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, their demographics and the cost associated with that treatment 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.

Introduction

Chronic Hepatitis C (HCV) is an important public health concern with an estimated 20,000 to 50,000 people infected in Ireland[1]. Of those, only the minority (approximately 12,000) are diagnosed and fewer still (approximately 8,000) have engaged in tertiary level hepatology care[2]. At the present time, HCV therapeutics is undergoing enormous expansion with novel agents promising all oral regimens with minimal side-effects and excellent efficacy[3-6]. 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 number of patients progressing to end-stage liver disease 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[7,8]. 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. At the beginning of this new era in HCV care, we aimed to establish an estimate of the number of HCV patients treated from 2001-2012 and the drug costs associated with that treatment.

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 is a national database used primarily to reimburse the provision of health care 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 database using the World Health Organisation (WHO) Anatomical Therapeutic Chemical (ATC) classification. The HSE-PCRS database also collates basic demographic information pertaining to each GMS claimant including age, sex and region. It does not, however, contain any clinical diagnosis or outcomes data. Prescriptions for the treatment of HCV infection were identified by searching for co-prescription of pegylated interferon 2– or pegylated interferon 2† along with ribavirin from 2000 to 2012 using the Anatomical Therapeutic Chemical (ATC) classification codes within the HTDS. The rates of co-prescribing of synthetic anti-anaemics (EPO), and granulocyte colony stimulating factor (G-CSF) were identified using the same methods.

The incident number of patients prescribed these medications was established through unique patient identifiers in the database. The costs of these prescriptions were quantified using unit drug costs from the national health payer adjusted for dispensing fees and discounts. As the treatment course for many patientsâ spanned different calendar years, the prevalence of HCV patients on treatment in a particular year is also presented to accurately reflect clinic capacity. If a treatment course spanned different calendar years, the costs are included in the year that they are accrued e.g. 48 week treatment course commencing in October Year 1 and completing in August Year 2. The cost of 13 weeks of treatment is captured and included in the total costs associated with Year 1 and the costs of 35 weeks of 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 are not captured through the PCRS database. Therefore, prescriptions dispensed to patients treated through this service were established through interrogation of the pharmacy records in GUIDE and the drug costs associated with their care were calculated. This was combined 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 446 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=1567 (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 prescriptions.

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 â 12,166). The average cost of antivirals per course of HCV treatment was 10,845 (95% CI 10,503- 11,187) 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=252). The average treatment cost per course was 4728 (95% CI 4149- 5307). For those who received treatment with G-CSF (n=203), the average treatment cost per patient was 2,261 (95% CI 2,277 - 3,045).

Discussion

The morbidity and mortality associated with HCV infection, along with the global burden of disease, makes HCV treatment a worldwide priority[9]. The new interferon-free regimens greatly simplify treatment and remove many of the previous barriers to HCV treatment[10]. However, the drug costs associated with the novel treatment options represent a challenge to health-care payers in Ireland and internationally[11]. 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 regimens such as simeprevir plus sofosbuvir in Ireland. In the US, treatment courses of simeprevir plus sofosbuvir can be in the region of $150,000[12]. 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 â cureâ [13]. 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

antivirals in other healthcare settings[12,14,15]. 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 euro 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 requirement for EPO support, as anaemia is not a significant adverse effect of the second-generation direct-acting antivirals[3-6]. Thus, the 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. Hepatitis C treatment with pegylated-interferon and ribavirin is lengthy and very resource intensive. Patients experience a myriad of side-effects, both physical and psychological[16]. Because of this, they require a large amount of support and monitoring to enable them to complete their treatment regimens successfully. This limits the number of patients that an individual treatment centre can manage. The number of patients treated to date has been relatively modest, (in the order of 5-12% of affected patients), in part because of these capacity constraints. When developing budget impact estimates for the new direct-acting anti-virals, it is important to inform them with estimates of current service capacity. This data provides those figures. However, it is likely that a switch to all-oral regimens of shorter duration and reduced side-effects will result in an increase in capacity.

The role of treatment protocols and strong governance must be emphasised to ensure the appropriate and cost-effective use of these agents. Prospective outcome registries facilitate collection of data on prescriptions that can be linked with patient outcomes such as sustained viral response. The creation of the ICORN National Outcomes Treatment Registry is an important development in this regard and will provide real-world effectiveness data on the new agents as well as information on adverse effects and real-world cost of care.

There are some limitations with this data. The PCRS data is sourced from pharmacist reports which may underestimate usage as pharmacists receive a flat fee per month regardless of the number of drugs dispensed and will sometimes only report the first drug dispensed. Due to this it is likely that we have underestimated the total activity and costs of HCV therapy in Ireland. However, the inclusion of the data from the GUIDE department in St. James Hospital has been an important addition in improving the data capture and the robustness of the estimates. Ideally, the data on prescription and cost would be linked to clinical outcome data to give a more complete picture of the cost-effectiveness of HCV treatment. Unfortunately, this is not possible with the current PCRS database, as it does not include clinical data. The ICORN treatment registry will overcome these limitations in the future. While acknowledging these shortcomings in our data, we feel that it is useful to present an impression of the national activity and costs of HCV treatment over the past decade or so, and to provide an indication of the capacity of the HCV services in Ireland.

In conclusion, the budget impact of HCV treatment has been significant to the Irish healthcare system from 2001-2012. The advent of second-generation direct acting anti-virals provides the opportunity to treat more patients, more successfully for their HCV. While the funding for the new agents will pose a challenge to the healthcare services, 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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