The Budget Impact of Hepatitis C Treatment in Ireland 2001-2012

Abstract:
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Abstract
Chronic Hepatitis C (HCV) is estimated to infect 20,000 to 50,000 people in Ireland. National estimates of the number of patients who have been treated for HCV, the demographics and the cost associated with the treatment are not published. Prescriptions for the treatment of HCV from 2000–2012 were established by interrogating the records of the High-Tech Drug Scheme and the pharmacy records of the Genitourinary Medicine and Infectious Diseases department of St. James Hospital. 2320 patients were initiated on treatment for HCV. Over 27 million was spent on HCV treatment. 25.5 million was spent on anti-viral therapy and 2 million was spent on haematological growth factor support for the management of adverse effects. The budget impact of HCV treatment has been significant in Ireland. New agents for HCV will have a greater budget impact but should require less spend on adverse event management.

Introduction
Chronic Hepatitis C (HCV) is an important public health concern with an estimated 20,000 to 50,000 people infected in Ireland. Of those, only the minority (approximately 12,000) are diagnosed and fewer still (approximately 8,000) have engaged in tertiary level hepatology care. At the present time, HCV therapeutics is undergoing enormous expansion with novel agents promising all oral regimes with minimal side-effects and excellent efficacy. These new agents will be challenging to fund in the current fiscal environment although some of the costs may be off-set by a reduction in the numbers of patients in the future and by a reduction in the costs associated with the management of haematological adverse effects generated by the current standard-of-care treatments. There has been progress made recently under the auspices of the Irish HCV Outcomes and Research Network (ICORN) and the National HCV strategy in improving our understanding of the HCV epidemic in Ireland. However, national estimates of the number of patients who have been treated for HCV, their demographics and the cost associated with that treatment have yet to be published. Establishing such estimates gives a baseline against which to benchmark future treatment endeavours. It also gives an assessment of the capacity of national HCV treatment services that is useful for service planning.

Methods
This study was carried out using data obtained from the Health Service Executive Primary Care Reimbursement Service (HSE-PCRS) pharmacy claims database. The HSE-PCRS pharmacy database contains data on prescriptions dispensed from all community health services and prescription medication in Ireland, through a number of national schemes, including the High Tech Drug Scheme (HTDS). The HTDS is a community drugs scheme that caters for high cost medicines initiated in hospital but subsequently dispensed in the community. Prescription medications dispensed through the scheme are recorded in the HSE-PCRS pharmacy database with the corresponding Anatomical Therapeutic Chemical (ATC) classification.

The incident number of patients prescribed these medications was established through unique patient identifiers in the HSE-PCRS database. The rates of co-prescribing of synthetic anti-anaemics (EPO), and granulocyte colony stimulating factor (G-CSF) were identified using the same methods.

The number of patients progressing to end-stage liver disease and by a reduction in the costs associated with the treatment is captured and included in the total costs associated with Year 2. Prescriptions dispensed to patients attending the Hepatitis C clinic based within the Genitourinary and Infectious Diseases (GUIDE) service in St. James Hospital were also established. Prescriptions for the treatment of HCV from 2000 to 2012 were established through interrogation of the pharmacy records in GUIDE and the drug costs associated with this service were calculated with the HTDS data to form an overall estimate of patient numbers and cost of drug treatment. Descriptive statistics are presented as sums, means and 95% confidence intervals. Analysis was performed using SAS v9.3 and Excel.

Results
There were 2398 courses of pegylated interferon and ribavirin administered to 2320 patients between January 2001 and December 2012. Annual prevalent treatment numbers peaked in 2009 with 496 patients receiving HCV treatment. Figure 1 displays the annual number of incident and prevalent cases receiving HCV treatment between 2001–2012. The majority of those treated were male (n=1565 (67%)) and aged between 25-45 years (62%).

In total, 27,614,326 was spent on medication for the treatment of HCV between 2001-2012. Annual overall drug costs are presented in Figure 2. This comprised of antiviral costs of 25,550,270 (15,460,488 for pegylated interferon and 10,089,781 for ribavirin) and 2,064,056 for haematological growth factor support (1,406,381 for EPO and 657,675 for G-CSF). Figure 3 displays the annual cost of the antivirals and haematological growth factor cost projections.

The prescription of EPO and G-CSF in this setting peaked in 2007 with 17% of patients initiated on EPO (n=40/235) and 13% initiated on G-CSF (n=31/235). Figure 4.

The average cost per patient initiated on treatment for HCV was 11,771 (95% CI 11,376-12,166). The average cost of antivirals per course of HCV treatment was 15,845 (95% CI 15,503-16,187) and for haematological growth factor support, in those who received such therapy, 4,377 (95% CI 3,908-4,598). 10.8% of patients received treatment with EPO (n=235). The average treatment cost was 4728 (95% CI 9-5307). For those who received treatment with G-CSF the average treatment cost per patient was 261 (95% CI 157-145).

Discussion
The morbidity and mortality associated with HCV infection, along with the global burden of disease, makes HCV treatment a worldwide priority. The new interferon-free regimens greatly simplify treatment and remove many of the previous barriers to HCV treatment. However, the drug costs associated with the novel treatment options represent a challenge to health-care payers in Ireland and internationally. From the data presented above, treatment with pegylated interferon and ribavirin cost on average 11,000 per patient. As yet, we do not exact prices for oral regimes such as simeprevir plus sofosbuvir in Ireland. In the US, treatment courses of simeprevir plus sofosbuvir can be in the region of $150,000. There is little doubt that the benefits of HCV treatment to the individual are considerable, with research demonstrating an improvement in health-related quality of life values in Irish patients achieving a sustained virological response or cure. From the perspective of the health-care payer, it is possible that investing in HCV treatment at the present time may be cost-effective as it may lead to an avoidance of high-cost health states such as liver transplantation in the future. This has been demonstrated for first and second generation direct-acting antiviral agents that have not been published. Prescriptions for the treatment of HCV from 2000–2012 were established by interrogating the records of the High-Tech Drug Scheme and the pharmacy records of the Genitourinary Medicine and Infectious Diseases department of St. James Hospital. 2320 patients were initiated on treatment for HCV. Over 27 million was spent on HCV treatment. 25.5 million was spent on anti-viral therapy and 2 million was spent on haematological growth factor support for the management of adverse effects. The budget impact of HCV treatment has been significant in Ireland. New agents for HCV will have a greater budget impact but should require less spend on adverse event management.
antivirals in other healthcare settings. A full cost-effectiveness analysis is being undertaken by the authors to establish whether the direct-acting anti-virals are cost-effective in the Irish health-care service. The budget impact of HCV treatment from 2001-2012 has been significant in Ireland. Twenty-seven million euro has been spent on providing drug treatment for this indication. Two million of this budget was provided for haematological growth factor support. The novel interferon-free regimens would remove the need for G-CSF and those that are also ribavirin-free would remove the requirements for EPO support, as anaemia is not a significant adverse effect of the second generation regimens. However, money that is currently being spent on the management of haematological adverse effects, could be redirected to the budget for anti-virals and provide a modest cost-offset. However, with the introduction of new interferon-free regimens, there is likely to be a cost-offset from a reduction in costs associated with the management of adverse effects. A full cost-effectiveness analysis is currently underway to further examine this area and the data provided in this study will inform that study and health-care decision makers developing budgets.

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References


