

New treatment for hepatitis C infection

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Interferon (IFN) is a protein that occurs naturally in the body in very small amounts. It assists the immune system in fighting, for example, certain cancers and viruses by 'interfering' with and inhibiting the development and replication of cells. In the 1970s, medical science developed a synthetic IFN. Interferon therapy became standard treatment for hepatitis C infection following the identification of the virus in 1988.

By the mid-1990s, IFN was being trialled in combination with another antiviral called ribavirin. These treatment regimens were long and arduous, taking up to a year to complete, and more often than not, treatment did not cure hepatitis C infection. The aim of treatment for hepatitis C is a cure, and this is defined by the term: sustained virological response (SVR). This means that hepatitis C remains undetectable for a period of six months. Attaining a SVR is associated with improved health and wellbeing.¹

Unmodified IFN monotherapy achieves a cure rate of around 20% and unmodified IFN plus ribavirin combination therapy cures up to one-half of people in treatment. A cure depends on a range of factors, including the type of hepatitis C virus (i.e. genotype), age, viral load, and degree of fibrosis or cirrhosis. The side-effects of IFN and ribavirin treatments are at times profound, consisting of a range of debilitating physical² and psychiatric symptoms.^{3,4} Add to this the stigma of being hepatitis C positive and we start to see the difficulties associated with being in treatment.

Past research into the impact on health of treatment for hepatitis C infection has used quantitative measures of quality of life (QoL), like the SF36 Health Survey and the Sickness Impact Profile (SIP). These instruments indicate significant decrements in physical

and mental functioning during IFN-based treatment. However, these are generic instruments, not specifically designed for measuring the symptoms of hepatitis C infection, and the results do not reflect in detail the experience of illness and treatment. Clinical observation and anecdote is the other source of information about the impacts of treatment for hepatitis C. Currently, there are no published findings of qualitative studies on the impact of hepatitis C treatments. This is a major gap in the research literature.

Side-effects

The most commonly reported side-effects of IFN-based treatments include: fatigue, headaches or migraine, nausea and insomnia. However, the most often cited reasons for discontinuing treatment is the psychiatric side-effects, which include: depression, anxiety, amotivation, anorexia, paranoia, accentuation of previously existing phobias and suicidal ideation. Because of side-effects, the decision to commence IFN treatment in hepatitis C patients is approached cautiously.

Recent developments in hepatitis C treatment

In the last few years a new treatment has emerged—pegylated IFN (pegIFN) and ribavirin combination therapy. This new treatment has been shown to almost double previous average cure rates.⁵ It has a cure rate of 80% for genotypes 2 and 3, and of 50% for patients overall. It has been found to be effective in those considered difficult to treat e.g. those with genotypes 1 and 4, HIV co-infected, and those with advanced fibrosis or cirrhosis.⁶ This new drug formulation is seen as the front-line defence in hepatitis C

treatments—it was recently included in the PBS S100 prescriptions category.

Pegylation is a process whereby interferon molecules are 'coated' in order to slow their absorption into the bloodstream. This means that dosing can be reduced from three to one subcutaneous injection a week. Ribavirin is an anti-viral agent, usually administered orally in high doses twice-daily. Ribavirin has detrimental effects on blood and close monitoring is needed to control anaemia and other blood disorders that arise from its use. Because ribavirin causes foetal abnormalities, using the drug is particularly risky during pregnancy. Similar risks apply to men taking ribavirin while trying to conceive.

Implications of the new treatment

There is a clinical imperative to maintain high levels of these toxic drugs in the body for extended periods in order to affect a cure. This has prompted one US hepatologist, Michael Fried, to remark: "All patients treated with peginterferon and ribavirin will experience some adverse events during therapy". From a social research point of view, this statement highlights a need for investigation of how people cope with treatment-related 'adverse events' and the impact of these events on quality of life and treatment adherence.

Although several studies suggest similar tolerability of IFN and pegIFN,⁷⁻¹¹ there are indications from studies that have used carefully selected participants with no prior physical or mental health issues (apart from hepatitis C infection) that patients report a higher frequency of particular side-effects from this new treatment.¹²

Less than 1% of patients experience serious adverse events including loss of vision, loss of hearing, congestive heart failure, induction or exacerbation of autoimmune diseases, severe depression, suicidal ideation and suicide, and panic attacks. However, over 30% experience depression, anorexia, weight loss, irritability, alopecia, nausea and insomnia and more than 50% experience fatigue, headache and myalgia.² Patients are required to undertake treatment for at least 24 weeks and sometimes for 48 weeks. Paradoxically, dangerous side-effects from this new treatment result in dose reduction¹² and/or discontinuation of treatment even though treatment needs to be sustained, and in sufficient doses, in order to clear the virus.

Conclusion

A combination of therapeutic advances and structural changes has paved the way for people with hepatitis C to access treatment. A cure is now possible in 50–80% of patients, the drugs are subsidised as part of the highly specialised drug program, and prescribing by accredited general practitioners is being trialled in NSW, Victoria and the ACT at present. Dosing regimes are also now less time demanding and the treatment restriction on current injecting drug users has been lifted. In addition, it is now widely accepted that treatment of acute hepatitis C can prevent the onset of chronicity. Given these developments, the future is likely to see many more people directed toward treatment for hepatitis C infection.

To date there have been no qualitative studies looking at the impacts of any hepatitis C treatments. However we know that narratives of chronic illness have assisted many people, including clinicians, in coming to terms with disease, its treatment, and associated life upheaval.^{13, 14} As far back as 1998, a US hepatologist, D.K. Owens called for a qualitative study to understand how bothered patients were by their hepatitis C symptoms, because he felt that quantitative measures were limited in helping him understand his patients' health and well being. Judging from the medical literature, the same call needs to be made with regard to this new hepatitis C treatment.

New study

The NCHSR is commencing a qualitative study in order to develop additional management strategies beyond observation of clinical markers (e.g. haematological monitoring) to address the physical, emotional and social side-effects of treatment. This study will explore the following areas: psychosocial implications of side-effects; impacts on QoL; side-effects management strategies; experience vs. expectations of treatment; provision of information about side-effects; implications for patients who discontinue treatment; impact of hepatitis C-related stigma and discrimination; varying treatment experiences of different groups; and the effect of treatment success and failure on future outlooks.

The sample will consist of people undergoing pegIFN and ribavirin treatment for hepatitis C infection ($n=30$) and healthcare workers ($n=10$). The results of this study will inform clinicians about strategies for coping with the side-effects of treatment and adhering to treatment regimens.

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SRB 3/001

Bernstein, D., Kleinman, L., Barker, C. et al. (2002). Relationship of health-related quality of life to treatment adherence and sustained response in chronic hepatitis C patients. *Hepatology* 35(3), 704–708.

Since quality of life can be considerably impacted by both hepatitis C (HCV) infection and its treatment, the authors conducted a pooled analysis of data on the impact of new treatments on health-related quality of life (HRQL), collected from three international randomised controlled trials. These studies enrolled 1,441 participants in Australia, Canada, France, Germany, Mexico, New Zealand, Spain, Switzerland, Taiwan, the United Kingdom and United States, randomly allocated to either pegylated or standard interferon treatment groups. In addition to their treatment regimes, participants completed the SF-36 Health Survey and the Fatigue Severity Survey at baseline and weeks 2, 12, 24, 48 and 72. This analysis found a direct connection between a sustained virologic response (SVR) and improved HRQL. Although 10% of participants discontinued treatment before 24 weeks, due in most cases to worsening fatigue and declines in both physical and mental HRQL, those that received pegylated interferon reported better HRQL and less fatigue, particularly in domains that relate to the impact of health on work and other productive activities.

SRB 3/002

Bianchi, G., Loguercio, C., Sgarbi, D. et al. (2000). Reduced quality of life in patients with chronic hepatitis C: effects of interferon treatment. *Digestive & Liver Disease* 32(5), 398–405.

The impact of HCV treatments on HRQL in patients without cirrhosis was evaluated using the Nottingham Health Profile (NHP), a questionnaire that is particularly focused on the impact of distress on quality of life, and the Medical Outcome Survey SF-36, which is focused on measures of wellbeing. 126 patients were recruited from an Italian hospital, including 37 currently using and 89 not using interferon treatment. Interestingly, the SF-36 demonstrated no differences between the treated and untreated patients in terms of HRQL, but the NHP detected changes in those patients currently on treatments in the domains of Energy, Physical Mobility, Pain and Concern for Family Life. This demonstrates that HCV treatments can cause considerable distress suggesting that their positive medical benefits may be outweighed by their many negative side-effects. However, measures of HRQL is also related to age in that older people were less likely to report the experience of side-effects as distressing, perhaps because older patients might accept reduced levels of health more easily.

SRB 3/003

Bonaccorso, S., Marino, V., Biondi, M. et al. (2002). Depression induced by treatment with interferon-alpha in patients affected by hepatitis C virus. *Journal of Affective Disorders* 72(3), 237–241.

Bonaccorso et al. present the results of an Italian study on depression as a side-effect of interferon treatment. The 30 participants, including 24 men and six women, were administered interferon three times per week for three months. Mental health was measured using the Montgomery Asberg Depression Rating Scale (MADRS) and evaluations by two psychiatrists using the DSM-IV criteria for a major depressive episode. At baseline, none of the participants was considered to have suffered a major depression and during the three-month trial there were no changes in either physical status or pharmacological treatment. After three months treatment, 40.7% were evaluated as clinically depressed, with no significant gender difference. Additionally, there was a considerable increase in other mental health issues, including irritability, sadness, insomnia and loss of appetite. Since there was no change in physical condition during this time, the authors conclude that the increase in depressive and other symptoms can be directly related to interferon treatment, rather than any deterioration in general health.

SRB 3/004

Chong, C., Gulamhussein, A., Heathcote, E.J. et al. (2003). Health-state utilities and quality of life in hepatitis C patients. *American Journal of Gastroenterology* 98(3), 630–638.

Quality of life with hepatitis C is usually estimated by clinicians rather than by patients. Therefore, Chong et al. conducted a survey of people with HCV infection in order to develop a scale of health-state 'utilities' that most accurately reflected patient experiences. The main finding of this analysis was that people with HCV infection show evidence of significant impairments in their health-related quality of life, considerably below community standards for health. They also found that there was no great difference between those at an earlier and later stage of HCV development, suggesting that changes in the clinical health of the liver do not necessarily impact to a significant degree on the experience of wellbeing. This also indicates the importance of eliciting patient perspectives on quality of life, particularly since the majority of people who had progressed to a SVR post-treatment considered themselves to have a quality of life similar to the rest of the general population, contradicting clinical arguments for restricting such treatment to only a minority of patients.

SRB 3/005

Dieperink, E., Ho, SB., Thuras, P. et al. (2003). A prospective study of neuropsychiatric symptoms associated with interferon-alpha-2b and ribavirin therapy for patients with chronic hepatitis C. *Psychosomatics* 44(2), 104–112.

A small group of US war veterans with HCV were recruited into this study on the psychiatric effects of interferon combination treatments. Of the 55 participants, 42 received treatment and 13 did not. A variety of mental health measurement tools were employed at

baseline, 4, 8, 12 and 24 weeks to evaluate each patient's psychiatric and family history, current mental health status and response to HCV treatments. Of participants that had not been receiving psychiatric care at the commencement of the study, 48% required such treatment by the end, and 23% were diagnosed with a major depression, which in all cases responded well to antidepressant therapy. However, the other half of this group did not require any psychiatric therapy, suggesting that prophylactic prescription of antidepressants for all patients undergoing interferon treatments is unnecessary. Additionally, 70% had a history of psychiatric or substance abuse disorders, and yet 28% achieved a SVR, demonstrating that patients with these histories should not be automatically denied interferon treatment.

SRB 3/006

Dore, G. (2001). Therapy decision making for people with chronic hepatitis C. In Crofts, N., Dore, G. & Locarnini, S. eds. *Hepatitis C: an Australian perspective*. East Hawthorn, Vic: IP Communications, 172–182.

This chapter explores some of the many considerations in making decisions about HCV treatment options. It stresses that clinical recommendations must be accompanied by a close investigation of the psychosocial issues involved in the experience of treatments. For example, side-effects will have a considerable impact in almost all cases, typically manifesting as mood disturbances, anaemia, hair loss and skin changes. Therefore, it is critical to consider the effects that treatments may have on the ability to work and to maintain happy family and social relationships. Other important factors to consider are whether current drug use may have a negative impact on the efficacy of treatments and whether pregnancy will have to be deferred for the duration and immediate period after concluding treatment. Since current HCV therapies cannot be guaranteed to achieve a SVR, they may not justify the reduced quality of life experienced, and therefore both the medical and psychosocial risks and benefits must be considered before making this decision.

SRB 3/007

Edlin, BR. (2002). Prevention and treatment of hepatitis C in injection drug users. *Hepatology* 36(5), S210–S219.

Edlin reviews the current literature on HCV prevention and treatment in injecting drug users (IDU), including key evidence to support the inclusion of IDUs in HCV treatment programs. Edlin claims that the three arguments most often drawn upon to defend withholding of HCV treatment from active drug users can be countered through effective medical care. First, the argument that IDUs are more likely to have problems achieving treatment adherence is shown to have little evidence, with numerous studies observing a similar level of adherence to non-IDU patients. Additional strategies for increasing adherence include improving doctor-patient relations, simplifying complex

regimens, and assisting with social needs such as finding permanent housing, looking into psychological issues and so on. Second, Edlin demonstrates that there is no basis for assuming that IDUs are more likely to have problems with the psychological side-effects of HCV treatments, with several studies from around the world demonstrating that with adequate attention, mental health issues can be prevented and treated as required, with little additional complication due to drug use. And third, the suggestion that IDUs have a greater potential for HCV reinfection is shown not to justify withholding treatment, particularly since HCV treatment offers the opportunity for harm reduction interventions which have been proven to dramatically reduce the risk of reinfection.

SRB 3/008

Fried, MW. (2002). Side effects of therapy of hepatitis C and their management. *Hepatology* 36(5), S237–S244.

Although clinical research on the efficacy and tolerance of pegylated interferon is still in its infancy, the authors review some of the most important findings from recent studies with a particular focus on the experience and management of side-effects. A randomised trial found that participants treated with peginterferon and ribavirin in combination reported side-effects at an equal or lesser level than those treated with standard interferon and ribavirin. Side-effects such as influenza-like symptoms (fever, myalgia and rigors), alopecia and depression occurred considerably less often in those taking the pegylated combination treatments. However, in another study, influenza-like symptoms (fever, myalgia and rigors) and gastrointestinal disturbances (nausea, diarrhea, and weight loss) were reported more often in those treated with the peginterferon combination, and depression was reported in similar frequencies in both groups. Rather than managing side-effects through dose reduction, the authors recommend that pre-emptive strategies be implemented to ensure maximum adherence over time, including adequate hydration, flexible dosing schedules, moderate exercise routines and regular follow-up visits to ensure early diagnosis of serious side-effects.

SRB 3/009

Gonzalez, SA. & Talal, AH. (2003). Hepatitis C virus in human immunodeficiency virus-infected individuals: an emerging comorbidity with significant implications. *Seminars in Liver Disease* 23(2), 149–166.

Co-infection with HIV creates the need for a different approach to HCV treatment and so the authors outline current recommendations for managing and treating HCV/HIV co-morbidity. They report many complications of coinfection, including the accelerated progression of HCV-related liver disease and higher levels of HCV RNA, which can increase the risk of parenteral and vertical transmission. HCV therapies can have myelosuppressive effects that can potentially result in decreased CD4 counts,

increasing the risk of opportunistic infections. Additionally, anti-retroviral therapies and in particular, protease inhibitors, can increase the risk of hepatotoxicity (treatment-induced liver damage). Strategies for maximising the efficacy of both HIV and HCV treatments may include beginning with HCV treatments and increasing the dosage and duration of therapy to ensure that a SVR is obtained prior to commencing treatment for HIV.

SRB 3/010

Kraus, MR., Schafer, A., Csef, H. et al. (2001.) Compliance with therapy in patients with chronic hepatitis C – Associations with psychiatric symptoms, interpersonal problems, and mode of acquisition. *Digestive Diseases and Sciences* 46(10), 2060–2065.

Compliance with the strict regimens of HCV treatment is very important in achieving a SVR, and so Kraus et al. investigated some of the potential issues that may impact on treatment compliance. Measures of emotional state, personality factors and mode of HCV acquisition were investigated in 74 patients attending a German university clinic for hepatitis C treatment. Participants were considered to be noncompliant if they did not start their intended treatment, missed at least two scheduled follow-up visits without reason, or terminated their therapy without consultation. Of the 23% of participants that were judged to be noncompliant, most were younger and had a history of IDU. However, there was no association between poor compliance and level of education or work status, and having a partner did not increase compliance. Those with lower compliance were more likely to score higher in measures of anger-hostility, depression, paranoid ideation and phobic anxiety and to have high scores in nearly all measures of interpersonal problems, with a particular prevalence of ‘intrusive’ characteristics.

SRB 3/011

Kraus, MR., Schafer, A., Faller, H. et al. (2003). Psychiatric symptoms in patients with chronic hepatitis C receiving interferon alfa-2b therapy. *Journal of Clinical Psychiatry* 64(6), 708–714.

Of 104 patients presenting with hepatitis C at a German university clinic, 84 were recruited to participate in a study of the psychiatric effects of HCV treatments and 20 agreed to act as a non-treatment reference group. The group on treatment demonstrated significantly higher levels of depression, anxiety and anger-hostility, with the highest incidence of depression reported within the first four weeks of therapy. There was no association between reporting depressive episodes prior to the commencement of treatment and the likelihood of an onset of depression during treatment nor did prior drug use predict depression. These findings suggest that the majority of psychiatric symptoms can be effectively managed so long as physicians monitor patients carefully in the first month

or two of treatment and consider the use of antidepressant medication during the treatment period.

SRB 3/012

Leone, NE. (2002). The role of nursing in managing treatment-associated adverse effects in patients with hepatitis C. *Gastroenterology Nursing* 25(5), 201–203.

Since the introduction of pegylated interferon therapy has offered little evidence of a decrease in side-effects, Leone offers advice on finding alternative remedies for eight major side-effects of HCV treatments. Firstly, weight loss and under-nutrition can be avoided by eating many small high-calorie and high-protein meals throughout the day, and the use of vitamin supplements, liquid nutrients and perhaps appetite-inducing and nausea-suppressing treatments. Fatigue and sleeplessness can be minimised by ensuring regular sleep and exercise routines and engaging in stress-relieving activities every day. Dehydration has been blamed for many additional side-effects, particularly muscle aches and headaches, and thus strategies to increase the amount of water drunk throughout the day should be tailored to each person’s lifestyle, perhaps including the use of water containers attached to a belt-holder and incorporating regular drinking times during the workday. Loss of libido is usually only temporary and can sometimes be related to fatigue and thus improved through exercise and adequate rest. The most alarming side-effect of HCV treatments is depression and nurses must play a key role in recognising preliminary signs as early as possible, to avoid the unnecessary progress to more severe stages such as suicidality.

SRB 3/013

Patil, R., Cotler, SJ., Banaad-Omiotek, G. et al. (2001). Physicians’ preference values for hepatitis C health states and antiviral therapy: a survey. *BMC Gastroenterology* 1(1), 6.

Although there is some research on patient attitudes to HCV treatments, very little has been published on physicians’ beliefs about the risks and benefits of prescribing these treatments. Patil et al. conducted a survey of 113 physicians from several US states attending continuing medical lectures on gastroenterology in 1999. The questionnaire offered visual analog scales for rating health state utilities from 0% (death) to 100% (life without hepatitis C). In general, these physicians felt that hepatitis C reduced health states by around 12%, even without the presence of symptoms or cirrhosis. However, they reported a very wide range of treatment side-effects and most commonly indicated that they believed patients would lose around 53% of their experience of health due to these side-effects. Therefore, it is unsurprising that these doctors required an average 60% SVR before they would prescribe HCV treatments, which at the time of publication was significantly higher than the average 30% SVR reported from standard interferon therapy. The authors suggest that since other

studies have indicated many patients would prefer to experience a temporary decrease in health to obtain a longterm SVR, physicians require further education on the benefits of HCV treatment.

SRB 3/014

Schaefer, M, Schmidt, F, Folwaczny, C. et al. (2003) Adherence and mental side effects during hepatitis C treatment with interferon alfa and ribavirin in psychiatric risk groups. *Hepatology* 37(2), 443-451.

People with a history of psychiatric illness and drug use are often excluded from receiving HCV treatments, despite the scarcity of studies detailing how ‘high-risk’ groups actually respond to such therapy. Schaefer et al. recruited 93 patients with chronic hepatitis C and a medical need for combination treatments, grouped as: 1) no psychiatric history or present condition or addiction; 2) current or pre-existing psychiatric condition; 3) methadone treatment program with no psychiatric history or present condition; and 4) former IDU with no psychiatric history or present condition. Participants from all four groups developed psychiatric symptoms during the course of their treatment, with no differences in frequency or severity. The second group reported more depressive symptoms; however this is partly related to the high number of pre-existing depressive conditions in this group. The second group also had the best compliance and lowest drop-out rate and even those with severe mental illnesses tended to become more stable and reliable during the course of treatment. In most cases, reported depression and suicidality were not associated with a pre-existing condition, and all cases improved with antidepressant treatment. The highest rates of non-completion and mental instability were in the fourth group (former IDUs), and group three (currently receiving methadone treatment) had very good compliance and completion rates with no difference in rates of psychiatric side-effects to the control group. The authors argue that although patients in high-risk groups may require a more comprehensive and detailed level of care during HCV treatment, they should not be excluded due to anticipated issues with psychiatric side-effects and treatment adherence.

Glossary

HRQL	Health-related quality of life
IFN	Interferon
SVR	Sustained virologic response
pegIFN	pegylated interferon

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