immediate-release methylphenidate

<sup>b</sup> Extended- and immediate-release methylphenidate

### 3.1 Key Themes of Unmet Needs

The key themes of potential unmet needs elicited from the qualitative interviews are categorized into the following domains: difficulties associated with diagnosis, presence of ADHD symptoms on medication, difficulties with school and psychosocial functioning, difficulties with home and family life, treatment concerns, and caregiver-specific concerns. These key themes were relevant across all eight countries, all ages, and in both cohorts.

#### 3.1.1 Difficulties Associated with Diagnosis

In general, caregivers reported that the process for obtaining an ADHD diagnosis for their child was difficult. Seventy-four percent of caregivers reported issues with

diagnosis, including lack of recognition of ADHD symptoms, lengthy waiting periods to receive specialist referrals, misdiagnosis, and visits to multiple doctors. The time frame for diagnosis ranged from a few months to several years. For nine caregivers, it took  $\geq 1$  year to obtain an ADHD diagnosis for their child and seven of these waited  $\geq 2$  years for a diagnosis. In several instances, the caregivers reported experiencing some blame for their child's symptoms and behaviors from healthcare providers before an accurate diagnosis was reached, attributing the child's symptoms and behaviors to a poor parent-child relationship or parenting issues.

Adolescents were not specifically asked about the process of obtaining a diagnosis. However, 75 % expressed concerns pertaining to the diagnosis, such as embarrassment, shame and annoyance about having ADHD, being

slower learners than their peers, and having more difficulty understanding information, or being perceived by their peers as ‘disabled’.

### 3.1.2 Presence of ADHD Symptoms on Medication

For the majority of the children/adolescents on medication, both stimulant and non-stimulant alike, ADHD symptoms were reduced, but not eliminated (Fig. 1). Eighty-eight percent of caregivers reported that their child still continued to experience some core ADHD symptoms while on medication. Similarly, all adolescents discussed experiencing impatience, difficulty concentrating, impulsivity, hyperactivity, and/or verbal and physical aggression while on medication.

### 3.1.3 Difficulties with School and Psychosocial Functioning

Eighty-four percent of caregivers reported an impact on school performance despite taking medication, resulting in poor or failing grades. Approximately a third (37 %) of the children/adolescents had been held back a year in school. While adolescents generally reported that they could concentrate better at school when they took their medication, all reported that even when taking medication they could still be easily distracted, have difficulty focusing, or become easily frustrated, which could lead to problems with completing homework and exams.

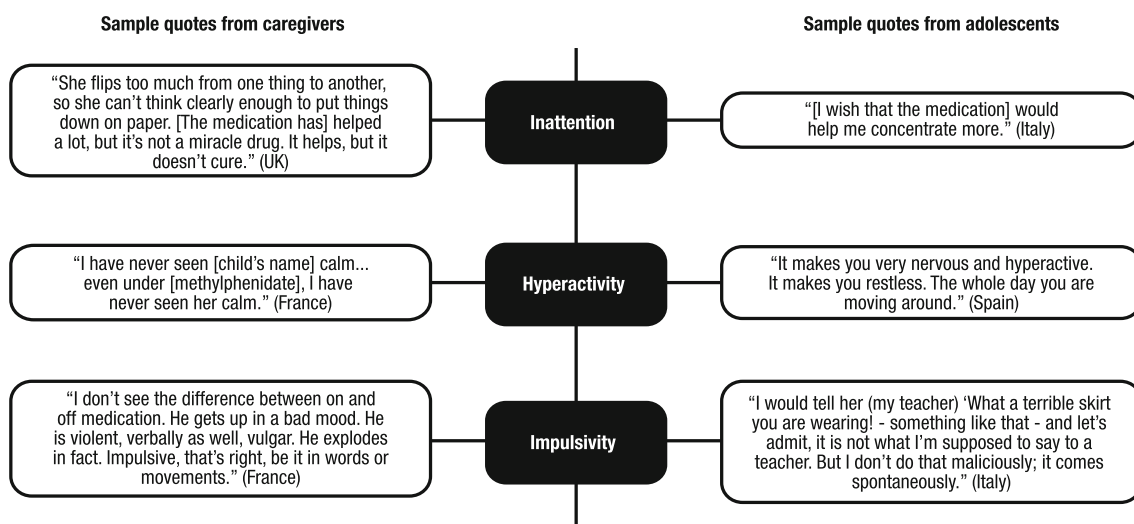
ADHD symptoms not only affected academic progress but also contributed to disciplinary problems at school, as noted by a majority (71 %) of caregivers and many (64 %) adolescents. Fifty-eight percent of caregivers reported that

disciplinary problems continued despite medication. Disciplinary problems resulted from behaviors such as fighting, talking at inappropriate times, not finishing tasks, inattention, getting to class late, missing school, and verbal aggression with both classmates and teachers/administration, which are likely to represent undertreatment of ADHD symptoms (Fig. 2).

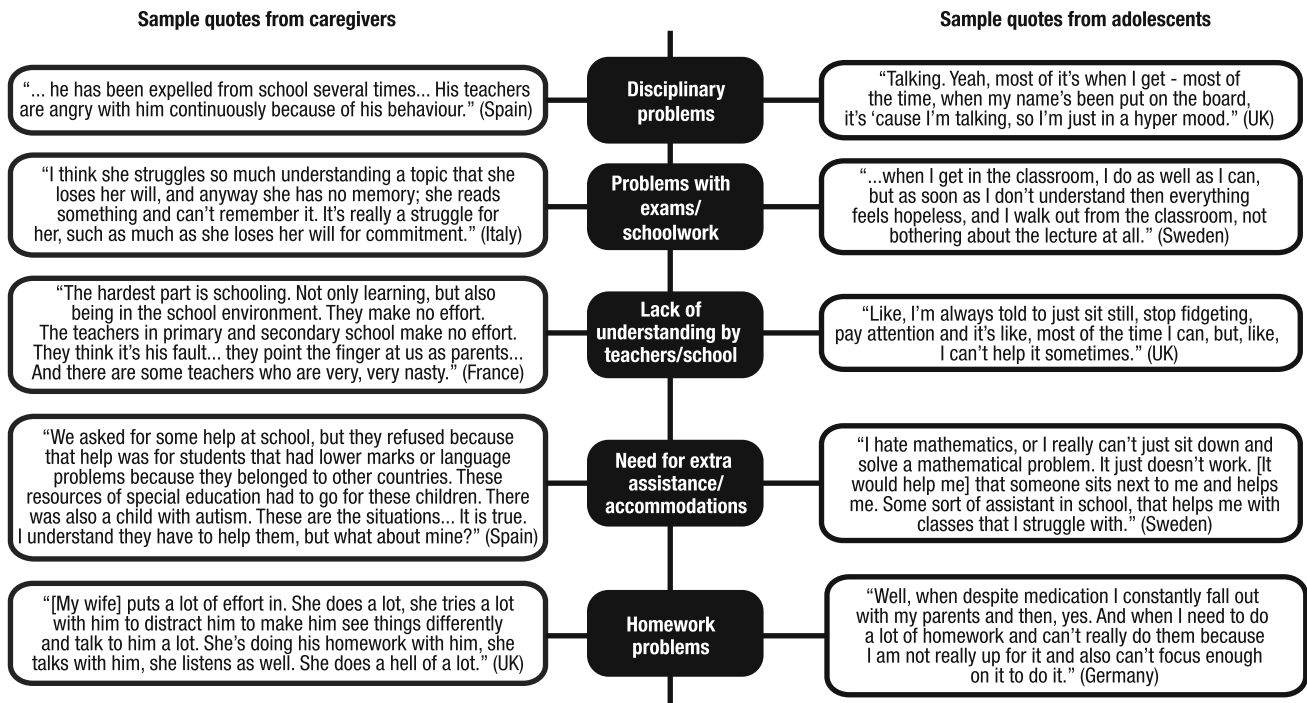
Fifty percent of caregivers reported that their children received special accommodations at school, such as extra attention from teachers (13 %), special classes (18 %), more time to complete assignments (5 %), individualized assistance going over homework and notes (5 %), or less homework (18 %), or attended a school for those with special needs (16 %). Nevertheless, over half (52 %) of the caregivers across all eight countries felt their educational institutions were not fully informed about ADHD and the best methods to educate and manage a child with the disorder. Over 50 % of adolescents conveyed a lack of understanding of ADHD by their teachers and classmates, or the feeling of being unsupported by their school. Caregivers expressed a need for more sensitive and involved teachers, smaller classes, more time to complete tasks, after-school tutoring, and/or an assistant for one-on-one help.

Almost 20 % of caregivers reported that their child required accommodations in extracurricular activities, including supervision during activities to make sure the child remained safe or secure, or providing breaks to compensate for restlessness or overstimulation.

Caregivers reported frustration with their child’s inability to keep up with school work and connect with others. They also reported that their child suffered emotionally in coping with ADHD; 34 % reported their child/



**Fig. 1** Remaining symptoms on medication. Adolescent and caregiver quotes regarding the continuation of symptoms while on medication. The most frequently reported symptom remaining while on medication was ‘Inattention’



**Fig. 2** Difficulty with school. Adolescent and caregiver quotes on school-related difficulties associated with attention-deficit/hyperactivity disorder. 'Problems with exams/schoolwork' was the most frequently reported issue for both cohorts

adolescent experienced low self-esteem and a lack of confidence, especially with regard to forming relationships. Seventy-nine percent of caregivers reported that ADHD-related behaviors affected their child/adolescents' ability to make and keep friendships. Some said their child found it easier to be friends with younger children because of emotional immaturity and that ADHD-related behaviors limited their ability to participate in extra-curricular and social activities. Others were concerned about their child being easily manipulated by bad influences, and being bullied (Fig. 3). Thirteen percent reported that their child had no friends at all, and nearly 40 % that their child was picked on or bullied by their peers and/or siblings because of ADHD.

Adolescents reported that ADHD had a negative effect on their interactions with friends and ability to be social, and 75 % reported issues pertaining to social interactions or forming new relationships. They limited social time to close friends who they felt understood their ADHD, but described feeling a need to be 'careful' around friends and worried that they were 'a lot to handle'.

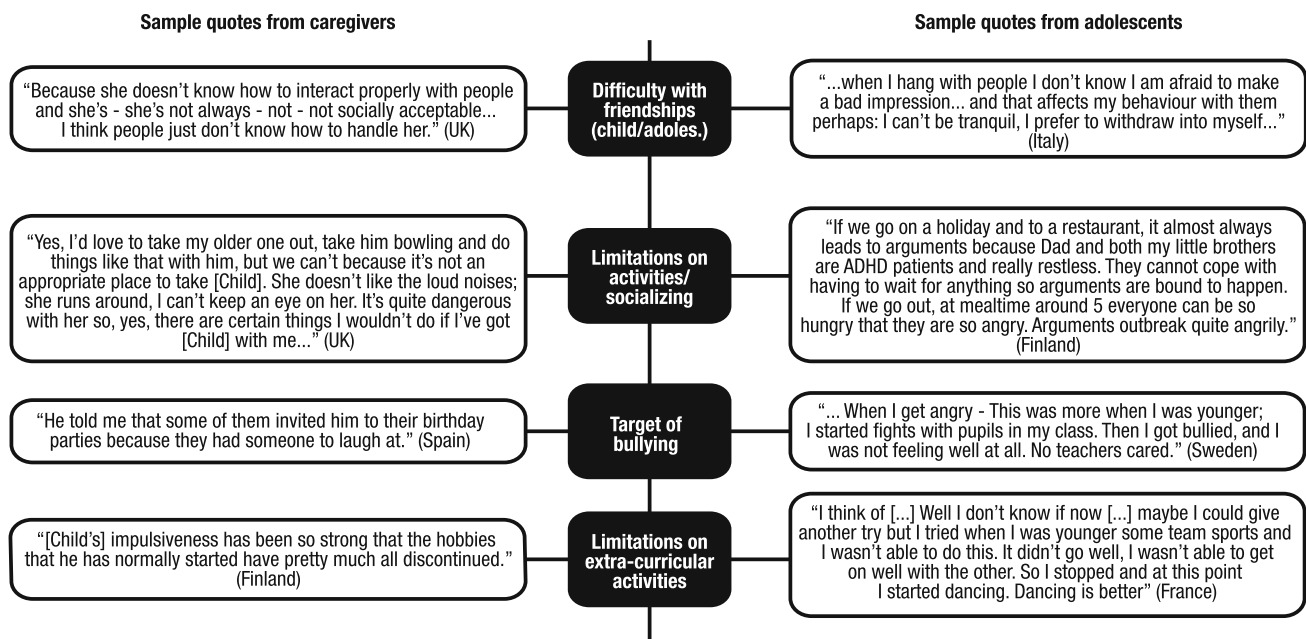
### 3.1.4 Difficulties with Home and Family Life

Caring for a child with ADHD was reported to be very demanding, requiring the caregivers to make accommodations to meet their child's needs. During a typical day, extra time was required by caregivers to make sure the

child/adolescent was organized and focused enough to complete simple daily tasks such as getting dressed, completing school assignments, and keeping track of belongings. Some caregivers (39 %) noted the importance of keeping the child to a routine and reported having to make personal sacrifices to maintain the routine.

A number of caregivers reported limiting the types of activities they participated in with their child/adolescent with ADHD. Caregivers avoided taking the child shopping, to social events, or public places where the child's behavior might cause disruptions. When attending social functions with their child, they described often leaving early or keeping to the edge of the crowd.

Additionally, both cohorts frequently reported that they felt ADHD affected family relationships. Adolescents reported arguing with their parents over incomplete homework and poor school grades. Some caregivers felt that their relationship with their child with ADHD was different than the relationship they had with their other children. They felt relationships with their children without ADHD suffered from focusing more attention and supervision on the child with ADHD. Adolescents felt their parents kept an overzealous eye on them because of their behaviors or treated them differently than their siblings, which sometimes caused problems between siblings. Adolescents reported arguing with siblings, having difficulty controlling outbursts of anger, and being sensitive to teasing by their siblings about their ADHD. This was



**Fig. 3** Impact on activities and social life. Adolescent and caregiver quotes regarding the attention-deficit/hyperactivity disorder-related impacts on a child's social life and activities. 'Difficulty with friendships' was most commonly reported

supported by caregivers who reported situations where the other sibling(s) treated the child with ADHD differently or poorly as a result of the child's behaviors owing to ADHD (Fig. 4).

Thirty-nine percent of caregivers reported that their child's ADHD had an impact on their relationship with their partner. For some, these difficulties stemmed from the partner's lack of acceptance or understanding of their child's ADHD diagnosis. A few (11 %) caregivers noted that their child/adolescent's ADHD did not negatively impact their relationship with their partner, one of whom noted that it had tightened the bond with their spouse.

### 3.1.5 Treatment Concerns

Caregivers reported a number of concerns about ADHD medications, such as adverse effects (21 %), unknown long-term adverse effects (26 %), the potential for dependency or abuse (18 %), and cost (11 %). With regard to behavioral therapy, a few caregivers (8 %) reported that it was ineffective. No other concerns regarding non-pharmacologic therapy were reported. When asked about their current medication, 24 % reported an issue that their child's ADHD medication was no longer effective by the afternoon, thereby making evenings at home particularly difficult. For those whose children had stopped a medication in the past, adverse effects and decreased efficacy were the primary reasons for discontinuing. Some (16 %) caregivers reported either allowing their children to deviate from their prescribed treatment regimen and take

medication 'breaks' or desiring to give their child medication breaks. This was generally related to concerns about or experiences with adverse effects (Fig. 5).

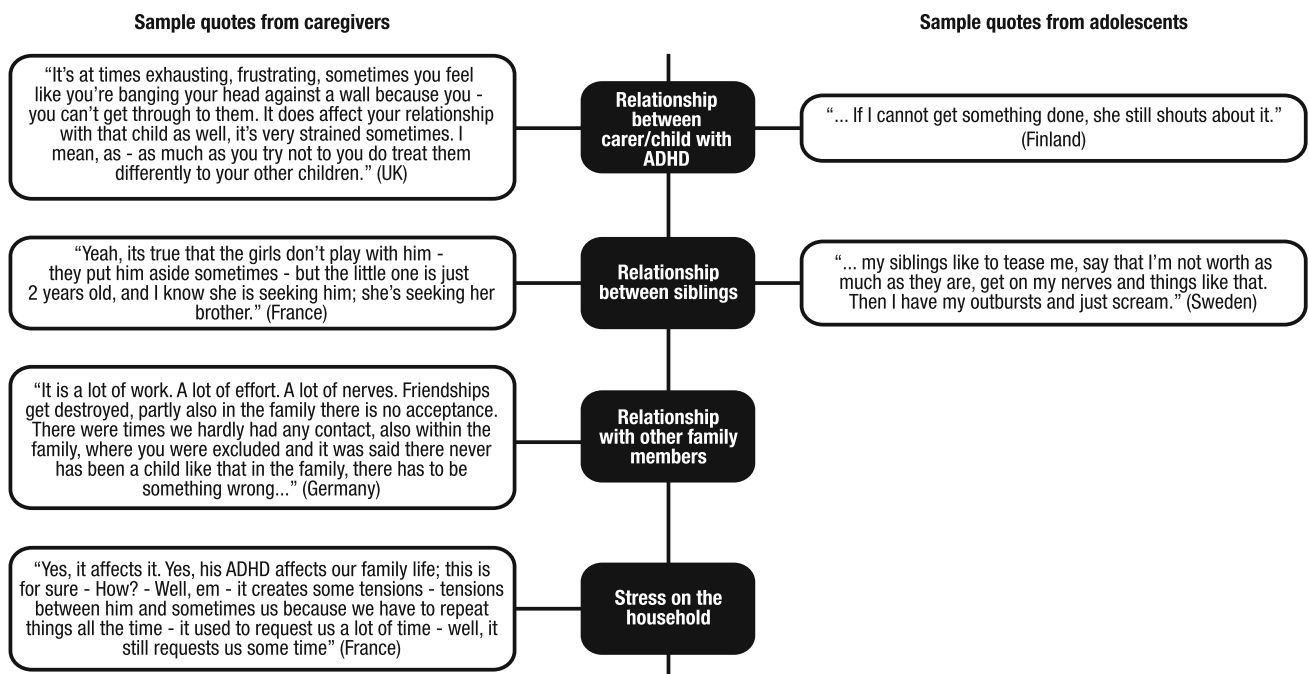
Some adolescents noted increased feelings of 'depression' or low mood when the medication was no longer effective at the end of the day and when describing a 'bad day' on medication. Approximately 20 % of adolescents reported that they felt their current ADHD medication subdued them too much. Approximately 10 % felt their medication affected their ability to fall asleep. Some (11 %) adolescents were unhappy with having to take medication 'for such a long time'. Of particular concern for some was the feeling of being 'controlled by medications' or losing their 'self' to medication.

Some adolescents noted feeling different than other adolescents and/or had difficulty in determining what was 'normal' behavior. Some felt different than their peers because they were required to take medication. They also noted difficulty discerning whether their behavior was an ordinary response to a situation or a result of their ADHD, regardless of being on medication. The inability to know whether their behavior was 'normal' or due to ADHD was noted by one adolescent as making it difficult to gauge the effectiveness of ADHD treatment.

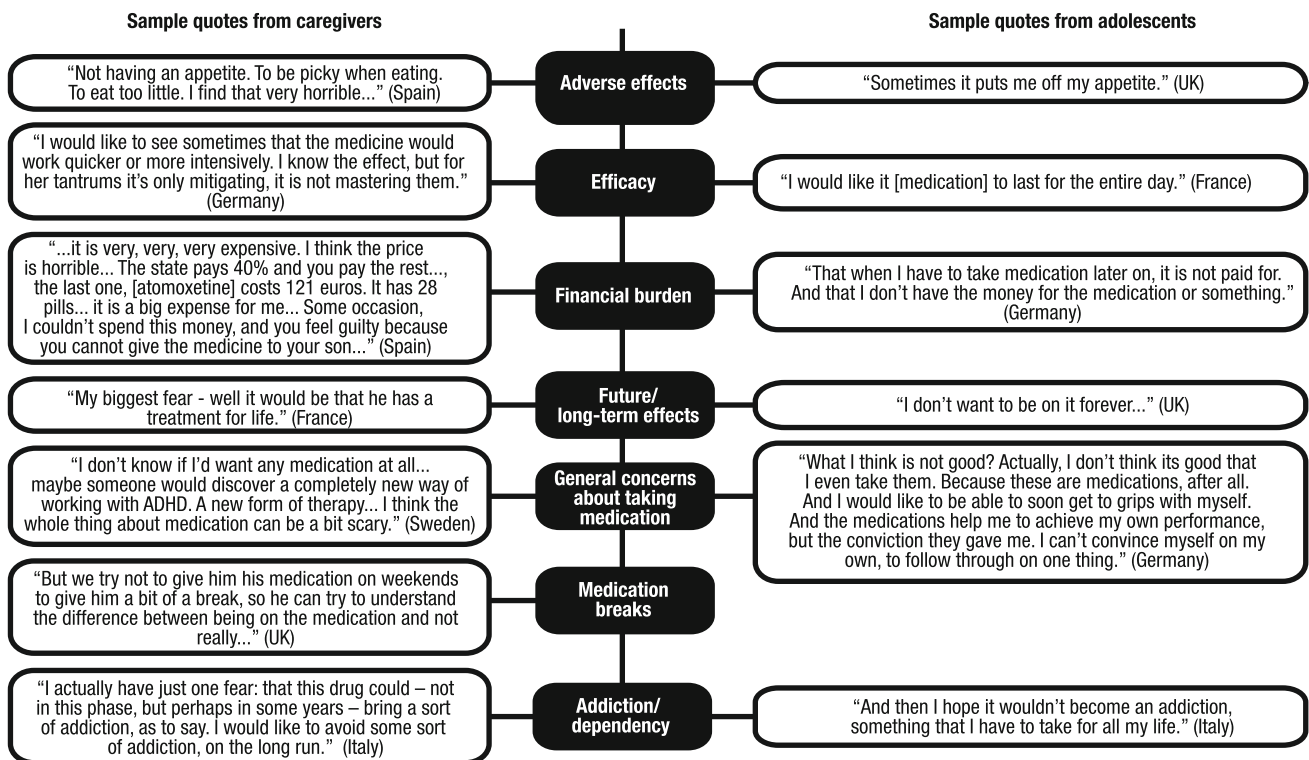
### 3.1.6 Caregiver-Specific Impacts

Caregivers of children with ADHD felt stressed and worried that their child's ADHD would negatively impact on their future ability to be successful in school and work,





**Fig. 4** Impact on family life, Adolescent and caregiver quotes regarding attention-deficit/hyperactivity disorder-related impacts on family relationships. While both the caregivers and adolescents frequently reported the ‘Relationship between caregiver/child’ and ‘Relationship between siblings’ as important impacts on family life, the caregivers frequently reported more general ‘Stress on the household’



**Fig. 5** Treatment concerns. Adolescent and caregiver quotes relating to taking attention-deficit/hyperactivity disorder medication. While caregivers were most concerned about ‘General concerns about taking medication’, ‘Future/long-term effects’, and ‘adverse effects’, the adolescents were most concerned about ‘efficacy’ and ‘adverse effects’

independent and accepted in society, and to keep off drugs and out of danger. Caregivers of younger children worried about how the disorder would present as the child became an adolescent. Some caregivers reported their child might engage in reckless or dangerous behavior, resulting in harm to themselves or others.

Nearly half (47 %) of caregivers reported that having a child/adolescent with ADHD adversely affected their social lives. Decreased socializing resulted from not being able to find a babysitter they could trust, friends and family excluding them from events because of the child's ADHD behavior(s), or the caregivers excluding themselves over concerns about their child being disruptive. Some felt these difficulties were because of others' lack of understanding of ADHD or the stigma attached to the disorder.

Caregivers' jobs and personal pursuits were also affected by their child's ADHD. About 25 % of caregivers reported having to reduce their working hours or stop working entirely to be home to care for their child/adolescent. Caregivers also had to make other sacrifices, including giving up on personal pursuits, personal time, and/or time alone with their partner.

Most caregivers (82 %) reported having to provide almost constant supervision for their child/adolescent. Caregivers had to supervise the completion of routine tasks, the child/adolescent's play and extracurricular activities, in addition to general supervision to ensure the child was safe. In general, caregivers reported feeling like they always had to be 'on alert' or 'on guard' when it came to caring for their child/adolescent and described the constant need for supervision as one of the most difficult aspects of having a child/adolescent with ADHD.

Caregivers also reported feeling exhaustion, a sense of helplessness, guilt, and feeling both emotionally and physically drained, and many (63 %) noted a need for additional support and assistance from their healthcare providers. Caregivers expressed that additional support from doctors and/or through therapy would be helpful in managing everyday issues related to their child's ADHD. Caregivers relayed a need for more government support, in areas such as social, education, and health services, and financial assistance and education for caregivers, teachers, and the general public.

### 3.2 Dyad Analysis: Caregiver vs. Adolescent Reports

A total of six caregiver/adolescent dyads completed interviews. In general, there was good agreement between adolescents and their caregivers regarding impacts of ADHD. The adolescents in the dyad group displayed self-awareness, as evidenced by the consistency of responses between caregivers and adolescents on themes related to school, medication adverse effects, and symptoms not fully

treated by the ADHD medication. The adolescents in the dyad group displayed less agreement with their caregivers with respect to accommodations made for them (e.g., extra assistance with homework or classwork); concerns, dislikes, and desired changes to ADHD medications; and reasons that past ADHD medications were stopped. Areas of discordance (i.e., where the concept was only reported by one of the individuals in the dyad) included the desire for the medication to control symptoms better (3/6 dyads were discordant), have fewer adverse effects (2/6 dyads were discordant), and last longer (2/6 dyads were discordant). In both cases of discordance for wanting fewer adverse effects, it was the adolescent who specifically reported wanting fewer adverse effects. For the other areas of discordance, no pattern emerged.

## 4 Discussion

Current ADHD treatment, pharmacologic and non-pharmacologic, is helpful but caregivers clearly report significant unmet needs with the current standard of care. This study identified concepts where unmet need might remain despite ADHD treatment for both children/adolescents with ADHD and their caregivers in the participating European countries. Current treatments help to reduce, but do not fully alleviate symptoms and have variable effectiveness over the course of the day. Persistence of symptoms may lead to underperformance and disciplinary issues at school, problems with social interactions and friendships, strained relationships among family members, and emotional issues, such as low self-esteem. Caregivers face significant burdens as well. They spend a substantial amount of time and effort helping their child manage their illness and dealing with the consequences of their child's behavior. Furthermore, caregivers of children on treatment continue to worry and feel stress, specifically with regard to potentially disruptive and dangerous behaviors, performance in school, long-term effects of medication, and their child's future. Thus, even with current management, this suggests that ADHD may impose a great burden on children/adolescents and their caregivers. This finding is consistent with the results of a caregiver survey in which children who were medicated still experienced substantial challenges, particularly with respect to family relationships [19].

A common issue reported by caregivers and adolescents alike, is that medication is generally effective only during school hours. The result is that caregivers tend to bear the brunt of the child's ADHD, outside of school hours, when the child is not medicated. Caregivers in our study reported feelings of exhaustion, helplessness, being overwhelmed because of the demands of caring for a child with ADHD,

and conflicts at home among family members related to the child's ADHD.

Despite the fact that participants reported persistent symptoms and impacts associated with ADHD, most participants acknowledged seeing a substantial difference in behavior when on versus off medication and noted that medication had improved their lives.

Adolescent interviews did not elicit any new issues that had not been elicited through the caregiver interviews. The adolescents in this sample displayed a general self-awareness of the symptoms, behaviors, and impacts associated with their ADHD, recognizing, for example, their challenges with social interactions and the fact that their ADHD impacts their family. This is contrary to other studies, which have demonstrated that adolescents are in general less self-aware of issues with peer and family interactions [20].

While studies related to patient and caregiver burdens associated with ADHD have been conducted, there is limited literature exploring this burden while the patient is on treatment. Nevertheless, a few studies support the findings seen here. A Swedish study conducted by Svanborg and colleagues [21] explored the impact of treatment on patient and family coping and found that, although atomoxetine benefited children in some areas, it failed to improve patients' self-image and caregivers' perceptions regarding family dynamics. Two recent studies support our finding that having a child with ADHD impacts family relationships [14, 15]. Both studies report that caregivers of a child with ADHD are more likely to divorce than those without. A recent UK study to explore correlates of caregiver unmet needs for those caring for adolescents and young adults with ADHD found that the domains most associated with caregiver burden were depression/anxiety and inappropriate behavior [13].

In addition to unmet needs related to symptom control, caregivers commonly reported a lack of support and understanding from school, the health system, and/or the community at large. Some expressed frustration regarding the lengthy diagnosis process, as well as having limited access to healthcare or support services.

Our study findings suggest that comprehensive care plans that include patient and caregiver support from the education and healthcare systems and additional counseling alongside pharmacologic management result in better, more consistent, and longer-lasting symptom control that may help reduce the negative quality of life impact on children/adolescents and caregivers.

This study has some limitations. The participants were volunteers recruited through patient panels and may not be representative of the entire ADHD population in the selected countries. While the goal of concept elicitation is to reach information saturation, which we attained for the

sample overall, we did not assess saturation at the country level as sample sizes per country were generally small. Thus, we were unable to draw conclusions regarding potential country-specific differences relating to unmet needs, rather just the overall concepts across these eight countries. Additionally, as ADHD is a highly comorbid disorder, this study is also limited because of the exclusion of children and adolescents with severe comorbidities that could have a major impact on their quality of life, such as schizophrenia or bipolar disorder. While our sample may not be generalizable to the ADHD population with comorbidities, it was our desire to focus on unmet needs specifically related to ADHD without the influence and confounding effects of other disorders. With this goal in mind, having any comorbid condition was initially a criterion for exclusion; however, owing to difficulties in meeting recruitment targets, this criterion was relaxed prior to initiating any interviews. Inclusion priority was then given to patients with no, few, or less severe comorbid conditions, such as learning disorders, speech disorders, sleep disorders, or oppositional defiant disorder. In our study population, six (21 %) adolescents and 16 (42 %) children of the caregivers sample did have comorbidities. In these cases, we requested that participants focus only on impacts associated with ADHD, but they may have had difficulty attributing specific impacts to ADHD vs. their other conditions. It is likely that children and young people with severe and complex comorbidities have even greater unmet needs.

## 5 Conclusions

Available ADHD treatments in the EU have been shown as effective at reducing symptoms and improving the lives of children/adolescents and their caregivers. However, some patients and their caregivers in this study described areas of unmet need, despite receiving treatment in many cases. In this sample, the impact in children/adolescents was most notable with regard to school performance and interpersonal relationships. For caregivers, the demands and stress associated with raising a child with ADHD take a toll on relationships with family members and friends, as well as their career. Caregivers also worried about the implications of long-term pharmacologic treatment as well as about their child's future well-being and ability to be successful in life. Caregivers reported a general lack of education and support within their communities, and they expressed a desire for additional support from the healthcare community in managing their child's condition and coping with everyday life. Service providers should consider ways of using more comprehensive multimodal treatments to potentially reduce the negative impacts of ADHD.

Based on the interview findings, the web-based Caregiver Perspective on Paediatric ADHD (CAPP) survey has been developed. CAPP will aim to validate and quantify the findings of this study among a larger sample and to further understand the impacts on children/adolescents with ADHD and their caregivers in several European countries. The ultimate aim will be to more broadly and quantitatively collect, understand, and analyze the burden of ADHD to potentially inform providers of how patient care can be improved and to minimize the impact of ADHD on the lives of children/adolescents and their caregivers, whether through additional and/or more effective treatments, further caregiver and community education, or more community support. While many of the issues faced by caregivers and their children with ADHD may not have easy solutions, information gathered through the CAPP study may shed light on what steps can and should be taken to improve the quality of life of these patients and their caregivers. The insights provided by CAPP regarding the perceived needs of patients and caregivers may improve patient/caregiver and provider communication and facilitate the identification of new solutions to optimize the provision of care.

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**Ethical Standards** Each participant provided the appropriate informed verbal consent and/or assent approved for the study. The study was reviewed and approved by a central institutional review board (IRB), MaGil IRB, Rockville, MD, USA and was performed in accordance with the ethical standards laid down in the 1964 (and later amendments) Declaration of Helsinki.

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## References

- Polanczyk G, Silva de Lima M, Horta BL, Biederman J, Rohde LA. The worldwide prevalence of ADHD: a systematic review and metaregression analysis. *Am J Psychiatry*. 2007;164:942–8.
- Preuss U, Ralston SJ, Baldrusson G, Falissard B, Lorenzo MJ, Rodrigues Pereira R, et al. Study design, baseline patient characteristics and intervention in a cross-cultural framework: results from the ADORE study. *Eur Child Adolesc Psychiatry*. 2006;15(Suppl 1):14–14.
- Taylor E, Dopfner M, Sergeant J, Asherson P, Banaschewski T, Buitelaar J, et al. European clinical guidelines for hyperkinetic disorder: first upgrade. *Eur Child Adolesc Psychiatry*. 2004;13(Suppl 1):7–30.
- Health Ministry of Spain. Guía de Práctica Clínica sobre el Trastorno por Déficit de Atención con Hiperactividad (TDAH) en Niños y Adolescentes. Available at: <http://www.anhpa.com/Documentos/Guiaclinica.pdf>. Accessed 2 Aug 2013.
- NICE (National Institute for Health and Clinical Excellence). Clinical Guidance 72. Attention deficit hyperactivity disorder (ADHD): diagnosis and management of ADHD in children, young people and adults. Available at: <http://www.nice.org.uk/nicemedia/live/12061/42059/42059.pdf>. Accessed 2 Aug 2013.
- Seixas M, Weiss M, Müller U. Systematic review of national and international guidelines on attention-deficit hyperactivity disorder. *J Psychopharmacol*. 2012;26:753–65.
- Coghill D. The impact of medications on quality of life in attention-deficit hyperactivity disorder: a systematic review. *CNS Drugs*. 2010;24:843–66.
- Danckaerts M, Sonuga-Barke EJ, Banaschewski T, Buitelaar J, Dopfner M, Hollis C, et al. The quality of life of children with attention deficit/hyperactivity disorder: a systematic review. *Eur Child Adolesc Psychiatry*. 2010;19:83–105.
- Escobar R, Soutullo CA, Hervas A, Gastaminza X, Polavieja P, Gilaberte I. Worse quality of life for children with newly diagnosed attention-deficit/hyperactivity disorder, compared with asthmatic and healthy children. *Pediatrics*. 2005;116:e364–9.
- Staikova E, Gomes H, Tartter V, McCabe A, Halperin JM. Pragmatic deficits and social impairment in children with ADHD. *J Child Psychol Psychiatry*. 2013;54:1276–83.
- Varni JW, Burwinkle TM. The PedsQL™ as a patient-reported outcome in children and adolescents with attention-deficit/hyperactivity disorder: a population-based study. *Health Qual Life Outcomes*. 2006;4:26.
- Harpin VA. The effect of ADHD on the life of an individual, their family, and community from preschool to adult life. *Arch Dis Child*. 2005;90(Suppl 1):i2–7.
- Cadman T, Eklund H, Howley D, Hayward H, Clarke H, Findon J, et al. Carer burden as people with autism spectrum disorder and attention-deficit/hyperactivity disorder transition into adolescence and adulthood in the United Kingdom. *J Am Acad Child Adolesc Psychiatry*. 2012;51:879–88.
- Kvist AP, Nielsen HS, Simonsen M. The effects of children's ADHD on parents' relationship dissolution and labor supply. Available at: [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1958748](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1958748). Accessed 2 Aug 2013.
- Wymbs BT, Pelham WE, Molina BS, Gnagy EM, Wilson TK, Greenhouse JB. Rate and predictors of divorce among parents of youths with ADHD. *J Consult Clin Psychol*. 2008;76:735–44.

16. Brinkman WB, Sherman SN, Zmitrovich AR, Visscher MO, Crosby LE, Phelan KJ, et al. In their own words: adolescent views on ADHD and their evolving role managing medication. *Acad Pediatr*. 2012;12:53–61.
17. FDA (Food and Drug Administration). Guidance for industry: patient-reported outcome measures: use in medical product development to support labeling claims. December 2009. Available at: <http://www.fda.gov/downloads/Drugs/Guidances/UCM193282.pdf>. Accessed 10 July 2014.
18. Joffe H, Yardley L. Content and thematic analysis. In: Marks DF, Yardley L, editors. *Research methods for clinical and health psychology*. London: Sage; 2004. p. 56–68.
19. Coghill D, Soutullo C, D'Aubuisson C, Preuss U, Lindback T, Silverberg M, et al. Impact of attention-deficit/hyperactivity disorder on the patient and family: results from a European survey. *Child Adolesc Psychiatry Ment Health*. 2008;2:31.
20. Factor PI, Rosen PJ, Reyes RA. The relation of poor emotional awareness and externalizing behavior among children with ADHD. *J Atten Disord*. 2013 [Epub ahead of print].
21. Svanborg P, Thernlund G, Gustafsson PA, Hägglöf B, Schacht A, Kadesjö B. Atomoxetine improves patient and family coping in attention deficit/hyperactivity disorder: a randomized, double-blind, placebo-controlled study in Swedish children and adolescents. *Eur Child Adolesc Psychiatry*. 2009;18:725–35.