Title: **QUALITY OF LIFE IN PERINATALLY HIV INFECTED CHILDREN IN EUROPE**

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**FINAL REPORT**

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Member state: Italy

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SUMMARY

The present project aimed to focus globally on the lives of children and adolescents with HIV infection in Europe and to understand how they cope with this chronic infection. For this purpose, eight centres co-operated which were involved in clinical care and/or epidemiological and clinical research on paediatric HIV infection at five European countries. A short questionnaire investigating the clinical, social and psychological issues was drawn. The questionnaire was conceived clear and concise to have a good “level of reply”. The questionnaire (originally in English) have been distributed to the participating centres and translated into Italian, Spanish, German and Swedish. Questionnaires filled in by clinicians and by parents/guardians were returned to the co-ordinating centres in Florence and London. Questionnaires were checked, data were input in a database specifically designed and, subsequently, they were analysed.

A total of 224 children were enrolled from the eight centres in the study. 151 children were living with their biological families (that is, excluding those living with adoptive or foster parents). Among the 151 children living with their biological families, more than three-quarters had at least one, and 28% had at least two other HIV-infected family members at the time of the survey. A total of 32% children had experienced an HIV-related death in their immediate family: their mother had died in 56% cases, both parents in 21%, their father in 17%, their mother and a sibling in 6%.

Overall, 45% of children were reported to be aware that they were HIV infected, with a median age of 10 years at the time of this disclosure. Disclosure of infection status significantly increased with increasing age of children ($\chi^2=50.7$, $p=<0.002$). Most schools or nurseries had not been informed of the HIV infection status of the child. In the other cases, more often the head teacher only had been informed.

Analysis of HIV-related characteristics of children shows that, although approximately two-thirds of children had progressed to moderate to severe HIV disease (CDC clinical stage B or C) at some stage during their follow-up, a quarter of these children had no current symptoms, and a
further quarter were only currently experiencing mild symptoms relating to the HIV disease. A total of 25 children had been admitted to hospital for at least one night in the 6 months prior to the questionnaire being completed. Hospitalisation was significantly associated with current CDC clinical staging.

Most children were currently on highly active antiretroviral therapy (HAART) regimens, and most had been on antiretroviral treatment (ART) for at least six years. A quarter of children were taking more than 10 pills a day, at the time of survey. With regard to children and adolescents with side effects from their ART, the most commonly reported side effects were rash, nausea, vomiting and/or diarrhoea and lipodystrophy. There was a strong association between duration of ART and likelihood of having had side effects. Similarly, there was a significant association between lifetime number of ART regimens and the likelihood of having experienced an ART-associated side effect. Parents or guardians were asked to provide an approximate indication of the extent to which the child adhered to their antiretroviral medication. Results shows a very high overall reported adherence, but with a trend towards lesser adherence with increasing age of the child/adolescent.

More than half of the parents/guardians surveyed felt that their child’s antiretroviral medication interfered in their everyday life, although this was mainly seen as a slight interference. Factors associated with this perception were the child’s age, with older adolescents at increased likelihood, and ethnicity, with parents/carers of black children more likely to report interference. Therefore, our investigation have shown that, even if HIV infection is now a chronic illness in developed countries such as western Europe, strategies to improve adherence to therapy among adolescents have to be undertaken. Moreover, cultural differences in acceptance of therapy may need an intercultural approach.

Dissemination of results will be increased by distribution of a leaflet (in five languages) thought to raise sensibilization among young people in favour of HIV-infected young people.
**Aims** of the present project were to evaluate quality of life of HIV-infected children and adolescents in Europe. For this purpose, eight centres working in clinical care and/or epidemiological and clinical research on HIV infection in the paediatric age at five European countries, were involved. The two co-ordinating centres in Florence and in London have been respectively the co-ordinators of the Italian Register for HIV Infection in Children and of the European Collaborative Study for a long-time.

Participating centres are listed in table 1 of the Appendix. The clinical centre at *St. Mary’s Hospital – Imperial College, London*, due to internal problems, abandoned the project, while a new clinical centre, (*Unit of Immunology and Infectious Diseases, Bambino Gesù Children’s Hospital, Rome*), was involved.

**During the first year** of the present project a first result was achieved preparing a questionnaire suitable for the evaluation of quality of life in HIV-infected children, as stated at the point 1 of the project aims. The two coordinating centres in Florence and London designed and developed the questionnaire with the competence of a paediatrician, an epidemiologist, two psychologists and a social worker.

Questionnaires were differentiated according to age. Copies of these questionnaires (English and Italian version) have already been presented in the first project report.

To validate them, these questionnaires were administered to a subset of 80 children in three different centres (out of seven participant clinical centres). Preliminary results (already reported) indicated that this questionnaire is globally a good tool to discriminate clinical condition basing on quality of life scores.

**During the second year** of the present project, preliminary results were critically discussed with all participating centres to decide how to proceed with the investigations.
Preliminary results had shown that the questionnaire results (and resulting quality of life scores) allowed to distinguish between children with mild to moderate clinical condition and children with severe clinical condition in the 5-11 years age-group, but not in other age-groups. As a matter of fact, scores reached in children <4 years and >12 years were not significantly correlated with clinical condition. We concluded that, probably, the questionnaire was not so effective in describing the relationship between HIV-related clinical condition and quality of life in the extreme age-groups. Moreover, sometimes questionnaires seemed to be too long and complex to fill in and to be well accepted by some parents/carers. As a matter of fact, in Europe, parents/carers of HIV-infected children (as other chronically affected children) are too often required to fill in questionnaires, particularly when their child is enrolled in clinical trials and this can be annoying to them. Hence the need to devise effective ways of administering this type of questionnaire to have a good “level of reply”.

The two co-ordinating centres in Florence and London and the participating centres aimed to focus globally on the lives of children with perinatal HIV infection in Europe and to understand how they cope with this chronic infection. This has been achieved by drawing up a shorter questionnaire investigating again the clinical, social and psychological issues.

These questionnaires have to be used also after the end of the present study as a complement of clinical assessment.

Therefore, the original questionnaire was consistently modified. The new questionnaire differs from the original as follows:

1. it is more clear and concise
2. initials, birth-date, clinical data and hospital patient identifier are separately written in a form completed by the health care provider. The parent's form,
labelled with hospital patient identifier in the top right corner of pages, is returned in a blank envelope directly to the co-ordinating centres in Florence and in London. This measure will ensure to the parents more privacy and leave them free in answering to the items.

3. Because highly active antiretroviral treatment (HAART) has consistently modified survival and clinical outcome of HIV-infected children, clinical staging according to CDC classification system was recorded both referring both to the most severe clinical feature (maximum CDC stage) and to current clinical features (current CDC stage). We believe that this may more properly describe current conditions of children and adolescents.

4. Only one version for all the age groups was performed. Some items concerning way of life, plays and activities are presented more generally and they can be referred to children/adolescents of any age. This arrangement is intended to prevent misleading replies by children in borderline ages.

5. Some items concerning acceptability of antiretroviral treatment (ART) were added. In industrialised countries, where availability of therapy has undoubtedly modified the clinical course of HIV infection, problems are emerging about compliance in assuming therapy, particularly in the adolescent age. The co-ordinating centres feel that, at present, in order to be effective, a questionnaire on quality of life has to explore this issue.

The new questionnaires (originally in English) have been distributed to the seven participating clinical centres and translated into Italian, Spanish, German and Swedish.
During the third year of the present project, the new questionnaire was administered to children and adolescents at the seven clinical centres. Questionnaires filled in by clinicians and by parents/guardians were returned to the co-ordinating centres in Florence and London. Questionnaires were checked and, thereafter, data were input in a database specifically designed at the co-ordinating centre of London. Subsequently, they were analysed and preliminary results were obtained.

These results were presented and discussed during an apposite meeting which took place in Florence, on December 1st 2003. Participants to the meeting are listed in table 2 of the Appendix. In this meeting preliminary results were discussed and suggestions for further analyses were collected.

Moreover, to wider spread the results, printing of a leaflet containing some results was planned. The purpose was to increase knowledge of feelings of children and adolescents living with HIV infection among young people, taking the occasion to remind how HIV infection may be prevented. The leaflet has been translated in the five languages of the countries engaged in the project. Thereafter, the leaflet will be distributed among young people in schools and communities.

Case definition and statistical analysis
Clinical HIV-1 stage was classified according to the recommendations by the Centres for Disease Control and Prevention (CDC). We defined “maximum CDC stage” as the most severe clinical feature ever occurred in the life of each child (according to CDC criteria) and “current CDC stage” clinical features in the last year. Plasma viral load was measured quantitatively by means of the Amplicor HIV Monitor Test (Roche Diagnostic System, Inc., Branchburg, NJ) and results are expressed as log10 HIV-1 RNA copies/mL. CD4+ T-lymphocyte counts were measured using the standardised
fluorescent-activated cell sorting technique. According to the USA guidelines for the use of antiretroviral agents in paediatric HIV infection, CD4+ T-lymphocyte percentages, rather than their absolute counts, were taken into account as these percentages reflect the immune status of HIV infected children more accurately. Age and duration of treatment were expressed as median and range. Differences in proportions were evaluated by $\chi^2$ square test. Logistic regression models were used to estimate crude odds-ratios (OR).

**Children and Adolescents Living with HIV infection in Europe**

**Results**

A total of 224 children were enrolled from the eight centres in the study. With regard to the parent/guardian part of the questionnaire, 102 were completed by the child’s mother, 30 by their father, 16 by a grandparent, 13 by an aunt or uncle, 28 by a foster parent, 23 by an adoptive parent, 1 by the infected adolescent themselves, and 11 by another person.

**Description of the population**

The socio-demographic characteristics of the infected children and adolescents are presented in Table 1, and their HIV-related characteristics in Table 2. With regard to the CDC clinical staging of the children, Figure 1 shows how the child’s maximum CDC staging relates to their current clinical status. Although approximately two-thirds of children had progressed to moderate to severe HIV disease (CDC clinical stage B or C) at some stage during their follow-up, a quarter of these children had no current
symptoms, and a further quarter were only currently experiencing mild symptoms relating to the HIV disease.

Most children were currently on HAART regimens, and most had been on ART for at least six years (Table 3). With regard to the 59 children and adolescents with side effects from their ART, the most commonly reported side effects were rash (n=15), nausea, vomiting and/or diarrhoea (n=13) and lipodystrophy (n=11). There was a strong association between duration of ART and likelihood of having had side effects: 27% (8/29) and 26% (12/46) children on ART for less than 3 years and 3-5 years respectively had experienced side effects relating to their treatment, increasing to 32% (16/50) for durations of ART of 6-8 years and 47% (21/45) for durations of 9 or more years ($\chi^2=3.91$, p=0.048). Similarly, there was a significant association between lifetime number of ART regimens and the likelihood of having experienced an ART-associated side effect, with 78% (14/18) children with at least six changes having had at least one side effect compared with 27% (44/161) of those with fewer changes ($\chi^2=18.8$, p<0.002).

Impact of HIV infection on everyday life

HIV infection in other family members

A total of 202 children were vertically infected with HIV, thus the prevalence of HIV-infection among other family members was high in the surveyed population. However, information on the prevalence of HIV infection among the child’s family members at the time of the survey was also sought, as there may have been changes over time (in particular, the death of infected parents). Information was available for 151 children who were living with their biological families (that is, excluding those living with
adoptive or foster parents). In 34 (23%) of these 151 families, the child in the survey was currently the only HIV-infected member of the family: six of these children had acquired HIV infection through contaminated blood or blood products, one had unknown mode of acquisition, and in the remaining cases either the mother (n=18) or the mother and father (n=8) had been HIV-infected but had died. In the remaining 117 families where at least one other living family member was also HIV-infected, this was most commonly the mother (n=66, 54%), although in 37 (32%) families both the mother and the father were infected, in 8 the father was infected and in the remaining six families one or both parents and a sibling were also infected. Thus, of the 151 children living with their biological families, more than three-quarters had at least one, and 28% (43/151) had at least two other HIV-infected family members at the time of the survey.

A total of 72 (32%) children were had experienced an HIV-related death in their immediate family: their mother had died in 40 (56%) cases, both parents in 15 (21%), their father in 12 (17%), their mother and a sibling in 4 (6%), and a stepfather in one case. Figure 2 shows the social care settings of the 58 children whose mothers had died. Information on the children’s ages at the time of their mother’s death was available for 42 children: 3 (7%) were aged less than one year at the time of their mothers death, 21 (50%) aged 1-5 years, 13 (31%) aged 6-10 years and 5 (12%) were aged 11-15 years. Nineteen (33%) of the mothers who died were from Africa and three (5%) were from South America, with the remainder from Western Europe.

Disclosure

Overall, 98 children were reported to be aware that they were HIV infected (45% of the 216 with this question completed), with a median age of 10 years at the time of this
Disclosure. Disclosure of infection status significantly increased with increasing age of children \((\chi^2=50.7, \ p=0.002)\) (Figure 3). There were no significant associations between the child’s gender, current health status, ethnicity or care setting and disclosure in univariable analysis.

Hospitalisation

A total of 25 children had been admitted to hospital for at least one night in the 6 months prior to the questionnaire being completed, for a median stay of 4 days (range, 1 to 28 days). Hospitalisation was significantly associated with current CDC clinical staging, with 10% (2/20) hospitalised children having no symptoms (N), 30% (6/20) class A symptoms, 30% (6/20) class B symptoms and 30% (6/20) class C symptoms, compared to 32% (59/182), 38% (69/182), 17% (31/182) and 13% (23/182) respectively of non-hospitalised children \((\chi^2_{\text{trend}}=8.55, \ p=0.0035)\). Only 12% (3/25) of the hospitalised children had undetectable plasma viral loads (i.e. below 50 copies/ml), significantly more of the non-hospitalised children had undetectable virus (57/173, 33%) \((\chi^2=4.52, \ p=0.034)\).

School

Most children in the survey attended school or a nursery or day care setting (Figure 4). In the youngest age group (children aged <6 years), three children were looked after at home and did not attend any nursery or day care setting and 1 child was living in an institution. In the oldest age group, two subjects were working, one was at university and one had left school. Most schools or nurseries had not been informed of the HIV infection status of the child, and the prevalence of disclosure varied somewhat (but not statistically significantly) by age: schools and nurseries of younger children were more
likely to have been informed that those of older children (Figure 5). Of the 87 children whose schools or nursery/creche had been informed of their HIV infection status, in 41 (47%) of cases the head teacher only had been informed, in 13 (15%) the class teacher only, and in 30 (34) cases a combination of people, including the school doctor or school nurse (no information provided for 3 cases) and/or teaching staff. In Sweden there were several cases where the schools had been informed that there was an HIV-infected child attending, but this was done anonymously, i.e. the actual child was not specified. Thirty children were reported to be receiving or to have received additional help at school (median age 8 years). This included assistance from support teachers, extra support in a smaller group of children, additional classes, occupational therapy, speech therapy, extra home tuition and extra language assistance for migrant children. A total of 48 children had missed school due to ill health on a total of 50 occasions in the month preceding the survey. The length of absence was provided for 40 occasions, with a median of 3 days (range, 1 to 31 days). The most common reason for school absence was cold/cough/influenza (11 cases).

Impact of antiretroviral therapy on everyday life

Most children were currently receiving a HAART regimen, and a quarter of children were taking more than 10 pills a day (Figure 6). Parents or guardians were asked to provide an approximate indication of the extent to which the child adhered to their antiretroviral medication. This information is presented in Figure 7, classed by age group of the child, and shows a very high overall reported adherence, but with a trend towards lesser adherence with increasing age of the child/adolescent.
More than half of the parents and guardians surveyed felt that their child’s antiretroviral medication interfered in their everyday life, although this was mainly seen as a slight interference (Figure 8). Whether ART was perceived as interfering in the child or adolescent’s everyday life was associated with several socio-demographic factors including the age of the child, with older adolescents at increased likelihood, and ethnicity, with parents/carers of black children more likely to report interference (Table 4). Predictive factors relating to the ART itself include the child having to take more than 10 pills per day, a large number of lifetime ART regimen changes, and experience of side effects relating to ART. To further explore the ethnicity association, the interference variable was stratified by type of carer, with parents classified by their ethnic origin (figures 9a and b).

General health status

Figure 10 presents the parents’ and guardians’ perceptions of the general health status of the infected child. To explore predictive factors for some children being perceived as less well than others, this variable was re-classified dichotomously into “less well” children, classified as those whose parents put them in any group other than the “generally well” category, and “well” children. Predictive factors for being classified as “less well” by parent or carer from univariable logistic regression analysis were absence from school in the past month, hospitalisation in the past 6 months (Table 5). None of the following characteristics were associated with a child being classified as being ‘less well’: gender, age, ethnic group, CD4 percentage, duration of ART. There was a slightly higher proportion of less well children with moderate to serious HIV disease compared to those seen as “generally well” (42% versus 32%) but this did not reach statistical significance (see table). Similarly, there was a non-significant trend towards a higher
likelihood of “less well” health status with increasing number of treatment changes the
child had accrued: for example, 8% (3/36) of children with no treatment changes were
classified as less well, increasing to 12% (6/73) for those with three to five changes, and
17% (3/18) for those with six more regimen changes.
Table 1
Socio-demographic characteristics

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong> n=213</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median</td>
<td>10.7 years</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>10 months-20 years</td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong> n=213</td>
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<td></td>
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<tr>
<td>Male</td>
<td>94</td>
<td>(44)</td>
</tr>
<tr>
<td>Female</td>
<td>119</td>
<td>(56)</td>
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<tr>
<td><strong>Ethnicity</strong> n=217</td>
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<tr>
<td>White</td>
<td>155</td>
<td>(71)</td>
</tr>
<tr>
<td>Black</td>
<td>50</td>
<td>(23)</td>
</tr>
<tr>
<td>Other</td>
<td>12</td>
<td>(6 )</td>
</tr>
<tr>
<td><strong>Area of birth</strong> n=211</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Western Europe</td>
<td>162</td>
<td>(77)</td>
</tr>
<tr>
<td>Central / Eastern Europe</td>
<td>15</td>
<td>(7 )</td>
</tr>
<tr>
<td>Africa</td>
<td>29</td>
<td>(14)</td>
</tr>
<tr>
<td>South America</td>
<td>3</td>
<td>(1 )</td>
</tr>
<tr>
<td>Asia / S.E. Asia</td>
<td>2</td>
<td>(1 )</td>
</tr>
<tr>
<td><strong>Maternal area of birth</strong> n=211</td>
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<td></td>
</tr>
<tr>
<td>Western Europe</td>
<td>131</td>
<td>(62)</td>
</tr>
<tr>
<td>Central / Eastern Europe</td>
<td>14</td>
<td>(7 )</td>
</tr>
<tr>
<td>Africa</td>
<td>53</td>
<td>(25)</td>
</tr>
<tr>
<td>South America</td>
<td>9</td>
<td>(4 )</td>
</tr>
<tr>
<td>Asia / S.E. Asia</td>
<td>4</td>
<td>(2 )</td>
</tr>
<tr>
<td><strong>Social care setting</strong> n=222</td>
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<td></td>
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<tr>
<td>Parent(s)</td>
<td>137</td>
<td>(62)</td>
</tr>
<tr>
<td>Grandparent(s)</td>
<td>17</td>
<td>(8 )</td>
</tr>
<tr>
<td>Other family</td>
<td>13</td>
<td>(6 )</td>
</tr>
<tr>
<td>Foster parents</td>
<td>29</td>
<td>(13)</td>
</tr>
<tr>
<td>Adoptive parents</td>
<td>23</td>
<td>(10)</td>
</tr>
<tr>
<td>Institution</td>
<td>2</td>
<td>(1 )</td>
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<tr>
<td>Lives independently</td>
<td>1</td>
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Table 2
HIV-related characteristics

<table>
<thead>
<tr>
<th>Mode of acquisition (n=222)</th>
<th>N</th>
<th>(%)</th>
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</thead>
<tbody>
<tr>
<td>Mother-to-child transmission</td>
<td>202</td>
<td>(91)</td>
</tr>
<tr>
<td>Blood transfusion / products</td>
<td>9</td>
<td>(4 )</td>
</tr>
<tr>
<td>Nosocomial transmission</td>
<td>1</td>
<td>(0.5)</td>
</tr>
<tr>
<td>Intra-familial transmission</td>
<td>1</td>
<td>(0.5)</td>
</tr>
<tr>
<td>Unknown*</td>
<td>9</td>
<td>(4 )</td>
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<table>
<thead>
<tr>
<th>Current CDC stage (n=210)</th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>N - not symptomatic</td>
<td>66</td>
<td>(31)</td>
</tr>
<tr>
<td>A – mildly symptomatic</td>
<td>76</td>
<td>(36)</td>
</tr>
<tr>
<td>B – moderately symptomatic</td>
<td>38</td>
<td>(18)</td>
</tr>
<tr>
<td>C – severely symptomatic</td>
<td>30</td>
<td>(14)</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>Maximum CDC stage (n=198)</th>
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<tbody>
<tr>
<td>N</td>
<td>16</td>
<td>(8 )</td>
</tr>
<tr>
<td>A</td>
<td>48</td>
<td>(24)</td>
</tr>
<tr>
<td>B</td>
<td>75</td>
<td>(38)</td>
</tr>
<tr>
<td>C</td>
<td>59</td>
<td>(30)</td>
</tr>
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<table>
<thead>
<tr>
<th>Current CD4 percentage (n=224)</th>
<th></th>
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<tbody>
<tr>
<td>≥ 25%</td>
<td>16</td>
<td>(7 )</td>
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<tr>
<td>15-24%</td>
<td>54</td>
<td>(26)</td>
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<tr>
<td>&lt;15%</td>
<td>141</td>
<td>(67)</td>
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<table>
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<tr>
<th>Current HIV RNA load n=204</th>
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<tbody>
<tr>
<td>Median (max)</td>
<td>400</td>
<td>(813,000)</td>
</tr>
<tr>
<td>&lt;50 copies/ml</td>
<td>61</td>
<td>(30)</td>
</tr>
</tbody>
</table>

* 2 from Romania, 2 from Italy, 5 from endemic areas
### Table 3  Antiretroviral therapy use

<table>
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<tr>
<th>Antiretroviral therapy (n=221)</th>
<th>N</th>
<th>(%)</th>
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<tbody>
<tr>
<td>Never treated</td>
<td>20</td>
<td>(9)</td>
</tr>
<tr>
<td>Prior but not current ART</td>
<td>4</td>
<td>(2)</td>
</tr>
<tr>
<td>Current but no details</td>
<td>9</td>
<td>(4)</td>
</tr>
<tr>
<td>Dual therapy</td>
<td>16</td>
<td>(7)</td>
</tr>
<tr>
<td>HAART</td>
<td>172</td>
<td>(78)</td>
</tr>
<tr>
<td>3 drugs</td>
<td>123</td>
<td></td>
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<tr>
<td>4+ drugs</td>
<td>49</td>
<td></td>
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<table>
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<tr>
<th>Number of changes to ART regimen (n=189)</th>
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<tbody>
<tr>
<td>None</td>
<td>37</td>
<td>(20)</td>
</tr>
<tr>
<td>1-2</td>
<td>74</td>
<td>(39)</td>
</tr>
<tr>
<td>3-5</td>
<td>60</td>
<td>(32)</td>
</tr>
<tr>
<td>6+</td>
<td>18</td>
<td>(9)</td>
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<table>
<thead>
<tr>
<th>Age at initiation of ART (n=173)</th>
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<tbody>
<tr>
<td>Median</td>
<td>2.9</td>
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<tr>
<td>Interquartile range</td>
<td>11 months - 6.7 years</td>
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<table>
<thead>
<tr>
<th>Duration of any ART (n=173)</th>
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<tbody>
<tr>
<td>Median</td>
<td>6.3</td>
<td></td>
</tr>
<tr>
<td>Interquartile range</td>
<td>4.2-9.2 years</td>
<td></td>
</tr>
<tr>
<td>&lt; 3 years</td>
<td>31</td>
<td>(17)</td>
</tr>
<tr>
<td>3-5 years</td>
<td>50</td>
<td>(28)</td>
</tr>
<tr>
<td>6-8 years</td>
<td>50</td>
<td>(28)</td>
</tr>
<tr>
<td>≥9 years</td>
<td>47</td>
<td>(26)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Duration of current ART regimen</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Median</td>
<td>1.5</td>
<td></td>
</tr>
<tr>
<td>Interquartile range</td>
<td>6 months – 3 years</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>ART side effects (n=183)</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>124</td>
<td>(68)</td>
</tr>
<tr>
<td>Yes</td>
<td>59</td>
<td>(32)</td>
</tr>
</tbody>
</table>
Table 4: Factors associated with reported interference of ART with everyday life.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Any interference with everyday life*</th>
<th></th>
<th>Odds ratio (95% CI) for positive findings</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No (N (%))</td>
<td>Yes (N (%))</td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>N (%)</td>
<td>N (%)</td>
<td></td>
</tr>
<tr>
<td>&lt;6 years</td>
<td>14 (47)</td>
<td>16 (53)</td>
<td></td>
</tr>
<tr>
<td>6-9 years</td>
<td>21 (47)</td>
<td>24 (53)</td>
<td></td>
</tr>
<tr>
<td>10-14 years</td>
<td>30 (41)</td>
<td>43 (58)</td>
<td></td>
</tr>
<tr>
<td>≥15 years</td>
<td>10 (28)</td>
<td>26 (72)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>χ^2=3.60, p=0.3</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ethnic group of child</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>59 (41)</td>
<td>84 (59)</td>
<td>1.00</td>
</tr>
<tr>
<td>Black</td>
<td>10 (29)</td>
<td>24 (71)</td>
<td>1.69 (0.75-3.79) ns</td>
</tr>
<tr>
<td>Other</td>
<td>8 (80)</td>
<td>2 (20)</td>
<td>0.18 (0.04-0.86) p=0.03</td>
</tr>
<tr>
<td></td>
<td><strong>χ^2=8.17, p=0.017</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Boys</td>
<td>27 (34)</td>
<td>53 (66)</td>
<td></td>
</tr>
<tr>
<td>Girls</td>
<td>47 (46)</td>
<td>55 (54)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>χ^2=2.81, p=0.09</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carer competing question</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biological parent</td>
<td>44 (41)</td>
<td>63 (59)</td>
<td></td>
</tr>
<tr>
<td>Other family member</td>
<td>13 (50)</td>
<td>13 (50)</td>
<td></td>
</tr>
<tr>
<td>Foster parent</td>
<td>13 (59)</td>
<td>9 (41)</td>
<td></td>
</tr>
<tr>
<td>Adoptive parent</td>
<td>5 (26)</td>
<td>14 (74)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>1 (11)</td>
<td>8 (89)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>χ^2=8.81, p=0.07</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Duration of ART</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 3 years</td>
<td>12 (40)</td>
<td>18 (60)</td>
<td></td>
</tr>
<tr>
<td>3-5 years</td>
<td>23 (50)</td>
<td>23 (50)</td>
<td></td>
</tr>
<tr>
<td>6-8 years</td>
<td>19 (39)</td>
<td>30 (61)</td>
<td></td>
</tr>
<tr>
<td>≥9 years</td>
<td>15 (33)</td>
<td>30 (67)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>χ^2=1.14, p=0.29</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of pills per day</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≤ 5</td>
<td>41 (55)</td>
<td>33 (45)</td>
<td>1.00</td>
</tr>
<tr>
<td>6-10</td>
<td>26 (37)</td>
<td>45 (63)</td>
<td>1.67 (0.82-3.41) ns</td>
</tr>
<tr>
<td>≥11</td>
<td>10 (26)</td>
<td>28 (74)</td>
<td>2.70 (1.10-6.61) p=0.03</td>
</tr>
<tr>
<td></td>
<td><strong>χ^2=9.77, p=0.002</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Side effects of ART</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Never</td>
<td>55 (47)</td>
<td>63 (53)</td>
<td>1.00</td>
</tr>
<tr>
<td>Ever</td>
<td>16 (27)</td>
<td>43 (73)</td>
<td>2.35 (1.19-4.62) p=0.014</td>
</tr>
<tr>
<td></td>
<td><strong>χ^2=6.19, p=0.013</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. of ART regimen changes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>13 (42)</td>
<td>18 (58)</td>
<td>1.00*</td>
</tr>
<tr>
<td>1-2</td>
<td>40 (56)</td>
<td>32 (44)</td>
<td></td>
</tr>
<tr>
<td>3-4</td>
<td>18 (31)</td>
<td>41 (69)</td>
<td></td>
</tr>
<tr>
<td>≥5</td>
<td>3 (17)</td>
<td>15 (83)</td>
<td>1.93 (1.00-3.73) p=0.05*</td>
</tr>
<tr>
<td></td>
<td><strong>χ^2=13.4, p=0.004</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CDC clinical staging (max)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>N / A</td>
<td>20 (43)</td>
<td>27 (57)</td>
<td></td>
</tr>
<tr>
<td>B / C</td>
<td>45 (37)</td>
<td>77 (63)</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>χ^2=0.46, p=0.50</strong></td>
<td></td>
<td></td>
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</tbody>
</table>

* baseline is <5 lifetime changes
Table 5: Predictive factors for parent/guardian perception of poor general health

<table>
<thead>
<tr>
<th></th>
<th>Well</th>
<th>Less well</th>
<th>Odds ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>N</td>
<td></td>
</tr>
<tr>
<td>Not absent from school in past month</td>
<td>148</td>
<td>10</td>
<td>Ref</td>
</tr>
<tr>
<td>Absent from school in past month</td>
<td>39</td>
<td>9</td>
<td>3.42 (1.30-8.99) p=0.013</td>
</tr>
<tr>
<td>No hospitalisation in last 6 months</td>
<td>166</td>
<td>13</td>
<td>Ref</td>
</tr>
<tr>
<td>Hospitalisation (at least 1 night)</td>
<td>19</td>
<td>6</td>
<td>4.03 (1.37-11.8) p=0.011</td>
</tr>
<tr>
<td>No / mild HIV symptoms</td>
<td>126</td>
<td>11</td>
<td>Ref</td>
</tr>
<tr>
<td>Moderate / severe HIV symptoms</td>
<td>59</td>
<td>8</td>
<td>1.55 (0.59-4.06) n.s.</td>
</tr>
</tbody>
</table>
Figure 1
Maximum CDC clinical staging, by current clinical staging

Current CDC stage:  
- N  
- A  
- B  
- C

Maximum CDC clinical stage

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>16</td>
<td>48</td>
<td>75</td>
</tr>
<tr>
<td>n</td>
<td>15</td>
<td>20</td>
<td>25</td>
</tr>
</tbody>
</table>
Figure 2: Current family setting of children whose mothers had died

- Aunt or uncle: 39%
- Adopted: 9%
- Fostered: 4%
- Grandparent: 30%
- Father: 18%
Figure 3: Disclosure of child’s infection status, by age group (n=205)
Figure 4: School / day care attendance, by age group (n=205)
Figure 5: Awareness of the school / day care provider of the child’s HIV infection status (n=216)
Figure 6: Burden of pill-taking (n=158)
Figure 7: Parent or guardian* perception of the child’s adherence to their antiretroviral medication, by age of the child

* one infected young person (in >14 year age group) completed the questionnaire themselves
Figure 8: ART interference in everyday life

How much does taking ART interfere with your child’s everyday life?

- not at all: 41.5%
- a little: 33.2%
- quite a lot: 18.6%
- a lot: 6.7%
Interference of ART on everyday life: stratified analyses

Figure 9a: Interference of ART on daily life (classified binomially), stratified by type of carer who answered the question

![Bar chart showing interference of ART on daily life stratified by carer type.]

Figure 9b: “How much does taking antiretroviral medication interfere with your child’s everyday life?” – results stratified by carer type

![Bar chart showing interference of ART on daily life stratified by carer type.]

- White European parent n=79
- Black African parent n=17
- Adoptive parent n=19
- Foster carer n=22
- Other family n=26
Figure 10  General health status of the child (reported by the parent or guardian)

“In the last month, has your child been …”

- Generally well
- A little less well than usual
- Considerably less well than usual
- Unwell most of the time

![Bar chart showing general health status of the child]
Conclusions

Aims of the present project were to develop a questionnaire for the evaluation of quality of life (QoL) in HIV-infected children and adolescents. This questionnaire had to be used for scientific and public-health purposes. The first questionnaire developed was thought to be a complete QoL tool, but preliminary results on a subgroup of children showed that this questionnaire was not well accepted by the parents/carers and that its suitability with clinical conditions in borderline ages was little. The second questionnaire developed was, indeed, well accepted and give, according to our results, a global picture on how a child in Europe lives with this disease.

The first finding is demographic. In fact, even if most children were born in Western Europe, a consistent proportion of children were born in Africa or in Eastern Europe to mothers coming from Africa or from Eastern Europe. This is an important issue to be considered for public-health strategies and to correctly address prevention strategies.

Analysis of social setting showed that among HIV infected children only two third live with both parents, and one third had experienced an HIV-related death in their family, mainly the mother who was died in half of the cases when children were less than 5 years of age. When the mother was died, most children live with the father or grandparents or other relatives. Thus, our results confirms that HIV infection is, even now, a disease of the whole family, which is often weak and disrupted.

Analysis of clinical characteristics showed that 30% of children were classified as severely symptomatic (category C according CDC criteria) because of any clinical features they ever had in their life. However, most likely due to the wide application of HAART regimens all over in Western Europe, only 14% of children are currently
severely symptomatic (category C) and most of them are currently not/mildly symptomatic (category N/A). As a whole, children and adolescents in our study are currently clinically quite well, and this was the perception of the majority of parents/guardians when interviewed on children’s general health status in the previous month.

Factors associated with a parent/guardian perception of poor general health were absence from school and hospitalisation. As in many other chronic conditions, the child and the family get used with the disease and perceived a general well status as the absence of an acute episode and/or hospitalisation. Nevertheless, most children are well because of HAART, but a consistent proportion of them have a current CD4 percentage <15%, so they might be prone to infections and other HIV-related conditions if they were not taking antiretroviral treatment.

HAART was in fact administered to the majority of children. ART was felt by more than half of the parents and guardians to interfere with children/adolescents’ everyday life, mainly among black African parents or when the patients were older adolescents. This was in agreement with a less adherence to ART in adolescent age.

Therefore, our investigation have shown that, even if HIV infection is now a chronic illness in developed countries such as western Europe, strategies to improve adherence to therapy among adolescents and to simplify antiretroviral regimen (i.e. once daily regimen) have to be undertaken. Moreover, cultural differences in acceptance of therapy may need an intercultural approach, with the intervention of cultural mediators.

Finally, children’s and adolescents’ difficulties in disclosure their own infection status show that there is a need of fighting discrimination about an HIV-infected girl/boy,
even now. Local, national and international campaign of sensibilization among young people in favour of HIV-infected young people may be very useful.

**Dissemination of results**

To disseminate results of the present study the participating centres decided:

1. to distribute in the schools and young people communities the leaflets (enclosed). For this purpose, voluntary associations and social workers were involved.

2. to submit an article containing the results to a specific journal.
## Appendix: Table 1 - Updated list of organisations and people involved (local co-ordinators)

<table>
<thead>
<tr>
<th>CENTRE</th>
<th>PEOPLE INVOLVED</th>
<th>Address</th>
<th>Telephone/fax number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Paediatrics, University of Florence</td>
<td>Prof. Maurizio de Martino, Dr Luisa Galli</td>
<td>Via Luca Giordano 13, Florence Italy</td>
<td>Tel +39.055.576593 Fax +39.055.570380</td>
</tr>
<tr>
<td>Department of Epidemiology and Public Health – Institute of Child Health, University College – London</td>
<td>Dr M-L Newell, Dr Claire Thorne</td>
<td>30 Guilford Street - WC 1 N 1 EH London, UK</td>
<td>Tel +44.171829 8699 Fax +44.1712422723</td>
</tr>
<tr>
<td>Department of Paediatrics – Padua</td>
<td>Dr Carlo Giaquinto</td>
<td>Via Giustiniani 3 – Padua, Italy</td>
<td>Tel. +39-049-8213585 Fax +39-049.8753865</td>
</tr>
<tr>
<td>Unit of Immunology and Infectious Diseases, Bambino Gesù Children’s Hospital, Rome</td>
<td>Dr Guido Castelli Gattinara</td>
<td>Piazza S. Onofrio 4 Rome, Italy</td>
<td>Tel: +3906- 6859- 2190 Fax: +3906- 6859- 2508</td>
</tr>
<tr>
<td>Department of Paediatrics – University of Turin</td>
<td>Prof. P-A Tovo</td>
<td>Piazza Polonia 94 – Turin - Italy</td>
<td>Tel.+39.113135262 Fax +39113135382</td>
</tr>
<tr>
<td>Charité-Virchow-Klinikum Klinik fur Allgemeine Padiatri, Berline</td>
<td>Prof I Grosch-Woerner</td>
<td>Mittelallee 8 – Berlin - Germany</td>
<td>Tel.+49.3045066501 Fax +49.3045066956</td>
</tr>
<tr>
<td>Unit of Infectious Diseases – Children’s Hospital La Fe, Valencia</td>
<td>Prof. F. Asensi-Botet</td>
<td>Avda Campanar 21 – Valencia - Spain</td>
<td>Tel.+34.963862700 Fax +34.963868700</td>
</tr>
<tr>
<td>Astrid Lindgrens Children’s Hospita, Stockholm</td>
<td>Dr E. Belfrage</td>
<td>SE-171 76 – Stockholm - Sweden</td>
<td>Tel.+46.851755120</td>
</tr>
</tbody>
</table>

New centres/people are indicated in bold
## Appendix: Table 2 – List of participants to the meeting in Florence, December 1st, 2004

<table>
<thead>
<tr>
<th>Participants</th>
<th>Role</th>
<th>Centre</th>
</tr>
</thead>
<tbody>
<tr>
<td>M de Martino</td>
<td>paed pc</td>
<td>Florence</td>
</tr>
<tr>
<td>L Galli</td>
<td>paed pm</td>
<td>Florence</td>
</tr>
<tr>
<td>A Guarino Amato</td>
<td>psy</td>
<td>Florence</td>
</tr>
<tr>
<td>P Gervaso</td>
<td>paed</td>
<td>Florence</td>
</tr>
<tr>
<td>N Battiglia</td>
<td>f res</td>
<td>Florence</td>
</tr>
<tr>
<td>AM Campaioli</td>
<td>secr</td>
<td>Florence</td>
</tr>
<tr>
<td>ML Newell</td>
<td>md pm</td>
<td>London</td>
</tr>
<tr>
<td>C Thorne</td>
<td>res</td>
<td>London</td>
</tr>
<tr>
<td>F Asensio Botet</td>
<td>paed lc</td>
<td>Valencia</td>
</tr>
<tr>
<td>G Suarez</td>
<td>paed</td>
<td>Valencia</td>
</tr>
<tr>
<td>E Belfrage</td>
<td>paed lc</td>
<td>Stockholm</td>
</tr>
<tr>
<td>M Nanneson</td>
<td>sw</td>
<td>Stockholm</td>
</tr>
<tr>
<td>M Merlo</td>
<td>adm</td>
<td>Padua</td>
</tr>
<tr>
<td>O Rampon</td>
<td>paed</td>
<td>Padua</td>
</tr>
<tr>
<td>S Oletto</td>
<td>sw</td>
<td>Padua</td>
</tr>
<tr>
<td>G Castelli Gattinara</td>
<td>paed lc</td>
<td>Rome</td>
</tr>
<tr>
<td>S Baldassari</td>
<td>psy</td>
<td>Rome</td>
</tr>
<tr>
<td>C Gabiano</td>
<td>paed lc</td>
<td>Turin</td>
</tr>
<tr>
<td>MA Cammilli Giammei</td>
<td>secr</td>
<td>Turin</td>
</tr>
</tbody>
</table>

*paed pc*= paediatrician / project coordinator  
*paed pm*= paediatrician/project manager  
*paed lc*= paediatrician / local co-ordinator  
*md pm*= medical doctor /project manager/  
*paed*= paediatrician  
*psy*= psychologist  
*sw*= social worker  
*res*= researcher  
*f res*= fellow researcher  
*secr*= secretary  
*adm*= administrator
From a background of coordinating large cohorts of HIV infected women and their children in Italy and Europe we felt it was timely to focus in particular on the lives of children with HIV infection in Europe, to help us understand how they cope with this chronic infection. To do this, we are asking the parents or carers of children and adolescents with HIV infection across Europe to answer some questions for us, in an anonymous survey, and in addition we ask the regular health care professional of these children/adolescents to give us some background clinical information.

We would be grateful if you could complete the first page of this form, and complete the hospital patient identifier in the top right corner of page one and the accompanying pages 2 and 3. The latter pages are to be completed by the parent or carer of the child, and it is important for you to ensure that pages refer to the same child. The hospital identifier is the only means by which this can be achieved. Please then hand on the remaining pages to the parent/carer for completion. The parent’s form can be returned in a blank envelope to you, and you can then return all forms to either Luisa Galli or Claire Thorne at the addresses below.

If you have any problems or questions please contact:

Dr Luisa Galli  
Division of Paediatrics and Infectious Diseases  
Department of Paediatrics, University of Florence  
Anna Meyer Children's Hospital  
via Luca Giordano 13  
I-50132 Florence, Italy  
Tel: +39 055 5662540  
Fax: +39 055 570380  
l.galli@meyer.it

Dr Claire Thorne  
Centre for Paediatric Epidemiology  
Institute of Child Health  
30 Guilford Street  
London  
WCIN 1EH  
Tel : +44 20 7905 2105  
Fax : +44 20 7813 8145  
c.thorne@ich.ucl.ac.uk

Thank you for giving up your time and agreeing to be part of this important survey.
Children and adolescents living with HIV infection in Europe

This page to be completed by the health care provider

Date form completed (dd/mm/yy): ..........................

Hospital: .................................................. Name of health care provider: ..........................

Child’s date of birth (dd/mm/yy): ...................... Gender: Male / Female

Ethnic group: White / Black / Other Country of birth: ..........................

Mother’s country of birth: ......................... Father’s country of birth: ..........................

What is the child’s social care situation?
- Living with his/her family  □  Fostered  □
- Adopted  □  Other, specify  ..............................................

Child’s most likely mode of HIV acquisition
- Mother-to-child transmission  Yes / No
- Blood products / transfusion  Yes / No
- Unknown  Yes / No
- Other (please specify below)  Yes / No

…………………………………………………………..

Who else in the family is HIV infected (tick all that apply)?
- No one  □  Mother  □  Father  □  Sibling (number) .............

Has there been an HIV-related death in the family?  No / Yes

If yes, who died and when?  ...........................................................................................................

Current clinical/ immunological status

Current CDC stage .............. Date of onset (dd/mm/yy): ............. Max CDC stage: .............

Most recent CD4 count: .............. CD4 % ......................... Date: (dd/mm/yy): .....................

Most recent viral load: ................. Assay: ......................... Date: (dd/mm/yy): .....................

Has this child been admitted to hospital for at least 1 night in the last 6 months?  No / Yes

If yes, what for ............................................ and for how many nights? ................................

Antiretroviral treatment

When was the child first treated with antiretroviral therapy? (specify age or date at initiation) ..............

What is the child’s current antiretroviral treatment (please specify drugs):

..............................................................................................................................................

When was this current regimen started? (month/year) ..............................................................

How many treatment changes has this child ever had? (please circle)
- Never treated  None  1-2  3-5  6+

Has the child ever suffered any side effects related to antiretroviral therapy?  No / Yes

If yes, please give details (eg type of side effect, dates/ages etc):
From a background of coordinating large cohorts of HIV infected women and their children in Italy and elsewhere in Europe we felt it was timely to focus in particular on the lives of children and adolescents with HIV infection in Europe, to help us understand how they cope with this chronic infection. To do this, we are asking the parents or carers of children and adolescents with HIV infection to answer some questions for us, in an anonymous survey.

We would be grateful if you could complete this form, possibly together with your child if you think this is appropriate. We do not need to know your name and none of the information provided will be communicated to anyone else. We will use the responses provided in summary format only.

**Family, school and daycare**

1. What is your relationship to the HIV-infected child in your care? (eg mother, father, foster carer etc)

2. Who does the child currently live with? *(please tick all that apply)*:
   - Mother
   - Father
   - Other relative(s), specify
   - Adoptive parent
   - Foster carer
   - Other(s), specify

3. Does the child attend *(tick all that apply)*:
   - School
   - Nursery/creche
   - Other day care *(specify)*

4. Is the school or nursery/creche aware of the HIV infection status of your child? Yes / No
   - If yes, Who has been told? *(please tick all that apply)*
     - Head teacher
     - Class teacher
     - Other (please specify)

5. Does the child receive any extra help at nursery or school? (for example, a special support teacher)
   - Not applicable
   - No
   - Yes *(please specify)*

6. Does the child regularly get help from any of the following? *(if yes, please indicate approximate number of visits per month)*:
   - Psychologist *(number of visits)*
   - Social worker *(number of visits)*
   - Support group *(number of visits)*
   - Other (specify) *(number of visits)*
Health status and treatment

7. In the last month has your child been *(please tick one)*:
   - Generally well, no major problems □
   - A little less well than usual □
   - Considerably less well than usual □
   - Unwell most of the time □

8. In the last month (excluding school holidays), has your child been absent from school because of ill health?
   - No / Yes  *If yes, please specify number of days and give details below:*

   ........................................................................................................................................

9. In the last month, has your child’s ill health prevented him/her from doing usual childhood activities such as playing with his/her friends, going to social events or participating in sporting activities?
   - No / Yes  *If yes, how many times?*

10. How many times has your child seen the doctor or nurse in the past 3 months?  .................

    Of these, how many were routine, scheduled visits?  .................  ....

11. Is your child currently treated for his/her HIV infection? Yes / No

    *If yes, how many pills does he/she take per day?  .................

12. How old was he/she when any HIV treatment started?  ...........................................

13. Would you say your child takes all his/her medicine *(please tick one only)*:
   - every time □
   - approximately 80% of the time □
   - approximately 50% of the time □
   - between 25% and 50% of the time □
   - less than 25% of the time? □

14. How much does taking antiretroviral medication interfere with your child’s everyday life? *(please tick one only)*

    - Not at all □
    - A little bit □
    - Quite a lot □
    - A lot □

15. Has your child suffered any side effects from their treatment?

    No / Yes  *If yes, please give details:  .................................................................

    ........................................................................................................................................

16. How does your child cope with having to take these drugs in relation to his/her normal day-to-day life (for example, while at school)?

    .........................................................................................................................................

    .........................................................................................................................................
17. How happy are you with the level of support that you and your child receive in relation to their treatment?

- Very unhappy
- Unhappy
- Quite Happy
- Very Happy

Disclosure

18. Is your child aware he/she is HIV infected?

- Yes / No
  If yes, how old was she/he when she/he became aware of this? 

19. Is your child aware that other people in the family are HIV infected?

- Yes / No / not applicable

20. Do you think that your child’s knowing about his/her HIV has made adherence to their antiretroviral treatment easier?

- Yes / No
  If yes, in what ways?

21. Do you think that your child’s infection has caused/causes any problems in his/her friendships?

- Yes / No
  If yes, in what ways?

If you have any additional comments, please feel free to write them here:

Thank you for taking the time to answer these questions. Your participation will help us understand how children and adolescents in Europe live with HIV infection and will identify areas in need of support.

If you would like further information please contact:
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Quest'indagine si propone di valutare come convivono, allo stato attuale, i bambini e gli adolescenti con infezione da HIV in Europa. Abbiamo pensato di farlo utilizzando come background la casistica di ampi studi multicentrici già esistenti in Italia e in Europa. Pertanto chiediamo ai genitori/tutori dei bambini/adolescenti con infezione da HIV di rispondere ad alcune domande inserite in un questionario totalmente anonimo. Chiediamo anche al medico curante del bambino/adolescente di fornirci alcune informazioni cliniche.

Ti saremmo grati se tu compilassi la prima pagina del questionario, avendo cura di assegnare un numero identificativo al paziente (da apporre sull’angolo destro in alto della prima pagina) che sia lo stesso sulle pagine 2, 3 e 4. Queste pagine devono essere consegnate al genitore/tutore, che le compilerà e le riconsegnàrà a te in una busta bianca chiusa. La busta chiusa e la prima pagina da te compilata devono essere inviate ai centri di coordinamento, cioè a Luisa Galli o a Claire Thorne.

E’ evidente l’importanza di annotare il numero identificativo su tutte le pagine, perché è l’unico modo per i centri di coordinamento per ricollegare i dati clinici con le risposte al questionario.

Per qualunque problema contattare:

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Grazie per avere accettato di partecipare a questa importante indagine.
La prima pagina deve essere compilata dal medico curante

Dati del bambino/adolescente

Data di nascita (gg/mm/aa)___/____/____  Sesso:  maschio  □  femmina  □

Etnia: Bianca/ Nera /Altro  Luogo di nascita (Stato)……………………………

Paese di origine della madre………………  Paese di origine del padre ……………………………

Condizione sociale del bambino:  
  vive in famiglia □  affidato □  adottato □  altro, specificare…………………………

Verosimile modalità di acquisizione dell’infezione da HIV:  
  trasmissione madre-figlio  SI / NO  trasfusione di sangue/emoderivati  SI / NO
  sconosciuta  SI / NO  altro (specificare……………….)  SI / NO

Chi altro in famiglia è HIV+ (barrare tutte quelle che interessano)?
  Nessuno □  Madre □  Padre □  Fratello/sorella (numero)………………

Se si, chi e quando? …………………………………………..

Attuale condizione clinica/immunologica

Attuale classificazione sec. CDC ……  Data di esordio (gg/mm/aa): ___/____/____

Classe CDC più severa: ……………

CD4 assoluti più recenti : ………….  CD4 % ………….  Data: (gg/mm/aa): ___/____/____

HIV-1 RNA più recente: ………….  Metodica: ………….  Data: (gg/mm/aa): ___/____/____

E’ stato ricoverato almeno 1 notte negli ultimi 6 mesi?  No /  Si

  Se si, per quale motivo ………………………………..  E per quante notti? ………

Terapia antiretrovirale

Quando è stato iniziata la terapia antiretrovirale per la prima volta? (specificare età o data) …………………

Qual’è il regime terapeutico antiretrovirale attuale? (specificare i farmaci):
……………………………………………………………………………………………………

Quando è stato iniziato l’ attuale regime terapeutico? (mese/anno) …………………………..

Quanti altri regimi terapeutici sono stati in precedenza somministrati? (cerchiare)
  Mai trattato  Nessuno  1-2  3-5  6+

Sono mai stati rilevati effetti collaterali correlati alla terapia antiretrovirale? No /  Si

  Se si, specificare (eg tipo di effetto collaterale, date/età etc):
……………………………………………………………………………………………………
Qualità di vita dei bambini e adolescenti con infezione da HIV

Questa indagine si propone di valutare come convivono, allo stato attuale, i bambini e gli adolescenti con infezione da HIV in Europa. Abbiamo pensato di farlo utilizzando come background la casistica di ampi studi multicentrici già esistenti in Italia e in Europa. Per tanto chiediamo ai genitori/tutori dei bambini/adolescenti con infezione da HIV di rispondere ad alcune domande inserite in un questionario totalmente anonimo. Chiediamo anche al medico curante del bambino/adolescente di fornirci alcune informazioni cliniche.

Vi saremmo grati se voleste compilare questo questionario, magari insieme a vostro/a figlio/a se lo ritenete opportuno. Non abbiamo bisogno di conoscere la vostra identità. I dati verranno elaborati direttamente da statistici e non verranno comunicati a nessuno. I risultati delle risposte verranno utilizzati solo a fini statistici.

Famiglia, scuola e asilo

1. Qual'è il tuo grado di parentela con il bambino/a - ragazzo/a ?   (es. madre, padre, genitore adottivo) ………………………………………………………………………………………………………

2. Con chi vive di solito il bambino/a - ragazzo/a ? (per favore barrare )
   Madre □
   Padre □
   Genitore adottivo □
   Genitore affidatario □
   Altri specificare ………………………………………………………………………………

3. Il bambino/a - ragazzo/a frequenta Scuola □
   Asilo / Nido □
   Altre □ (specificare) ………………………

4. La scuola/asilo è a conoscenza dell'infezione del bambino/a - ragazzo/a ?   Si / No
   Se si, a chi è stato comunicato:
   Direttore/Preside □
   Insegnante della classe □
   Altro (specificare) ………………………………………………………………….

5. Il bambino/a - ragazzo/a ha qualche supporto extra all'asilo / scuola (es. insegnante di sostegno)
   No □
   Si □
   (specificare) ………………………

6. Il bambino/a - ragazzo/a riceve regolarmente un supporto
   (se si, indicate approssimativamente il numero di visite mensili):
   Psicologo □ …………… numero di visite
   Assistente sociale □ …………… numero di visite
   Gruppo di supporto □ …………… numero di visite
   (con associazioni di volontariato o altro) …………… numero di visite
   Altro (specificare) ……………………… numero di visite
Stato di salute e terapie

7. Nell’ultimo mese suo figlio/a è stato/a (barrare nella caselle)
   Globalmente bene, nessun problema importante ☐
   Un po’ meno bene del solito ☐
   Molto meno bene del solito ☐
   Non bene per la maggior parte del tempo ☐

8. Nell’ultimo mese (escluso le vacanze scolastiche), suo/a figlio/a è stato assente da scuola per motivi di salute?
   No / Si, per favore specificare il numero di giorni e dettagliare sotto:
   ……………………………………………………………………………………………………………………

9. Nell’ultimo mese, lo stato di salute ha impedito a suo/a figlio/a di partecipare alle attività comuni come giocare con gli amici, recarsi ad eventi sociali o partecipare ad attività sportive?
   No / Si, quante volte? ……………………………

10. Quante volte suo/a figlio/a è stato visitato da un medico/infermiere negli ultimi 3 mesi? ………
    Di queste, quante erano visite routinarie/programmate? …………………………………………………

11. Suo/a figlio/a è al momento in terapia per l’infezione da HIV? SI / NO
    Se si, quante compresse o capsule al giorno assume? ……………………………

12. A che età è stata iniziata la terapia? ……………………………

13. Se lei dovesse quantificare in che percentuale, rispetto a quanto prescritto, suo/a figlio/a assume la terapia (per favore barrare una sola risposta)
    sempre 100% ☐
    circa per l’80% ☐
    circa per il 50% ☐
    tra il 25 - 50% ☐
    meno del 25% ☐

14. Assumere la terapia antiretrovirale quanto interferisce con la vita di tutti i giorni? (per favore barrare una sola risposta)
    per niente ☐
    un po’ ☐
    abbastanza ☐
    molto ☐

15. Suo/a figlio/a ha avuto effetti collaterali correlati alla terapia?
    No / SI: se sì, per favore specificare ……………………………………………………………
    …………………………………………………………………………………………………………………

16. Come fa fronte suo/a figlio/a al fatto di dover assumere questi farmaci nella sua vita quotidiana (per esempio a scuola)?
    …………………………………………………………………………………………………………………
    …………………………………………………………………………………………………………………
    …………………………………………………………………………………………………………………
17. Quanto è soddisfatto/a del supporto che lei e suo/a figlio/a ricevete in relazione alla terapia?

   Molto insoddisfatto  ☐   Insoddisfato  ☐   Abbastanza soddisfatto  ☐
   Molto soddisfatto  ☐

**Comunicazione della diagnosi**

18. Suo/a figlio/a è consapevole di avere l'infezione da HIV?
   SI  /  No  Se sì, quanti anni aveva quando ne è venuto/a a conoscenza? .................

19. Suo/a figlio/a è a conoscenza dell'eventuale stato di infezione di altre persone in famiglia?
   SI  /  No  /  non pertinente

20. Lei pensa che la consapevolezza dell'infezione abbia facilitato l'aderenza alla terapia antiretrovirale (puntualità e precisione nell'assunzione dei farmaci)?
   SI  /  No  Se sì, in quale modo? ........................................................................................................

   ............................................................................................................................................................

21. Lei pensa che l'infezione abbia causato problemi a suo/a figlio/a nelle relazioni con gli amici?
   SI  /  NO  Se sì, in quale modo?

   ............................................................................................................................................................

   ............................................................................................................................................................

Se ha qualsiasi commento, per favore lo scriva qui sotto liberamente:

   ............................................................................................................................................................

   ............................................................................................................................................................

   ............................................................................................................................................................

Grazie per aver speso un po' del suo tempo nel rispondere alle domande. La sua partecipazione ci aiuterà a comprendere come i bambini e gli adolescenti in Europa convivono con l'infezione da HIV e, ad identificare gli aspetti che necessitano di maggior supporto.

**Per ulteriori informazioni contattare:**

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CALIDAD DE VIDA DE NIÑOS Y ADOLESCENTES CON INFECCIÓN POR HIV

Familia, escuela y cuidados de día

1. ¿Qué relación tiene con el niño HIV a quien cuida? (ej. madre, padre, tutor, etc.)
   ................................................................................................................................

2. ¿Con quién vive normalmente en niño? (señalar lo que corresponda)
   Madre ..... Padre ..... 
   Otro familiar (especificar) ..... 
   Padre adoptivo ....................... Tutor ..... 
   Otros (especificar) ...........

3. Asiste el niño (señalar lo que proceda): Escuela ....................
   Guardería ..................
   Otros centros de día ........

4. El personal de la escuela o guardería ¿conoce la situación del niño?
   Sí ........ No ..........
   En caso afirmativo, ¿a quién se ha informado?
   Director del colegio .......... 
   Maestro del niño ............. 
   Otros (especificar) ..........

5. ¿Recibe el niño apoyo especial? (por ejemplo, maestro de repaso)
   No aplica ........
   No ..................
   Sí .................. (especificar)

6. ¿Recibe el niño ayuda regular de alguna de las siguientes personas?
   Psicólogo .............. Trabajador social ..............
   (número de visitas) (número de visitas)
   Grupo de soporte ...... Otros (especificar) ............
   (número de visitas) (número de visitas)
Condiciones de vida y tratamiento

7. ¿Cómo ha estado el niño en el último mes? (señalar una respuesta)
   En general, bien, sin grandes problemas ........
   Menos bien que lo habitual .........................
   Bastante peor que de costumbre ..................
   La mayoría del tiempo mal ..........................

8. En el último mes, exceptuando los días que no hay escuela, ¿ha faltado a clase por razón de enfermedad?
   No ......  Sí ....
   En caso afirmativo, especificar el número de días y dar detalles
   .............................................................................................................................................

9. En el último mes el niño ¿ha tenido que renunciar a actividades propias de la infancia: jugar con sus amigos, ir a celebraciones sociales, practicar deporte, etc. a causa de la enfermedad?
   No .....  Sí ....
   Si es que sí, ¿cuántas veces? ............

10. ¿Cuántas veces ha acudido el niño al médico o a la enfermera en los últimos tres meses? ..........

11. ¿El niño está actualmente siendo tratado por su infección HIV?
   Sí .....  No ....
   En caso afirmativo, ¿cuántas pastillas toma al día? ............

12. ¿Qué edad tenía cuando empezó el tratamiento anti-HIV?

13. Cumplimiento de la pauta terapéutica (señalar sólo una opción):
   - En todo momento ............................................
   - Aproximadamente el 80 % del tiempo .............
   - Aproximadamente el 50 % del tiempo............... 
   - Entre el 25 % y el 50 % del tiempo ............... 
   - Menos del 25 % del tiempo..............................

14. ¿Qué repercusión tiene el tratamiento antirretrovíral en la vida diaria del niño? (señalar sólo una opción)
   Ninguna .....  Poca .....  Bastante .....  Mucha .........

15. ¿Ha sufrido el niño algún efecto no deseado de su tratamiento?
   No ......  Sí ......  En caso afirmativo dar detalles .............................................................
   .............................................................................................................................................

16. ¿Cómo compagina el niño tener que tomar los medicamentos con sus actividades normales diarias (por ejemplo, cuando está en la escuela)?
   .............................................................................................................................................
   .............................................................................................................................................
17. Grado de satisfacción con la ayuda que recibe el niño y sus padres para el tratamiento:
   Muy insatisfechos ..... Insatisfechos ....... Bastante satisfechos .... Muy satisfechos ....

**Información sobre la enfermedad**

18. ¿Sabe el niño que está infectado por el HIV?
   Sí ..... No....... En caso afirmativo, ¿a qué edad lo supo? ........................

19. ¿Sabe el niño que otros miembros de su familia están infectados por el HIV?
   Sí ..... No ...... No aplica ............

20. ¿Piensa que el conocimiento que tiene el niño sobre su infección por el HIV facilita el cumplimiento del tratamiento antirretroviral?
   Sí ..... No ...... En caso afirmativo ¿de qué modo? ..............................................................

21. ¿Cree que la infección de su hijo origina problemas con sus amigos?
   Sí ..... No ...... En caso afirmativo ¿de qué tipo? ..............................................................

Si tiene algún comentario que hacer puede hacerlo en este espacio:
Fecha de cumplimentación (día, mes, año): ..................
Hospital ...................................... Nombre de quien atiende al niño ...................
Fecha de nacimiento (día, mes, año) ............... Sexo: Niño / Niña
Grupo étnico: blanco/ negro /otro País de nacimiento .........................
País de nacimiento de la madre ................. País de nacimiento del padre ...........
¿En qué situación social se encuentra el cuidado del niño?
  Vive con la familia ....... En tutela ..........
  En adopción ............... Otros (especificar) ............

Vía más probable de contagio del HIV
Transmisión madre-hijo       Sí / No       Hemoderivados Sí / No
Desconocida                  Sí / No       Otras (especificar)

¿Algún otro familiar infectado? (señalar lo que corresponda)
Ninguno ..... Madre ..... Padre ..... Hermanos (número) ......
¿Ha habido algún fallecimiento por HIV en la familia? Sí .... No ....
Si ha habido, ¿quién y cuándo murió? .........................

Estado actual clínico e inmunológico
Fase  CDC .... Fecha de aparición (día, mes, año).... Máxima fase de CDC ....
Último recuento de CD4: ...... % de CD4 ...... Fecha (día, mes, año) ..........
Última carga viral: ........ Método: .............. Fecha (día, mes, año) ........
¿Ha sido hospitalizado al menos una noche en los últimos 6 meses? Sí.... No ....
Si lo ha sido, ¿por qué razón? ............ y por cuántas noches ............

Tratamiento antiretroviral
¿Cuándo recibió por primera vez antirretrovirales? (edad y fecha) ................
Tratamiento antirretroviral actual (especificar drogas) ..................................

¿Cuándo empezó este tratamiento? (mes/año) ......................

¿Cuántos cambios de tratamiento se han realizado en este niño?
  No tratado Ningún cambio  1-2   3-5   6 ó más

¿Ha sufrido algún efecto secundario relacionado con los antirretrovirales?
  Sí .... No ....
En caso afirmativo detallar tipo, fecha, edad, etc. ..................................................
Kinder und Heranwachsende mit HIV-Infektion in Europa

Diese Seite ist vom Pflegepersonal auszufüllen

Datum des Eintrags (TT/MM/JJ): ............................

Krankenhaus: .............................................. Name des Kindes
Träger: ....................................................

Geburtsdatum des Kindes (TT/MM/JJ): ................. Geschlecht: Männlich / Weiblich

Ethnische Zugehörigkeit: Weiß / Schwarz/ Andere Geboren in (Land):

...........................................................

Mutter geboren in (Land): ............................... Vater geboren in (Land): ............................

Soziale Situation des Kindes
- Lebt in der Familie  [ ]  - Bei Pflegeeltern  [ ]
- Adoptiert  [ ]  - Andere: ..............................................................

Anzunehmender Weg der HIV-Infektion beim Kind:
Mutter-Kind-Transmission Ja / Nein Blutprodukte / Transfusion Ja / Nein
Unbekannt Ja / Nein Andere (Bitte genau angeben) Ja / Nein

..............................................................

Wer ist in der Familie außerdem infiziert?
- Niemand  [ ]  - Mutter  [ ]  - Vater  [ ]  - Geschwister (Anzahl) ..............

Gab es in der Familie einen Todesfall im Zusammenhang mit HIV? Nein / Ja

Wenn Ja, wer starb zu welchem Zeitpunkt? ..............................................................

Aktueller klinischer / immunologischer Status

Aktueller CDC Status.............. Seit wann (TT/MM/JJ): ............... Schlechtestes CDC Stadium: ....

Letzte CD4 Zellzahl: .............. CD4 % .............. Datum: (TT/MM/JJ): ..............

Letzte Viruslast: ................. Assay: ........ Date: (TT/MM/JJ): ..............

Ist das Kind in den vergangenen sechs Monaten in ein Krankenhaus stationär eingewiesen worden? Nein / Ja

Wenn Ja, warum ........................................ Und für wie viele Tage? ..............................

Antiretrovirale Therapie

Wann hat das Kind erstmals eine antiretrovirale Therapie erhalten? (Alter oder Datum des Beginns)

..............................................................

Welches ist die aktuelle antiretrovirale Therapie (bitte Medikamente nennen):

..............................................................
Wann wurde die aktuelle Therapie begonnen? (Monat/Jahr) ………………………………

Wieviele Therapiewechsel hat das Kind insgesamt gehabt? (bitte umkreisen)

Nie behandelt Kein 1-2 3-5 6+

Hat das Kind jemals unerwünschten Wirkungen der antiretroviralen Therapie gehabt?
Nein / Ja
Wenn Ja, bitte aufführen, (z.B. Art der unerwünschten Wirkung, Datum, Alter, ...):

………………………………………………………………………………………………………………
Kinder und Heranwachsende mit HIV-Infektion in Europa

Dieser Teil des Formulars soll von den Eltern/Erziehungsberechtigten

Familie, Schule, Kindergarten

1. In welcher Rolle sorgen Sie für das Kind? (z.B. Mutter, Vater, Pflegeeltern)

………………………………………………………………………………………………………………………….

2. Bei wem lebt das Kind zur Zeit? (Bitte alle zutreffenden ankreuzen):
Mutter □ Vater □

Andere Verwandte (bitte nennen):…………………………………………………………………………………………………………………………
Adoptiveltern □ Pflegeeltern □

Andere:…………………………………………………………………………………………………………………………

3. Das Kind geht zur: Schule □
Kindergarten □
Anderes □ (bitte angeben) ………………………………………

Wenn Ja, wer wurde dies mitgeteilt? (bitte alle zutreffenden ankreuzen)
Stufenlehrer □
Klassenlehrer □

Andere (bitte angeben) ……………………………………………………………………………………………

5. Bekommt das Kind eine Sonderförderung im Kindergarten oder in der Schule? (Nachhilfelehrer u.a.)
Keine Angaben möglich □
Nein □
Ja □ (bitte angeben) ………………………………………

6. Erhält Ihr Kind regelmäßige Hilfe von:

Psychologe □ .......... Besuche pro Monat □ .......... Besuche pro Monat
Selbsthilfegruppe □ .......... Besuche pro Monat □ .......... Besuche pro Monat

Andere: .......... Besuche pro Monat ...... Besuche pro Monat
Gesundheitsstatus und Behandlung

7. Ging es Ihrem Kind im vergangenen Monat...
   - Allgemein gut, keine großen Probleme ☐
   - Etwas schlechter als sonst ☐
   - Deutlich schlechter als sonst ☐
   - Meistens schlecht ☐

8. Hat Ihr Kind im vergangenen Monat wegen Krankheit gefehlt?
   - Nein / Ja Wenn Ja, bitte geben Sie die Anzahl der Tage und Einzelheiten an:
     ……………………………………………………………………………………………………………………………….

9. Hat diese Krankheit Ihr Kind bei alltäglichen Aktivitäten beeinträchtigt? (z.B. mit Freunden spielen, Teilnahme beim Sport)
   - Nein / Ja Wenn Ja, wie oft?

10. Wie oft ist Ihr Kind in den vergangenen drei Monaten bei einem Arzt gewesen? …………………
    Wieviele Vorstellungen waren Routine, welche außerhalb der Routine? ……………… …

11. Erhält Ihr Kind zur Zeit eine Behandlung gegen HIV? Ja / Nein
    Wenn Ja, wieviele Tabletten muss Ihr Kind am tag einnehmen? ………………

12. Wie alt war Ihr Kind bei Beginn der Therapie? ………………………….

13. Wie, glauben Sie nimmt Ihr Kind die Tabletten?:
   - jedes Mal ☐
   - ungefähr 80% ☐
   - ungefähr 50% ☐
   - zwischen 25% und 50% ☐
   - weniger als 25% ☐

14. Wie sehr beeinträchtigt die Tabletteneinnahme das Alltagsleben Ihres Kindes? (bitte nur eines ankreuzen)
   - Gar nicht ☐ Etwas ☐ Ziemlich ☐ Sehr ☐

15. Hatte ihr Kind Nebenwirkungen von der Behandlung?
   - Nein / Ja Wenn Ja,, bitte Einzelheiten angeben:
     ……………………………………………………………………………………………………………………………….

16. Wie gut kommt Ihr Kind damit zurecht, im Alltag die Tabletten einzunehmen (z.B. in der Schule)?
    ………………………………………………………………………………………………………………………………………
17. Wie zufrieden sind Sie mit der Unterstützung, die Sie im Rahmen der Behandlung Ihres Kindes bekommen?

Sehr unzufrieden ☐ Unzufrieden ☐ ganz zufrieden ☐ Sehr zufrieden ☐

18. Weiß Ihr Kind von seiner HIV-Infektion?

Ja / Nein Wenn Ja, wie alt war es, als es davon erfuhr? ………….

19. Weiß Ihr Kind, dass andere in der Familie infiziert sind?

Ja / Nein / keine Angaben möglich

20. Glauben Sie, dass Ihr Kind die Therapie besser einhält, wenn es von der Erkrankung weiß?

Ja / Nein Wenn Ja, auf welche Weise?

…………………………………………………………………………………
…………………………………………………………………………………

21. Glauben Sie, dass die Infektion Ihres Kindes zu Problemen im Umgang mit Freunden geführt hat?

Ja / Nein Wenn ja, auf welche Weise?

…………………………………………………………………………………
…………………………………………………………………………………

Wenn Sie weitere Kommentare mitteilen möchten, können Sie diese gerne in diesem Kästchen aufschreiben:

Vielen Dank, dass Sie sich die Zeit genommen haben, diese Fragen zu beantworten. Ihre Teilnahme wird uns helfen, zu verstehen, wie Kinder und Heranwachsende mit HIV-Infektion in Europa leben, und in welchen Bereichen Sie mehr Unterstützung benötigen.

Für weitere Informationen können Sie gerne folgende Adresse kontaktieren:
Dr Luisa Galli,
Division of Paediatrics and Infectious Diseases
Department of Paediatrics, University of Florence
Anna Meyer Children's Hospital
via Luca Giordano 13, I-50132 Florence, Italy
Tel: +39 055 5662540
Fax: +39 055 570380 l.galli@meyer.it
Children and adolescents living with HIV infection in Europe

From a background of coordinating large cohorts of HIV infected women and their children in Italy and Europe we felt it was timely to focus in particular on the lives of children with HIV infection in Europe, to help us understand how they cope with this chronic infection. To do this, we are asking the parents or carers of children and adolescents with HIV infection across Europe to answer some questions for us, in an anonymous survey, and in addition we ask the regular health care professional of these children/adolescents to give us some background clinical information.

We would be grateful if you could complete the first page of this form, and complete the hospital patient identifier in the top right corner of page one and the accompanying pages 2 and 3. The latter pages are to be completed by the parent or carer of the child, and it is important for you to ensure that pages refer to the same child. The hospital identifier is the only means by which this can be achieved. Please then hand on the remaining pages to the parent/carer for completion. The parent’s form can be returned in a blank envelope to you, and you can then return all forms to either Luisa Galli or Claire Thorne at the addresses below.

If you have any problems or questions please contact:

Dr Luisa Galli
Division of Paediatrics and Infectious Diseases
Department of Paediatrics, University of Florence
Anna Meyer Children's Hospital
via Luca Giordano 13
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Tel: +39 055 5662540
Fax: +39 055 570380
lgalli@meyer.it

Dr Claire Thorne
Centre for Paediatric Epidemiology
Institute of Child Health
30 Guilford Street
London
WC1N 1EH
Tel : +44 20 7905 2105
Fax : +44 20 7813 8145
c.thorne@ich.ucl.ac.uk

Thank you for giving up your time and agreeing to be part of this important survey.
Children and adolescents living with HIV infection in Europe
Barn och ungdomar med HIV i Europa

This page to be completed by the health care provider/ denna sida fylls i av sjukvårds personal

<table>
<thead>
<tr>
<th>Datum för ifyllande (dd/mm/åå):</th>
<th>........................................</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sjukhus: ..................................</td>
<td>Namn på sjukvårds personal: ...............</td>
</tr>
<tr>
<td>Barnets födelsedag (dd/mm/åå):</td>
<td>Kön: Man / Kvinna</td>
</tr>
<tr>
<td>Etnisk tilhörighet: Europe / Afrikan / Other</td>
<td>Födelseland: ................................</td>
</tr>
<tr>
<td>Moderns födelseland: .........................</td>
<td>Fadernsfödelseland: ........................</td>
</tr>
<tr>
<td>Hur är barnets levnadssituation?</td>
<td>Lever med sin familj ☐ Fosterhem ☐ Adopterad ☐ Annan, specificera ..............................</td>
</tr>
</tbody>
</table>

**Barnets troligaste smittväg för HIV-infectionen**
- Mor till barn smitta: Ja / Nej
- Blod produkter / transfusion: Ja / Nej
- Okänd: Ja / Nej

*(specificera nedan)*

| Vem/vilka i familjen är också HIV-infekterad (markera alla med HIV-infection)? |
|---------------------------------|----------------------------------|
| Ingen ☐ Modern ☐ Fadern ☐ Syskon (antal) ............... | |

Har någon i familjen avlidit i HIV? Nej / Ja Om Ja, vem och när? ........................................

**Nuvarande kliniska/ immunologiska status**

- Nuvarande CDC stadium ................................ Tidpunkt (dd/mm/åå): ............... Max CDC stadium: ............... |
- Senaste CD4-tal: ....................... CD4 % ......................... Datum: (dd/mm/åå): ....................... |
- Senaste virus mängd: ....................... Mätmetod: ......................... Datum: (dd/mm/åå): ....................... |
- Har barnet varit på sjukhus minst en natt senaste 6 månaderna? Nej / Ja |

**Aldrig behandlad**
- Om Ja, vad var orsaken? ......................... Och hur många nätter? ............................

**Antiretroviral behandling**

När började barnet första gången med antiretroviral behandling? *(specificera ålder eller startdatum)* ............................

Vilken är barnets nuvarande antiretrovirala behandling (specificera läkemedlen): ............................

När påbörjades den nuvarande regimen? (månad/år) ............................

Hur många behandlingsbyten har barnet haft? *(markera med cirkel)*

<table>
<thead>
<tr>
<th>Aldrig behandlad</th>
<th>Inget byte</th>
<th>1-2</th>
<th>3-5</th>
<th>6+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Har barnet haft några biverkningar av den antiretrovirala behandlingen? Nej / Ja</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Om ja, var god beskriv detaljerat (t.ex. typ av biverkan, datum/ålder, hur länge, hinder för aktiviteter, etc.)*

<table>
<thead>
<tr>
<th>..........................................................</th>
<th>..........................................................</th>
<th>..........................................................</th>
<th>..........................................................</th>
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</thead>
</table>
From a background of coordinating large cohorts of HIV infected women and their children in Italy and elsewhere in Europe we felt it was timely to focus in particular on the lives of children and adolescents with HIV infection in Europe, to help us understand how they cope with this chronic infection. To do this, we are asking the parents or carers of children and adolescents with HIV infection to answer some questions for us, in an anonymous survey.

We would be grateful if you could complete this form, possibly together with your child if you think this is appropriate. We do not need to know your name and none of the information provided will be communicated to anyone else. We will use the responses provided in summary format only.

**Familj, skola och barnomsorg**

1. Vilken relation har du till barnet som du är vårdnadshavare till? (t.ex. mamma, pappa, foster förälder etc)

2. Vem/vilka bor barnet hos? (markera alla som är tillämpliga):
   - Mamma
   - Pappa
   - Andra släkting(ar), specificera
   - Adoptiv förälder
   - Foster förälder
   - Annan, specificera

3. Går barnet i (markera alla tillämpliga):
   - Skola
   - Daghem/lekskola
   - Annan barnomsorg (specifika)

4. Har man på skolan eller daghemmet/lekskolan vetskap om ditt barns HIV-infektion? Ja / Nej
   - Om Ja, vem har fått veta? (Markera alla tillämpliga)
     - Rektor
     - Klass lärare
     - Annan person (Var god specificera)

5. Får barnet extra stöd i skolan eller på daghemmet? (t.ex., assistent eller speciellärarstöd)
   - Ej relevant
   - Nej
   - Ja (var god specificera)

6. Får barnet stöd eller hjälp från någon av följande? (Om ja, försök ange hur många gånger per månad):
   - Psykolog
   - Kurator
   - Stöd grupp
   - Annat stöd (specifika)
Hälso situation och behandling

7. Den senaste månaden har ditt barn mått: *(markera en)*:
   - I huvudsak bra, inga stora problem
   - Något sämre än vanligt
   - Betydligt sämre än vanligt
   - Dåligt hela tiden

8. Den senaste månaden (lovdagar ej medräknade), har ditt barn varit frånvarande från skolan eller daghemmet/förskolan på grund av sjukdom?
   - Nej   /   Ja   Om ja, var god ange antal dagar och vilka orsakerna var:

9. Har ditt barn, den senaste månaden, på grund av sjukdomssymptom förhindrats att göra vanliga fritidsaktiviteter exempelvis leka med hans/hennes vänner, deltaga i kalas eller andra sociala aktiviteter eller deltaga i sport/idrott?
   - Nej   /   Ja   Om Ja, hur många gånger?

10. Hur många gånger har ditt barn varit hos doktorn eller sjuksköterskan de senaste 3 månaderna?   … …
   
   Av dessa, hur många var planerade rutinbesök?

11. Får ditt barn för närvarande behandling mot sin HIV infektion? Ja / Nej
   
   Om Ja, hur många tabletter tar hon/han per dag?

12. Hur gammal var barnet när hans/hennes första HIV-behandling började?

13. Uppskattningsvis hur ofta tar ditt barn all sin medicin *(markera bara ett alternativ):*
   - varje gång
   - ungefär 80% av tiden
   - ungefär 50% av tiden
   - mellan 25% och 50% av tiden
   - mindre än 25% av tiden

14. Hur mycket stör medicineringen med antiretrovirala läkemedel ditt barns vardagsliv? *(markera bara ett alternativ)*
   
<table>
<thead>
<tr>
<th>Inte alls</th>
<th>Lite grann</th>
<th>Ganska mycket</th>
<th>Mycket</th>
</tr>
</thead>
</table>

15. Har ditt barn haft problem med biverkningar av medicineringen?
   
   - Nej   /   Ja   Om Ja, var god beskriv hur:

16. Hur klarar ditt barn av att behöva ta läkemedlen i förhållande till sitt vanliga vardagsliv (till exempel, att ta dom i skolan)?
   
   ……………………………………………………………………………………………………………………………………………………..
17. Hur nöjd är du med det stöd du och ditt barn får när det gäller behandlingen?

- Mycket missnöjd ☐
- Missnöjd ☐
- Ganska nöjd ☐
- Mycket nöjd ☐

Disclosure- vad barnet vet

18. Vet ditt barn om att hon/han är HIV infekterad?

Ja / Nej, Om Ja, hur gammal var hon/han när hon/han blev medveten om det? …………..

19. Är ditt barn medvetet om att någon annan i familjen är HIV infekterad?

Ja / Nej / ej relevant

20. Tror du att ditt barns kunskap om sin HIV har gjort det lättare att följa den ordinerade antiretrovirala behandlingen?

Ja / Nej, Om Ja, på vilket sätt? …………………………………………………………………………
…………………………………………………………………………………………………………………

21. Tror du att ditt barns infektion har orsakat/orsakar några problem med kamrater/vänskap för honom/henne?

Ja / Nej, Om Ja, på vilket sätt? …………………………………………………………………………
…………………………………………………………………………………………………………………

Om du har några nadra kommentarer/tankar får du gärna skriva dem här:

Thank you for taking the time to answer these questions. Your participation will help us understand how children and adolescents in Europe live with HIV infection and will identify areas in need of support.

If you would like further information please contact:
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