JOURNAL OF VIRAL HEPATITIS
JVH

Journal of Viral Hepatitis, 2010, **17,** 698–704 doi:10.1111/j.1365-2893.2009.01227.x

The impact of a managed care network on attendance, follow-up and treatment at a hepatitis C specialist centre

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Received August 2009; accepted for publication September 2009

SUMMARY. Infection with the hepatitis C virus commonly occurs in patient groups who have difficulty accessing conventional medical care, reducing their chance of successful antiviral therapy. Managed care networks (MCNs) have been suggested as a mechanism of improving access to care; however, there is little evidence to support their use in patients with hepatitis C. The aim of this study was to evaluate the impact of a MCN for patients with hepatitis C. This was a retrospective cohort study of all individuals in our area who had received a positive hepatitis C antibody test between August 1994 and June 2008. The MCN introduced a new referral pathway, which included nonmedical referrals and outreach nurse-led clinics. These interventions were introduced in 2004 and evaluated in 2008. After the introduction of the MCN, the proportion of individuals who accessed care increased from 61% (280/430) to 82.4% (721/875). There was an increase in nonmedical referrals with 81 (18.3%) being directly referred from Drug Problem Services and 75 (17%) from the Prison Service. The changes to referral did not have a negative impact on treatment outcomes as the number who completed treatment increased from 66.1% (43/65) to 73.7% (98/133) and the sustained virological response increased from 50.7% (33/65) to 60.9% (81/133). This study provides evidence that the collaboration of health care professionals within a network can have a radical effect in improving access to care in a traditionally hard to reach population. This has been achieved with little additional resource, but rather working smarter with existing staff.

Keywords: access to care, hepatitis C, managed care network, sustained viral response.

BACKGROUND

Hepatitis C virus (HCV) infection is now recognized as a major healthcare problem throughout the world. It is estimated that over 170 million people are infected worldwide [1]. In the United Kingdom (UK), the best estimates of prevalence suggest that approximately 0.4% of the population is infected, amounting to between 200 000 and 500 000 cases [2]. Data from the Trent HCV cohort study indicate that only around 50% of HCV-positive individuals identified are subsequently referred for further investigation and management [3]. HCV is a bloodborne RNA virus that is most frequently parenterally transmitted. Following the introduction of routine screening of blood donors in 1991, infection through blood products has become very rare leaving injecting drug use (IDU) as the commonest route of transmission in the UK. HCV infection is, therefore, predominately a disease of IDUs with prevalence rates reported to be from 30% to over 90% [4]. Individuals who use drugs often experience multiple problems and require support from drug services, psychiatric services and social services. In addition, they are often marginalized from society, have an illness that stigmatizes them in society [5] and they are known to experience difficulties accessing services particularly health care [6].

A review of HCV treatment in drug users concluded that individuals on methadone have similar response and compliance outcomes to non-IDUs [7]; therefore, a history of drug use should not be a contraindication for HCV treatment. However, in practice, most drug users with HCV have previously been considered ineligible for treatment because of high rates of psychiatric illness and alcoholism or concerns about adherence [8]. Guidelines for the management of HCV now advocate an inclusive approach to treatment, and it is recognized that efforts must be made to increase the availability of treatment to patients who have previously

Abbreviations: HCV, hepatitis C virus; IDU, injecting drug user; MCN, managed care network; PCR, polymerase chain reaction; RCT, randomized controlled trial; SVR, sustained viral response.

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This study is based on anonymous audit data and does not involve any participation from patients. This audit project did not require to be submitted for ethical approval.

been ineligible [9–11]. It is imperative that improving access to care and overcoming barriers to HCV specialist care are the most important goals in tackling what has been referred to as the 'HCV epidemic'.

The current health care systems are not meeting the needs of many individuals with HCV and access to care and non-attendance at clinics is a problem. The use of managed care and clinical networks has been advocated as a solution to the problems of this disease and patient group [12] using a combination of agreed multi-agency and disciplinary area-wide protocols, varied referral pathways, nurse-led treatment pathways and outreach clinics.

This paper presents an evaluation of a hepatitis C managed care network (MCN) introduced into a geographical area. It describes the local hepatitis C cohort and evaluates the effectiveness of multi-professional working using the proportion of individuals who are referred to the specialist service and the sustained virological response to therapy as outcome measures.

METHODS

Setting

This is a retrospective cohort study of all individuals living in Tayside who had received a positive hepatitis C antibody test between August 1994 (start of testing) and June 2008. The region of Tayside, which collocates with Tayside Health Board, is situated in the east of Scotland and includes the cities of Dundee and Perth and several small towns and rural areas, covering more than 1000 square miles and the health care needs of approximately 400 000 people. There is one main hepatitis specialist centre in Dundee, and individuals are served by 82 general practices throughout the region. All individuals who had received an initial positive hepatitis C antibody test in Tayside or had been referred into the specialist service were included in the study. All were captured using a hospital-based clinical database linked to the virology laboratory results database. In our region, we can identify and trace individuals in the hospital and community, as they will have been allocated a community health index number, which is used as their unique identifier for all health services interactions. For all individuals in the cohort, we reviewed medical records, data collected included demographical information, data on risk factors, laboratory tests, referral, follow-up and treatment. All patients in the study were allocated a code, and patient information used was anonymous.

Intervention

The managed care network was established in 2004 in response to an audit that had been carried out within national health service (NHS) Tayside. Despite the fact that there were 1243 new hepatitis C antibody-positive cases diagnosed, only 430 (34.6%) had been referred for specialist care, 282 (22.7%) had attended the clinic and 102 (8.2%) had received treatment. As in the majority of health care trusts, at this stage, individuals in Tayside were referred to the clinic solely by medical staff and, in most cases, by their general practitioner. As less than a quarter of patients had attended the specialist clinic, it was clear that this single mode of referral was not effective.

The role of the network was to enhance links between staff in primary and secondary care, to assist in the development of local services and to establish an accurate database of the local HCV population. The main action of the network was to bring all stakeholders together and create a multi-agency management and referral protocol. Within the network, educational sessions were carried out, a new referral pathway was introduced which included nonmedical referrals. A nurse-led clinic was established within the hospital clinic, as well as a series of outreach clinics in drug treatment clinics and prison clinics. Prior to 2004, all individuals referred were seen in clinic within the main hospital by a medical consultant with onward referral to nurse treatment clinics. After the introduction of the MCN, all individuals were appointed to either a nurse-led clinic within the main hospital or to an outreach clinic, and patients were reviewed about decisions regarding therapy on their second or subsequent visits. Interventions were introduced to encourage attendance, and if individuals did not attend their first appointment, they were not automatically reappointed; however, a letter was sent to the individual, and their referrer and appointments were rebooked if the individual or referrer contacted the service at any point.

There was limited additional resource of 0.5 of a whole time equivalent nurse added to the service. This resource was utilized mainly in clinics seeing new patients on their first attendance and made some contribution to treatment clinics.

RESULTS

The analysis was performed in two stages. First, the total HCV cohort was defined, and the crude outcomes were identified. Secondly, from this, the population that should have been referred for specialist hepatitis services was further studied. Referral to 'specialist services cohort' was used for the analysis of the effectiveness of the MCN intervention. This is a cumulative cohort, so that all patients known at each time point, who were available for referral, were used for analysis. The primary end point was the proportion of HCV antibody-positive, polymerase chain reaction (PCR)-positive individuals referred and accessing specialist services.

Testing and diagnosis

There were 1767 individuals who had tested hepatitis C antibody positive from the start of testing up until the close of the study period. Among them, 1331 (75.3%) were male.

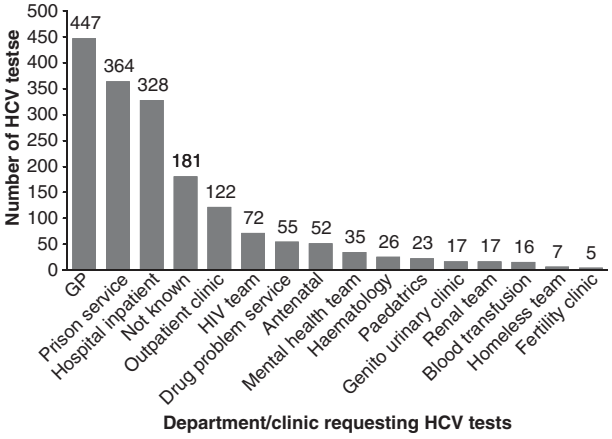

Fig. 1 Department/clinic requesting HCV test.

The mean age at diagnosis was 34.8 years. The majority 1292 (73.1%) were aged between 16 and 39. Tests were carried out at various locations with 447 (25.3%) of tests carried out in a general practitioner (GP) practice (Fig. 1). The risk factor was documented in 1304 of cases, of those, 1122 (86%) had drug use as a major risk factor. Of all subjects, 524 (29.6%) had a positive HCV antibody test only, HCV PCR was available on 1243 individuals and 928 (74.6%) were PCR positive.

Outcome of testing

A total of 875 (49.5%) had been referred to the specialist clinic by the end of the study period and will be described in more detail later. The remaining 892 (50.5%) individuals had not been referred for specialist HCV care and treatment. Data were collected to determine the reason for nonreferral. Table 1 details the number of individuals where referral was not indicated because they had died, were PCR negative, had moved from the region or had been an inmate in one of the three prisons within our health board area and had subsequently been liberated to a home address or transferred to another prison out of the region.

Table 1 Outcome of individuals not referred to hepatitis C virus clinic

Outcome	*n*	%
Dead	269	30.1
PCR NEG	145	16.2
Moved prison out with area	141	15.8
No contact/registered with local GP	137	15.3
Relocated from area	118	13.2
No trace	37	3.6
Follow-up by other unit	26	2.9
Tested as neonate/PCR negative	19	2.1
Total	892	

PCR, polymerase chain reaction.

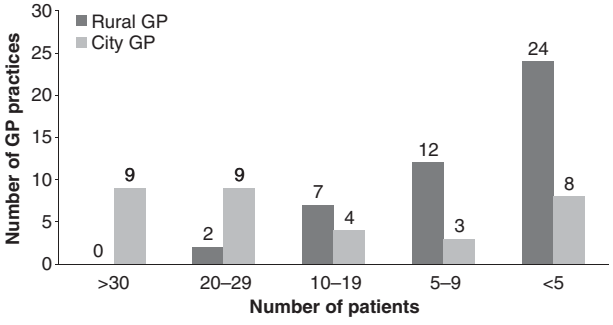

Fig. 2 Number of HCV patients per GP Practice.

At the end of this study, it was established that the total number of individuals who were registered with a GP, were HCV antibody positive and still resided in Tayside was 1012.

These individuals were not located in selected practices, they were scattered throughout 78 of the 82 GP Practices within our area. Nine practices had over 30 individuals registered, and 32 practices had <5 individuals per practice (Fig. 2).

In total, 137 (13.5%) individuals still resided in our region and had not been referred to our service. Data were collected to determine whether these individuals were engaging in other community services; 67 (48.9%) were in contact with local drug services, 6 (4.4%) were currently in Prison and 6 (4.4%) were under the care of the local Mental Health Team, 40 (29.2%) had attended their General Practitioner in the last 2 years and 18 (13.1%) had no contact with any Health Services within the last 2 years.

Referral to specialist service cohort

Of the 1012 HCV individuals in Tayside, the total number of individuals offered referral to the clinic was 875 (86.5%). The total number of individuals who accessed care increased from 282 of 430 (65.6%) referred pre-MCN to 721 of 875 (82.4%); this was a statistically significant difference ($\chi^2 = 48.16$, $P < 0.0001$). The new referral pathway resulted in changes in referral patterns. Before 2004, all individuals were referred by Medical staff either from primary or secondary care. The introduction of the new referral pathway resulted in the source of referrals changing. The percentage of attendees who had been referred by their GP reduced, whilst the percentage referred from Nursing Staff or Social Workers within the Drug Problem Services and the Prison Service increased significantly. The referral sources pre- and post-MCN are detailed in Table 2.

Clinic follow-up

After the introduction of the MCN, the time from first referral to attendance at first appointment reduced from a mean of

Table 2 Source of referral of attendees

Referral from	PRE-MCN	%	POST-MCN	%	TOTAL	%
General practitioner	187	66.7	174	39.2	361	50
Drug services	7	2.5	81	18.3	88	12.2
Prison service	4	1.4	75	17	79	10.9
Hospital	31	11	29	6.5	60	8.3
Sexual health services	19	6.7	20	4.4	39	5.4
Immunodeficiency service	9	3.2	21	4.7	30	4.1
Haematology unit	10	3.5	10	2.2	20	2.7
Other	3	0.9	13	2.9	16	2.2
Blood transfusion service	5	1.7	10	2.2	15	2
Renal unit	2	0.6	5	1.1	7	0.9
Mental health team	3	1	3	0.6	6	0.8
Total	282		441		721	

MCN, managed care network.

193 to 95.9 days. Of the 721 who had attended the Specialist Clinic, 379 (52.6%) are receiving continued follow-up, 122 (16.9%) have been discharged, 44 (6.1%) are dead, 45 (6.2%) have moved from our locality and 133 (18.4%) have been lost to follow-up.

Treatment and sustained viral response

Before the introduction of the MCN (pre 2004), 102 individuals had received Interferon therapy in our centre. Of these, 37 had received standard interferon and ribavirin and 65 had received pegylated interferon and ribavirin. After the introduction of the MCN, 146 received pegylated combination therapy. To assess the effectiveness of the MCN, the outcomes of individuals on Interferon treatment pre- and post-MCN were evaluated. Exclusions in the analysis included individuals who were co-infected with HIV (5/146) as no co-infected patients were treated pre-MCN or inmates treated in prison (8/146) because inmates were treated in conjunction with other prisons and follow-up data were not available.

Data were analysed on 65 who received treatment pre-2004, (Group 1) and 133 (Group 2) who received treatment between 2004 and 2007. Age, sex and genotype distribution of individuals were documented in both groups. 73.4% (47/64) of group 1 and 69.2% (92/133) of group 2 were male. The mean age was 46.1 years in group 1 and 42.6 years in group 2. The numbers who were Genotype 2/3 was 47.7% (31/65) in group 1 and was 57.1% (76/133) in group 2. The number who completed treatment (including stopping rules) increased from 66.1% (43/65) to 73.7% (98/133) and sustained viral response (SVR) increased from 50.8% (33/65) to 60.9% (81/133), this was not significantly different ($\chi^2 = 1.83$, $P = 0.2$). This illustrates importantly that by increasing referral and access to treatment, we did not impair quality of treatment or treatment response, Fig. 3 details other outcomes.

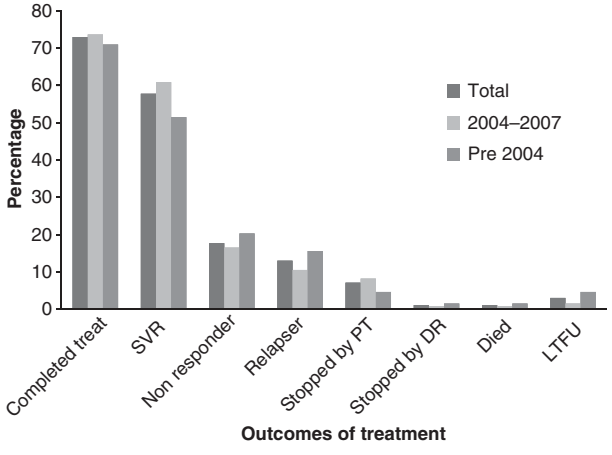

Fig. 3 Outcomes of treatment pre and post MCN.

Treatment outcomes were further analysed to determine whether individuals who had a recent history of intravenous drug use (within the last 12 months) and who were on a drug treatment programme had similar outcomes to non-IDUs. The percentage of individuals who completed treatment was similar in both groups and SVR was 60.9% in non-IDUs and 57.1% in recent IDU. (Table 3). The results of SVRs are not clinically significant and confirm previous observations that patients from an active drug dependency background can be successfully treated with similar response rates to standard treatment.

DISCUSSION

This paper shows the impact a MCN can have on referral and treatment of patients for hepatitis C. Patients with HCV infection with or without co-existing drug problems present many clinical challenges as care is delivered by different disciplines in different locations, leading to fragmentation of

Table 3 Outcomes of individuals on treatment with recent history of injecting drug use

	Group A – no recent drug use $n = 91$	%	Group B – used IV drugs within previous 12 months $n = 42$	%
Mean age (years)	46.2		39.1	
Male sex	69	75.8	31	73.8
Genotype 2/3	51	59	25	56
Completed treatment	67	73.6	31	73.8
SVR	57	62.2	24	57.1
Relapser	9	9.8	5	11.9
LTFU	1	1	2	4.7

SVR, sustained viral response.

care resulting in poor adherence and outcomes of treatment [13]. The reasons for these obstacles include lack of awareness of HCV and its treatment, under provision of appropriate services and clustering of infection amongst sectors of the population who do not readily access healthcare. One study which examined barriers to HCV treatment showed that there were four main obstacles to individuals commencing treatment, which included negative patient views of treatment, inadequate follow-up within primary care, delay in obtaining specialist input and a tendency not to consider treatment of past drug users. The authors concluded that these barriers could be reduced by using a model, which improved collaboration between the Specialist HCV team and Drug Treatment staff [14].

The introduction of the MCN aimed to reduce these barriers. The interventions focussed on education of all professionals involved including those working for health and social care agencies, both governmental and nongovernmental. It produced pathways of referral and management that followed patients rather than administrative boundaries and also addressed the geographical issues faced by patients.

The managed care network has been successful in increasing the number of individuals referred for hepatitis specialist care and the number who attended. The commencement of extra outreach clinics significantly reduced waiting times for clinic appointments, and this was shown to have a positive impact on attendance, underlining the importance of the timing of interventions. Professional awareness raising, education and changes to rights of referral clearly had a beneficial impact on referral practice. Improved disease knowledge of professionals was cascaded amongst patients, which helped to dispel some of the myths that are associated with HCV treatment. Easier access to specialist service decreased the number of individuals who failed to attend any appointment to <15% of our total HCV population.

A key result of the MCN was the creation of an accurate database, which is now updated prospectively and provides the MCN with current information on patient outcomes. This has been used very effectively particularly when building a business case for more staff and resources. It has also been able to establish the number of individuals who remain in our region, who have not been referred to specialist service and who are in current contact with other health and social services. This information has been crucial in the redesign of our service and will continue to be used for further evaluation and improvement.

There has been an increase in the number of individuals commencing Interferon therapy, which is ultimately the main reason for tackling the problem of access to care. Treatment for HCV with interferon alpha and ribavirin cures 40–80% of cases [15,16], large-scale randomized controlled trials (RCTs) have shown to be clinically effective and cost effective and are endorsed by National Guidelines [17]. However, previously not all patients have been eligible for treatment because of concerns about adverse reactions, including the exacerbation of psychiatric disease, particularly depression and unstable drug use. The large-scale RCTs excluded such subjects. Indeed, the majority of patients included were unrepresentative of the majority of individuals infected with HCV. Thus, the findings of the RCTs cannot be readily extrapolated to the general community with HCV. There has been little real world data about what can be achieved in a 'real world' setting. With the licensing of therapies for HCV, the transfer of this service to NHS nurses and doctors has not been accompanied by an appropriate increase in budget and expansion of clinical staff, nor of systematic training for those newly recruited to provide care for patients with HCV. In tandem with this change in how treatment is delivered, the indications for treatment have expanded to an increasingly difficult and complex group of patients. The MCN interventions acknowledge this difficulty and stopped treating patients' HCV disease in isolation, treating it in conjunction with their substance-related issues or psychiatry illness. Despite this much more challenging therapeutic environment treatment outcomes have not been compromised, completion rates remain high and virological cure rates are undiminished compared to the RCTs, this sets a benchmark for clinical performance.

LIMITATIONS TO THE STUDY

This is a small study limited to one geographical area. Determining the key impact of the MCN is difficult as there may be other factors that may have influenced the better outcomes. Evaluation was by necessity of 'before and after' design, there was no control group for the nonspecific effect of education and awareness raising from generic sources, and we, therefore, cannot be certain these other factors would not have increased referral to specialist services. Factors that could have improved access without the MCN would be capacity for extra clinics, reduced waiting times for clinics, the fact that we stopped doing routine liver biopsies before treatment and general increased awareness of hepatitis C amongst health care professionals and individuals infected with HCV.

In many cases, individuals lived in the area with a known HCV diagnosis in both time periods and were referred within the two time periods and an increased number who failed to attend pre-MCN attended after the introduction of the MCN. For this reason, the proportion of the total cohort who had been referred and accessed care was used for analysis as opposed to number of individuals referred before and after introduction of MCN as this may introduce bias against the MCN as those referred previously who have not attended are more likely to fail to attend again, but this is the reality that any MCN would have to function under. Therefore, analysis was performed for the total cohort diagnosed and available for referral at that time. This showed that a statistically significant improvement in referral and treatment outcomes was possible using an MCN approach. The improvement in treatment outcomes could have occurred because of the increased experience of the Specialist Nursing Team who support and guide patients through treatment and a general increase in awareness about HCV infection, but there is no evidence from other areas to support this.

Any development in this field aimed at getting more patients referred into a system, must set its end point not at entry into the system but at successful completion of therapy, which is the real goal of these developments. Despite current enthusiasm for these developments and the undoubted need for something to be performed, there is no evidence for the effectiveness of these interventions, in the literature. Indeed, by their very nature requiring a system-wide approach across whole geographical areas, they do not lend themselves to the methodology of the prospective randomized trial. In this study, we present evidence on the outcomes of the implementation of a MCN, using a total population-based cohort study.

CONCLUSION

The investigation of nonreferred patients has established the number of individuals who remain in our region and have not been referred to the specialist service, and this information has been vital to showing the success of the redesign of our service. This was only possible with the information technology available within our region for linking hospital practice firmly within the whole community. It also highlighted the movements of these patients and the significant mortality. This study provides evidence of the improvements in clinically relevant end points achieved by a system change in HCV care in a defined health care region using the methodology associated with MCNs. This has been achieved with little additional resource but rather working more effectively with existing staff. The end points of increased attendance and entry into therapy without reduction in sustained virological response are unarguably, the gold standard measures of success. This study demonstrates what can be achieved in HCV care and describes a blue print for its delivery, increasing patient attendance at clinics and converting this to entry into a treatment programme with no diminution of sustained virological response.

CONFLICTS OF INTEREST

None to declare.

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