Press Briefing
Paediatric Digestive Health (IBD)

Introduction from the UEG President:
Michael Manns

Paediatric IBD Treatment – Time for Change:
Gigi Veereman

Paediatric IBD Transition to Adult Care:
Britta Siegmund

Guest Speaker:
Luisa Avedano (CEO of EFCCA)

Questions and Close:
Michael Manns
Recommendations for PIBD

Paediatric Digestive Health Across Europe (UEG, 2016)

Future recommendations for PIBD

Advances have been made in the treatment of PIBD across Europe with new guidelines, training syllabi, research and the PIBDnet registry. However, to halt the increase in the incidence and the impact and severity of the disease, further action needs to be taken including:

- Greater understanding of the complex physical, psychological and social needs of children with PIBD
- Tailored care and services, including the transitional period into adult services, which are key to improving the patient’s experience and ensuring successful disease management.
- Funding to provide more extensive subspecialty paediatric GI training to meet the requirements of new guidelines
- Further research into all types of IBD, not just UC and CD, to fully understand the causes enabling the development of effective treatments and prevention strategies
- Further research into early life programming to understand the causes and enable the development of immune-mediated GI conditions and facilitate the development of advanced treatment and prevention strategies
- Long-term follow up, regular reviews and frequent medical interventions by multi-disciplinary teams
- Significant reductions in the delay between adult trials of new treatment and those in children to ensure that new appropriately formulated licensed treatments with proven safety profiles are available for children as soon as possible
Paediatric IBD

Professor Gigi Veereman
United European Gastroenterology Public Affairs Committee Member
European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) Secretary General
Paediatric IBD Treatment

Time for Change
Current challenges
Paediatric IBD – rising incidence and impact

• Levels of paediatric IBD (PIBD) are rising

• One quarter of individuals with IBD are diagnosed at under 20 years old, of which most are diagnosed in adolescence

• Children often present with more severe symptoms and therefore often require more aggressive forms of medication

• Can have a significant impact on child’s emotional and mental health
Paediatric IBD – low public health priorities

Children currently have a low priority at the public health level.

Delays in a diagnosis of up to 5 years is experienced in 18% of under 18 years olds with IBD.

- Low priority
- Lack of research to understand needs
Prescription of off-label adult medications

- Prescribing off-label adult medications to children with IBD
- Negative effects on the developing body and in the long-term
- Not properly studied
- Adequate treatment strategy not properly established
Paediatric clinical trials in gastroenterology

• Only 5% of Paediatric Investigation Plans (PIP) in gastroenterology (European Medicines Agency, period 2007-2011)

• Scarce in pharma-sponsored studies

• Lack of independent funding for large collaborative paediatric trials

• A need for financial and organisational support of existing scientific networks
Barriers to paediatric IBD trials
Issues with paediatric trials

• Implementation of trials are more complicated in children than adults

• Pharmacokinetic data difficult to obtain in children

• Reconsidering the use of placebo in diseases that have a similar course in adults and children

• Attitudes of parents, as well as physicians, towards clinical trials in children is a barrier

• Apathy regarding need to action studies for off-patent medicinal products for the treatment of PIBD
Adapting clinical trials

Install adapted trial designs and registries.

Crucial to establish the safety profile of medication given to children with particular attention on:

- Growth
- Nutritional status
- Pubertal and intellectual development
- Associated diseases or congenital problems
- Long term effects
Next steps in paediatric IBD
Steps to overcome challenges

• New EU Policy
• Paediatric Committee (PDCO) newly created to improve assessment and guidance for paediatric trials
• ESPGHAN – developing white book
• Considerable individual efforts
• New research structures, supported by independent funds, should be embedded into European scientific networks
• Need global effort - bring stakeholders together to address the urgent needs in paediatric research
EU must recognise that the children of today are our future and unresolved problems will create a burden across Europe
Thank you
Questions
PIBD Transition to Adult Care – Berliner TransitionsProgramm

Britta Siegmund
Med. Klinik für. Gastroenterologie, Infektiologie, Rheumatologie
Charité, Campus Benjamin Franklin
Paediatric Inflammatory Bowel Disease

- 25% IBD cases diagnosed during childhood
- 6x more likely to develop colorectal cancer
- 18% 5-year diagnosis
- Children present with a more severe form of the disease
- Up to 1 in 4 cases of IBD are diagnosed during childhood
- IBD patients are six times more likely to develop colorectal cancer
- Delays in the diagnosis of up to five years is experienced by 18% of under 18 year olds with IBD
- Children with IBD often present with a more severe and aggressive form of the disease than adults

- 52% negatively affected education
- IBD can have a significant impact on a child’s emotional and mental health
- 8x risk
- Children, siblings or parents of individuals with IBD have an eightfold increased risk of also developing IBD
- The period just before and after birth as well as early life events, including antibiotic use, may play a significant role in the development of IBD

Need for transitional care - Europe

Paediatric Digestive Health Across Europe (UEG, 2016) – recommendations for reducing the incidence and impact of PIBD across Europe:

‘Tailored care and services, including the transitional period into adult services, which are key to improving the patient’s experience and ensuring successful disease management’
Need for transitional care - Germany

- Almost 40% of children and adolescents in Germany live with a chronic health disorder
- Considerable increase in IBD prevalence in Germany since 1980s

Opinion of the German Expert Council

*International experience, local projects and the literature reflect the following picture with regard to medical care in the transitions phase in between adolescent and adult care:*

*During the transition from adolescent to adult care there is a risk for “lack-of-care” mainly due to a lack of coordination. This “lack of care” is well documented for several chronic diseases.*
Need for transitional care

Example: Kidney transplants

<table>
<thead>
<tr>
<th>Model of transfer from paediatric to adult care</th>
<th>Direct transfer</th>
<th>Integrated transition and young adult service</th>
</tr>
</thead>
<tbody>
<tr>
<td>Time period</td>
<td>2000–05</td>
<td>2006–11</td>
</tr>
<tr>
<td>Transfer process and adult care team</td>
<td>Single referral letter, 6 adult nephrologists</td>
<td>Young adult team (1 nephrologist, 1 nurse specialist, and 1 youth worker)</td>
</tr>
<tr>
<td>No of patients (male, female)</td>
<td>9 (3 male: 6 female)</td>
<td>12 (7 male: 5 female)</td>
</tr>
<tr>
<td>Median (range) age at transfer to adult care (years)</td>
<td>18 (16–18)</td>
<td>17.5 (16–18)</td>
</tr>
<tr>
<td>No (%) of late acute rejections</td>
<td>3 (33)</td>
<td>0</td>
</tr>
<tr>
<td>No (%) of renal allograft loss</td>
<td>6 (67)</td>
<td>0</td>
</tr>
<tr>
<td>Median (range) time to renal allograft loss</td>
<td>40 (1–62)</td>
<td>—</td>
</tr>
<tr>
<td>No of deaths</td>
<td>1 (due to miliary tuberculosis)</td>
<td>0</td>
</tr>
</tbody>
</table>

Harden PN et al. BMJ (2012) 344:e3718
Need for transitional care
Dear Professor Siegmund,

....

Our son Benjamin was diagnosed with UC in 2012, he has been suffering from symptoms over the last 6 years. All medications did not results in an improvement of his condition... Hence we are seeking for a second opinion. Our gastroenterologist recommended surgery...

Some additional facts: Benjamin was diagnosed with Psoriasis during Kindergarten, and he has several allergies,....

Yours sincerely
Dear Mr. XX,
I have one more question, could you provide your sons DOB?
Yours sincerely,
Britta Siegmund.

Dear Professor Siegmund,
Benjamin was born 19.07.1983.
Yours sincerely,
Transition: Paediatric care view

• Strong patient – physician bond

• Complex disease, difficult for transition

• Patients are used to their paediatrician

• Doubts whether adult care is equally as effective
Transition: Adult care view

- Parental communication more difficult
- Lack of independence of the patients
- Incomplete medical history
- Patients are on medications that have not been approved for IBD
- A lot of time, no money
Transition: what do we need?

- Well-structured transition process
- A detailed medical report
- A transition phase
- Control to ensure that patient does not get lost
- Effective communication
- Financial appraisal
- Both partners (paediatric and adult care) to facilitate the transition
Facilitating the transition – joint efforts
Berliner TransitionsProgramm (BTP)

The aim of the BTP is to overcome structural barriers from paediatric to adult care.

• The programme can be applied in different chronic diseases
• The programme can be applied in different regions
• The service provided is being financially reimbursed
BTP - Structure

Transition Process
• Transition specific elements (visits, etc.)

Case Management
• Contact person for all parties involved (patient, parents, etc.)

Materials
• Information booklet, flyer
• T(ransition) book
• Questionnaire – to evaluate the knowledge of the patient concerning the disease
• Structured medical report

Financing
• Reimbursement of transition-specific services
Structural elements of the BTP

BTP transition centre
Case Management

1st transition visit

Medical report

2nd transition visit

Joint visit

Final transition visit

Pediatric/ Adolescent Care  TRANSFER  Adult Care

12 Months  ⇐ 18 y/o  ⇐ 12 Months
### BTP: Diseases

<table>
<thead>
<tr>
<th>Disease</th>
<th>ICD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes mellitus Type 1</td>
<td>• E10.- (except E10.0); • E14.-</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>• G40.-; • G41.-</td>
</tr>
<tr>
<td>Nephrological diseases</td>
<td>• N18.- (except N18.80 and N18.89); • Z94.0</td>
</tr>
<tr>
<td>Inflammatory bowel diseases</td>
<td>• K50.-; • K51.-</td>
</tr>
<tr>
<td>Rheumatological diseases</td>
<td>• M08.- (except M08.7); • M09.-*; • M30.- bis M32.-; • M33.0 and M33.2; • M34.- bis M35.-; • M45.-; • L40.5+; • I77.6</td>
</tr>
<tr>
<td>Neuromuscular diseases</td>
<td>• G12.-; • G60.- bis G63.-; • G70.- bis G72.-</td>
</tr>
<tr>
<td>Oncological diseases</td>
<td>• C22.0; • C22.2; • C40.-; • C41.-; • C47.-; • C48.-; • C49.-; • C64.-; • C70.-• C71.-; • C72.-• C74.-; • C81.-; • C82.-• GC83.-; • C85.- • C86.-; • C91.-• C92.-; • C94.6.-• C96.0.-; • C96.2; • C96.5; • C96.6; • D33.9; • D45; • D46.-• D47.3; • D47.5</td>
</tr>
<tr>
<td>Endocrinological Diseases</td>
<td>• E23.-; • E25.-• Q96.-</td>
</tr>
<tr>
<td>ADHS</td>
<td>• F90.-; • F98.8</td>
</tr>
</tbody>
</table>
Participants per disease area

- Diabetes
- Epilepsy
- Rheumatology
- Nephrology
- Muscular Diseases
- IBD
### Medical Report

#### Diagnose

<table>
<thead>
<tr>
<th>Diagnose:</th>
<th>Erstdiagnose (Jahr):</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morbus Crohn (K50.--)</td>
<td>mm/jjjj</td>
</tr>
<tr>
<td>Colitis ulcerosa (K51.--)</td>
<td></td>
</tr>
<tr>
<td>Colitis indeterminata (K50.3)</td>
<td></td>
</tr>
<tr>
<td>Betreuungszeitraum:</td>
<td>mm/jjjj – mm/jjjj</td>
</tr>
</tbody>
</table>

#### Anamnese

### Familienanamnese (FA)*

<table>
<thead>
<tr>
<th>FA für CED:</th>
<th>FA für andere Autoimmunerkrankungen:</th>
</tr>
</thead>
</table>

### Eigenanamnese

**Auftreten der ersten Beschwerden? Wann?**

- Vor weniger als 3 Monaten
- Vor weniger als 6 Monaten
- Vor über einem halben Jahr

<table>
<thead>
<tr>
<th>Bauchschmerzen</th>
<th>Durchfall</th>
<th>Blutige Stühle</th>
<th>Abgeschlagenheit/Müdigkeit</th>
<th>Gewichtsverlust</th>
<th>Wachstumsstillstand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ja</td>
<td>Ja</td>
<td>Ja</td>
<td>Ja</td>
<td>Ja</td>
<td>Ja</td>
</tr>
<tr>
<td>Nein</td>
<td>Nein</td>
<td>Nein</td>
<td>Nein</td>
<td>Nein</td>
<td>Nein</td>
</tr>
</tbody>
</table>

#### Infektiologie/Impfschutz

- Tuberkulose (Anamnese/Quantiferon-Test)
- Röntgen-Thorax
- Hepatitis B-Impfung
- Impfung lt. STIKO-Empfehlung
- Windpocken (Varizellen) durchgemacht?
- Impfung gegen Windpocken (Varizellen)

- Ja   - Nein   - Unbekannt
- Ja   - Nein   - Unbekannt
- Ja   - Nein   - Unbekannt
- Ja   - Nein   - Unbekannt
- Ja   - Nein   - Unbekannt
- Ja   - Nein   - Unbekannt

#### Krankheitsspezifische somatische Anamnese

<table>
<thead>
<tr>
<th>Diagnostik lt. Porto-Kriterien, d. h. Gastroskopie + Koloskopie + Sonographie + MR-Enteroklysma</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ja</td>
</tr>
</tbody>
</table>
Monitoring – patient contact

Patientenkontakt halten – Der Prozess

Patienten
Die Patienten nutzen eine Smartphone App mit der sie im direkten Kontakt zum Fallmanagement stehen.

Die Patienten können Informationen des Fallmanagements empfangen, mit dem Fallmanagement chatten und diesen Termine senden.

Chat

Features
Weitere Features oder die Anbindung an andere Beteiligte der Transition, wie bspw das Einbinden der Ärzte, sind theoretisch denkbar.

Fallmanager
Das Fallmanagement führt über VETO CUBE die Kommunikation mit den Patienten durch.

Das Fallmanagement muss nicht länger auf verschiedene freie Messenger, Telefon, E-Mails, SMS und Sonstiges zurückgreifen. Zudem wird die Kommunikation über eine Schnittstelle zu dem Dokumentationsystem syncASE übertragen und rundet damit die komplette elektronische Fallbearbeitung ab.

Listen
Das Fallmanagement kann den Patienten Informationen über die Transition im Allgemeinen oder zum Beispiel Informationen über Krankheitsbilder zur Verfügung stellen.

Schnittstelle syncASE/synJOB
Das Berliner Transitionprogramm setzt syncCASE als Dokumentationsystem ein. Die gesundheitliche Situation sowie die Koordination und Begleitung des Übergangs in die Erwachsenenmedizin werden in syncCASE dokumentiert.
Monitoring – patient contact
Regions currently included

- Berlin
- Brandenburg
- Mecklenburg—West Pomerania
- Lower Saxony
- Schleswig-Holstein
- Hamburg
- Hessen
- For TK Germany
Successful transition in the future
Thank you

www.berliner-transitionsprogramm.de

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Questions
EFCCA Youth Group Project on Transition

Luisa Avedano
EFCCA CEO
EFCCA at a glance

The European Federation of Crohn’s and Ulcerative Colitis Association is a not for profit international organisation made up of 33 patient associations (30 within Europe, 3 outside EU)

Members:
Austria, Belgium(2), Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Israel, Italy, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom, Argentina, and New Zealand

EFCCA Youth Group:
Young IBD patients (18-30) from EFCCA members
EFCCA at a glance

**Mission**
To improve the well-being of people with IBD and give them a louder voice and higher visibility in Europe and worldwide, improving the life of people of IBD by:

- Becoming a reference point in the discussion on new drugs and innovative therapies
- Developing a more effective cooperation with UEG, ECCO and the Health Care Providers Community (N-ECCO)
- Boosting a stronger cooperation with sister organisations worldwide
- Increasing the number of stakeholders and supporters
EFCCA Youth Group

Activities:

- Training on social media
- EFCCA labelled summer camps
- Transition project
- Annual EFCCA Youth Meeting

...permanent seat on the EFCCA Governing Body
Transition To Adult Care Project

Background

• Lack of information and guidance in healthcare systems
• Risk of discontinuity in adherence to treatments
• Huge sense of the unknown that leads to fear of change
• Need stronger relationships between HCPs and patients
• Approach to patients can greatly differ in adult care compared to children’s care
• Lack of legal and financial framework for transition:
  • Clear leadership and the role of a Transition Coordinator needs to be defined
• Young patients would like to be more involved in the transition process and require peer-to-peer support and specialist care
Transition to adult care project

Where we are:

• Partnering with European Patient Forum and involving patients that represent other disease areas to achieve higher visibility and gain a stronger critical mass

• Questionnaire to be distributed among youngsters
Thank you
Questions