Hepatitis C Treatment Advocacy: Ireland

Brian O’Mahony
Haemophilia and Hepatitis C

- 775 people with Haemophilia in Ireland
- 252 people with Haemophilia infected with Hepatitis C before 1992
- 106 of these co-infected with HIV
- 112 died
- 138 currently living with Hepatitis C
- 81 cleared virus or had successful treatment
- 57 require treatment
Hepatitis C Treatment Advocacy

• Prioritisation of Hepatitis C for organisation
• Data and evidence
  - impact of Hepatitis C
  - why treat
  - why prioritise PWH
• Educate, inform and prepare PWH to build demand for access to treatment
• Interact and Advocate effectively and constantly with key stakeholders
Key Stakeholders

- People with Haemophilia and Hepatitis C
- Doctors- Hepatologists, Infectious disease specialists
- Paying authority
- HTA agency
- Ministry of Health
- Minister of Health
- Opposition Health spokespersons if necessary
- Pharmaceutical companies
- Media
- Other Hepatitis C organisations as required
Treatment Advocacy 2012

• Prior to 2012, treatment with Pegylated Interferon/ Ribavirin available without delay
• SVR rate in Genotype 1 approx. 40%
• New generation of treatment available in 2012:
  • Protease Inhibitor (Telaprevir / Boceprevir) with Peg Interferon and Ribavirin
• Advocacy required as therapies expensive and not readily reimbursed
HTA’s on Hepatitis C Treatment
Ireland 2012

Cost-effectiveness of boceprevir (Victrelis®) for the treatment of patients infected with genotype 1 hepatitis C virus in the Irish healthcare setting.

Economic evaluation of Telaprevir (Incivek®) as add-on therapy to pegylated interferon and ribavirin for the treatment of patients infected with Hepatitis C Genotype 1.

January 2012
Ireland Database Report 2012: Hep C status and disease outcomes
Planning to live with a deadly virus

National Hepatitis C Database
for infection acquired through blood and blood products
Baseline Report

THE IRISH TIMES Health Supplement. Tuesday, October 23, 2007

ConsumerHealth

Brian O’Mahony
Mr. James Reilly T.D.,
Minister for Health and Children,
Department of Health and Children,
Hawkins House,
Hawkins Street,
Dublin 2.

Dear Minister,

The Irish Haemophilia Society are very concerned about the delay in the availability of the new generation of Hepatitis C therapies for our members. The clinical situation for persons with haemophilia who were infected with Hepatitis C through the use of blood or blood products is devastating. A total of 257 persons with haemophilia were infected with Hepatitis C of whom 103 were also co-infected with HIV. To date, 107 have died of whom 70 were co-infected and 37 had Hepatitis C mono-infection. This means that, to date, 42% of our members with Hepatitis C have died. The rate of progression of liver disease in our members is clearly and alarmingly accelerating. In the 15 years up to October 2011, 6 people with haemophilia had undergone liver transplants. In the last 6 months, 4 people with haemophilia have undergone transplants. Clearly, it is vital that as many people with haemophilia as possible who have survived this deadly virus to date would have an opportunity to clear the virus. Approximately 80% of persons with haemophilia have Hepatitis C Genotype 1 which has not been associated with a high rate of sustained virological response to treatment in the past. The availability of the additional protease inhibitor therapies - Telaprevir and Boceprevir, has dramatically altered the probability of successful therapy for this cohort. The probability of successful therapy is now approximately 60%. These therapies are now licensed and available and indeed have undergone Health Technology Assessments which have demonstrated clear cost effectiveness.

We have been proactive in keeping our members with Hepatitis C and HIV up to date on developments in treatment as indeed have their Hepatologists and infectious disease specialists for those who are co-infected. Since last December, we have organized special meetings and published a special edition of our newsletter on this issue. Many of our members with Genotype 1 Hepatitis C have been assessed and are ready to start treatment and have been ready for some considerable time. Our initial indications were that treatment would commence in January or no later than February. We are very concerned about this inordinate delay and would like to see treatment commence without further delay before we see more people with haemophilia having to undergo liver transplants.

We are requesting an urgent meeting with you on this vital issue.

I look forward to your early response.

Yours sincerely,

Brian O’Mahoney,
Chief Executive
IRISH HAEOMOPHILIA SOCIETY

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Memo

Meeting with Minister for Health and Children, Dr. James Reilly on April 17th 2012

Re: Hepatitis C Treatment and Haemophilia

Hepatitis C and Haemophilia C
- 257 people with haemophilia were infected with Hepatitis C from Blood or Blood products provided by the HSA.
- 16% of these individuals were also co-infected with HIV.
- To date, 107 (42%) have died.
- 70 of those that have died were co-infected.
- 37 were mono-infected with Hepatitis C.

The overall picture is much worse for people with haemophilia due to many others who were infected via Blood or Blood products as seen by the much higher mortality rate. There are a number of possible reasons for this.
- Co-infection with HIV.
- Exposure to infected factor concentrates or, in many instances and a consequent higher viral load.
- Exposure to multiple genotypes of Hepatitis C.

Whatever the reasons, the figures and differences are apparent from the National Hepatitis C Database report from the HPSC (HPSC 2012 Report).

<table>
<thead>
<tr>
<th>Group</th>
<th>Haemophilia</th>
<th>April 17</th>
<th>Blood Transfusion/Reused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver Disease</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chronic</td>
<td>19.6%</td>
<td>4.9%</td>
<td>17.7%</td>
</tr>
<tr>
<td>Acute</td>
<td>4.0%</td>
<td>0.5%</td>
<td>4.2%</td>
</tr>
<tr>
<td>Edematous</td>
<td>24.6%</td>
<td>5.8%</td>
<td>23.0%</td>
</tr>
<tr>
<td>Endocarditis</td>
<td>11.3%</td>
<td>1.0%</td>
<td>6.4%</td>
</tr>
<tr>
<td>Death due to</td>
<td>11.4%</td>
<td>1.0%</td>
<td>6.4%</td>
</tr>
<tr>
<td>Liver disease</td>
<td></td>
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<tr>
<td>Death due to</td>
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<tr>
<td>Death due to</td>
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</tbody>
</table>
Data - Memo to Minister, 2012

- **Haemophilia and Hepatitis C**
  - 257 people with haemophilia were infected with Hepatitis C from Blood or Blood products provided by the state.
  - 106 of these individuals were also co-infected with HIV.
  - To date 107 (42%) have died.
  - 70 of those who have died were co-infected.
  - 37 were mono-infected with Hepatitis C
The clinical picture is much worse for people with haemophilia than for many others who were infected via Blood or Blood products as seen by the much higher mortality rate. There are a number of possible reasons for this:

• Co-infection with HIV.
• Exposure to infected factor concentrates on many occasions and consequent higher viral loads.
• Exposure to multiple genotypes of Hepatitis C.
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<th>Group</th>
<th>Haemophilia</th>
<th>Anti D</th>
<th>Blood Transfusion/Renal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver Disease</td>
<td>21.1%</td>
<td>6.6%</td>
<td>23.7%</td>
</tr>
<tr>
<td>Cirrhosis</td>
<td>10.6%</td>
<td>4.9%</td>
<td>17.7%</td>
</tr>
<tr>
<td>HCC</td>
<td>4.4%</td>
<td>0.4%</td>
<td>4.5%</td>
</tr>
<tr>
<td>Deceased</td>
<td>41.6%</td>
<td>5.4%</td>
<td>23.1%</td>
</tr>
<tr>
<td>Deceased due to Liver disease</td>
<td>11.5%</td>
<td>1.0%</td>
<td>6.4%</td>
</tr>
<tr>
<td>Deceased due to Liver disease or HIV</td>
<td>41.6%</td>
<td>1.0%</td>
<td>6.4%</td>
</tr>
</tbody>
</table>

HPSC Database, Ireland 2009 Report
Data - Memo to Minister, 2012

• Previous treatment
• Liver transplant to Date:
  • 13 liver transplants in 10 PWH
  • 4 currently alive
  • 4 died while awaiting liver transplants

• Preparation for treatment and the Society
• Economic case for treatment
If treatment is further delayed:

• More people with Haemophilia will develop cirrhosis or liver cancer.
• More people with Haemophilia will die.
• More people with Haemophilia will require expensive Liver Transplants which carries a very high risk of mortality.
• Severe liver disease may lead to a greater requirement for factor concentrate use which will cost more than the Hepatitis C treatment would have cost.
Economic Cost of Not providing safe Treatment in the past

- HIV
- Hepatitis A, B, C
- Cost of treatment
- Hospitalisation cost
- Cost of Inquiries
- Cost of Compensation
Outcome of Advocacy

• Minister for Health approved reimbursement at meeting with Society on World Haemophilia Day
Advocacy

• Decision to reimburse may not be the end of the process

• Additional steps with potential for delay:
  - paying authorities, clinicians, pharmacists, establishing protocols for treatment and reimbursement

• Potential for delay at every stage

• Your task not complete until treatment is completed successfully
Treatment Approved 2012

- Treatment did not begin until June
- Interim- 44 meetings or interventions:
  - Doctors, Pharmacists, Paying authority
- Mechanism to make the required funding available:
  - process slow and frustrating
- Further conversations with Minister
- Treatment commenced- support for all members on treatment and outcomes monitored
Educate, Inform, Prepare PWH

• Specific publications with comprehensible information – scientific and clinical
  - practical (diet, coping with side effects)
  - preparation (college and employment)
  - personal stories (make it real)
• Phone calls to each person with hepatitis C
• Group meetings with Hepatologists / ID consultants
Support to those on treatment

- Information and publications (Positive News)
- Individual meetings after clinic visits
- Regular Support phone calls from Society
- Peer to peer support
- Peer to peer encouragement and information on treatment outcome
- Diet guide for those on telaprevir
- Financial support for travel to hospital
- Provision of accommodation near hospital
Treatment Outcome 2012-2014

• Ireland – approx. 250 people treated
  - 20 with haemophilia
• SVR rate 51%
• **SVR rate in Haemophilia 80%**
• Compliance rate in haemophilia group was 100%
  - no PWH stopped treatment due to inability to cope with side effects
  - 30% of total group treated stopped due to side effects
Outcome measurements

• Quantitative survey of first 11 on treatment and qualitative data collection with their partners
• Data analysed and published
• Identified successful communication and intervention strategies and coping mechanisms
• Useful advocacy tool in battle to get access to next generation of treatment
Treatment Decisions: Sources of Information

- Information from other IHS members: 2.71
- Information available online: 2.55
- Phone calls from the Irish Haemophilia Society: 3.09
- Information Meetings organised by the Irish...: 4.30
- Information Newsletters from Irish...: 3.73
- Information leaflets from Pharmaceutical...: 1.91
- Consultation with the Hepatology Nurses /...: 3.82
- Consultation with my Hepatologist /...: 3.82

Impact levels: no impact, very high impact
Availability of new DAA treatments 2014

• Society had experience of previous treatment advocacy
• Society had outcome data on previous treatment
• Involvement in formal Hepatitis C bodies:
  - ICORN
  - Hepatitis C Consultative Council
  - Invited to join Ministry of Health Expert Advisory Group on Hepatitis C treatment
Issues

• High cost and budget impact of new treatments
• HTA process would take significant time
• Large number of people (>8,000) required treatment
• Large number undiagnosed (20 - 30,000?)
• Limited ability to fund in 2014
• Urgent clinical cases
• Society advocated within the group and publicly to raise profile of issue and increase decision speed
Rationale for Early Access....

Diagram showing the progression of HIV and Hep C over time, with points for perceived general health, time, point of infection, and death as a result of virus. Key terms include:

- **Compensating Liver**
- **Cirrhosis**
- **Tipping point**
- **Decompensation**
- **Liver Transplant**

Lines indicate the progression of conditions, with one line representing the progression of HIV in the 1980s (Pre ART's) and another for Hep C.
Early Access Program - 120

Patients with Cirrhosis
350 people

All other patients with Hepatitis C – Approximately 12,000
New "life saving" drugs which have a 95pc success rate, should be made available to sufferers with only months to live.

The Irish Haemophilia Society is calling for the drugs given as a once-off treatment.

It is estimated 350 patients require the treatment to tolerate the existing treatment care system for long-term damage, which can be life-threatening.

Brian O'Mahony, the society's chief executive, added: "The Department of Health is being asked to prioritise Hepatitis C patients, which involves a change in the system of care that is needed."

As a result of hepatitis C patients not receiving the care they need from the Health and the HSE to some which would save lives, O'Mahony added: "Access to new drugs could save 350 lives from hep C"
Haemophiliacs seek access to new treatment

Group says 350 Hepatitis C patients urgently need new therapies to stay alive

The Irish Haemophilia Society has called for early access to new treatments for Hepatitis C. Photograph: Andrew Matthews/PA Wire

Paul Cullen

The Irish Haemophilia Society has called for early access to new treatments for Hepatitis C. It says this group cannot medically tolerate the current Interferon treatment due to severe liver damage and the increased risk of death.

Of the 12,365 patients in Ireland who need Hepatitis C treatment, some 264 people with haemophilia have already identified by specialist hepatologists as needing urgent treatment.

Patients with Hepatitis C 'should have immediate access to potential lifesaving therapies' - Irish Haemophilia Society

Mark O'Regan

Published 15/09/2014 | 11:58

Email

Ireland | Health

Call for early access to Hepatitis C treatments

Monday 15 September 2014 21:41
Outcome - Early Access Programme

• Immediate treatment for those with decompensated cirrhosis and Child-Pugh score > 7

• Next clinical priority - cirrhosis
Treatment 2015

- National Treatment programme established with clinical lead and programme manager
- Budget of €30 million approved
- Roll out of treatment begins in May based on clinical criteria
- Society view:
  - Need to prioritise state infected people including PWH
  - Treat all post transplant in 2015, treat all state infected in 2015 or 2016
Hepatitis C – Players!

- Minister of Health
- CMO and Blood Policy unit, DOH
- Deputy CMO – Chaired Expert Group
- Health Service Executive - Primary care and reimbursement directorates
- HSE - programme manager
- ICORN - Doctors network
- NCPE - HTA agency
- Companies - Gilead, AbbVie, BMS, Merck, Janssen
Hepatitis C – Players!

- National Haemophilia Centre
- National Haemophilia Council
- IMRA - Regulator
- PSI – Pharmaceutical society
- St. James Hospital CEO / Finance Director
- Community response Organisation
- Anti D Group / Transfusion Positive
- Hep C Consultative Council
- Media
- Lawyers - legal options for accelerated access
Society Advocacy

• Interaction with all key stakeholders
• Clear data on people with haemophilia
• Constant interaction with HSE co-ordinator
• Interaction with clinicians – ICORN
• Media as required- including television appearance with head of HTA agency
• 3 meetings with Minister of Health- opportunistic
• Minister opened our Hepatitis C Conference, February
• 2 meetings between National Haemophilia Council and Minister of Health
• Meeting with Minister for Public Expenditure
252 People with infections on the database

112 RIP
  - 66 – Pre 1996
  - 29 – 1996-2006
  - 17 – 2006 - Present
    - 13 HCV related

140 Alive
  - 83 PCR Negative
    - 47 Treatment Cleared
    - 35 Spontaneous Clearance

57 PCR + or Unknown
  - 18 Treatment experienced
    - 11 (3) - G1
    - 3 (1) - G2
    - 3 (1) - G3
    - 1 (1) - G4
  - 24 Naïve
    - 12 (2) - G1
    - 5 (1) - G3
    - 2 (2) - G4
    - 1 (1) – G1/G3
  - 15 Unknown
    - 2 – G1
    - 1 – G3
    - 12 (2) – Unk Gen
    - 4 – Unk Gen
Hep C patients ‘will die without new therapies’

HUNDREDS of hepatitis C sufferers face liver failure or death within 12 months – unless they get access to new therapies.

The CEO of the Irish Haemophilia Society said the clock was ticking ‘very loudly’ for 350 people who cannot tolerate their interferon-based drugs.

Brian O’Mahony has now called on Health Minister Leo Varadkar and the HSE to provide early access to the new treatments, which cost around €45,000 and are administered as a one-off.

There are 12,365 patients here who need hepatitis C treatment, 350 of whom need immediate care.

‘What we’re worried about at the moment is the 350 people who urgently need treatment,’ said Mr O’Mahony.

Otherwise they face a very significant chance of death or liver failure or the requirement of liver transplant in the next year. They can’t wait.’

Interferon-based therapies can cause severe liver damage and can increase the risk of death if a patient uses them for a long period of time.

Mr O’Mahony said the State can save €10.5 million if the decision to provide treatment is taken before the end of October when one of the two new drugs is licensed.

Hepatitis C patients to finally start life-saving treatment

Nearly all 250 sufferers expected to recover after treatment costing up to €55,000 each

The first group of patients with advanced liver disease who have been approved will be treated at one of 10 centres across the State in the coming weeks. Photograph: Getty Images

Paul Cullen

Topics: News Health Suzanne Norris Department of Health Health Service Executive

Mon, Jun 1, 2015, 01:00   Recommend 11 Tweet 19 8+ 4

Some 250 seriously ill patients with hepatitis C are to begin receiving a life-saving new
Current and Future advocacy

• Ensure that all people with haemophilia are treated as soon as possible
• Continuously monitor progress of programme and advocate with stakeholders as required
• Interact politically and with media as required
• Collect outcome data on our members and share information with paying authority
• Continue to assist all members until hepatitis C eradicated