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AN AUDIT OF MANAGEMENT OF HEPATITIS B (HBV) AND HEPATITIS C (HCV): STRENGTHS AND WEAKNESSES ANALYSIS

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Abstract:

Objectives: *The evaluation of treatment response on large-scale cases of Hepatitis B & C in a national level program was the objective of research.*

Methods: *We consulted the records of all the cases treated under the National Hepatitis Prevention Program in the last two years that is 2016 – 2017 at twelve various sites and ensured the confidentiality of the record. We studied, analyzed and assessed the data at Allied Hospital, Faisalabad on all the cases who completed their follow-up and complied with the guidelines and excluded the rest who failed to do so. A special program was developed in order to assess the data.*

Results: *Research sample comprised of 7752 patients who were managed under the said program at twelve various sites. In the sample population six-month treatment was completed by 3440 patients (45.4%); whereas, only 1686 employed polymerase chain reaction test (49%) at the end of 6 months. The infection was not diagnosed in the time of six months in 1133 out of 1686 cases (67%); whereas, no response was observed in 553 cases (33%). Inclusion criteria was completed by a total of 454 cases and management of the disease was carried out in 85 cases (18.72%), complete treatment in 9 cases (10.58%), 3 cases were positive for HBV (3.52%) for clearance of antigen and anti-HBe production.*

Conclusion: *The inappropriate record keeping and poor incidence of follow-up in biochemical/ serological tests was observed as the loop hole in both the infected cases including HBV and HCV. This resulted in the wastage of financial and manpower resources as there was an obvious ill planning and factor of accountability was also missing.*

Keywords: *Viral Infection, Hepatitis B & C, HBV and HCV,*

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INTRODUCTION:

Viral hepatitis is basically spreading through Hepatitis B & C in Pakistan. Its prevalence as reported in the previous research studies ranges from 3 – 4 percent (HBV) and 4 – 6 percent (HCV) with an overall of ten percent [1, 3]. In another recently conducted survey the incidence has reached for (HBV, 2.5%) & (HCV, 5%). Hepatitis C is highly prevalent in almost every province of Pakistan [5 – 9].

There is a global variation in the genotype of HCV in terms of genotype duration and type. As the there is a dominance of genotype-III (80%) over genotype-II which requires a management of three-million-unit interferon, six monthly thrice a week subcutaneously including an antiviral ribavirin two time daily with a weight of (< 70 kg). Twelve months treatment is recommended for other genotypes. Best treatment results can be achieved through single criteria of viral clearance (70%), no response (30%) and discontinuation of treatment as well [11, 12].

Because of involved sophistications the HBV treatment is difficult by general healthcare practitioners. The response can be observed in the hepatitis B naïve cases having (pre-core/core mutants and wild type) with alanine aminotransferase (ALT) in raised levels may response through nucleoside analogue-lamivudine [13, 14]. Oral management of the medicine is carried out before taking breakfast as there is an absorption in the medium of acid, continue the management till wild type seroconversion and for mutant's life; whereas, no therapeutic role has been observed in the drugs about the delta infected cases [15].

This program targeted the needy and deserving patients of HBV and HCV as they were unable to afford the costly disease treatment. The healthcare facility was extended to general public in almost sixty-one healthcare units including medicines, laboratory staff and trained doctors. The evaluation of treatment response on large-scale cases of Hepatitis B & C in a national level program was the objective of research.

PATIENTS AND METHODS:

We consulted the records of all the cases treated under the National Hepatitis Prevention Program in the last two years that is 2016 – 2017 at twelve various sites and ensured the confidentiality of the record. We studied, analyzed and assessed the data at Allied Hospital, Faisalabad on all the cases who completed their follow-up and complied with the guidelines and excluded the rest who failed to do so. Diagnostic facility was made available at 61 healthcare sites and we targeted twelve sites for this particular research including 6 sites in Punjab and Sind and six from Federal Capital, Baluchistan and KPK.

Patients were enrolled after the consent of the area managers and fulfilling of inclusion criteria. We included patients in the age bracket of 18 – 50 years for Hepatitis C. No decomposition sign cases were considered as naïve cases having gastrointestinal bleed, ascites and encephalopathy and hepatitis B non-infected cases or they had related CVD and renal failures. On the monthly basis Blood CP and ALT was carried out to observe the drug reaction. A six-monthly verification of HCV RNA was also carried out for the confirmation of non-detection and response was named as ETR. A yearly SVR was carried out and it was observed that no detection of HCV RNA was made in the case of ALT as normal. There were mandatory and optional tests respectively ETR and SVR.

We included above five years old cases of Hepatitis B which had six months chronic disease of liver. All the cases having ALT as (1.5 – 2) times over the normal range observed twice in six months were included in the research. Patients were managed with one tablet of (lamivudine, 100 mg) before breakfast till the time of seroconversion. In the course of wild type treatment follow-up and ALT verification was carried out every fourth month and at every six-month duration testing of HBeAg/HBV DNA. HBV DNA as negative including normalization or lowering of ALT indicated the response. Seroconversion was the therapy end point as there was a loss of HBeAg and anti-HBe presentation was visible. In the group of mutants, HBV DNA non-detection with ALT levels normalization and their baseline persistent for one complete year was considered as the end point of the therapy. All the cases of HBsAg carriers (negative cases of HBV DNA); normal ALT and hepatitis C virus coinfected cases; less than five years age and Delta virus cases were not included in this research.
A special program was developed in order to assess the data.

RESULTS:

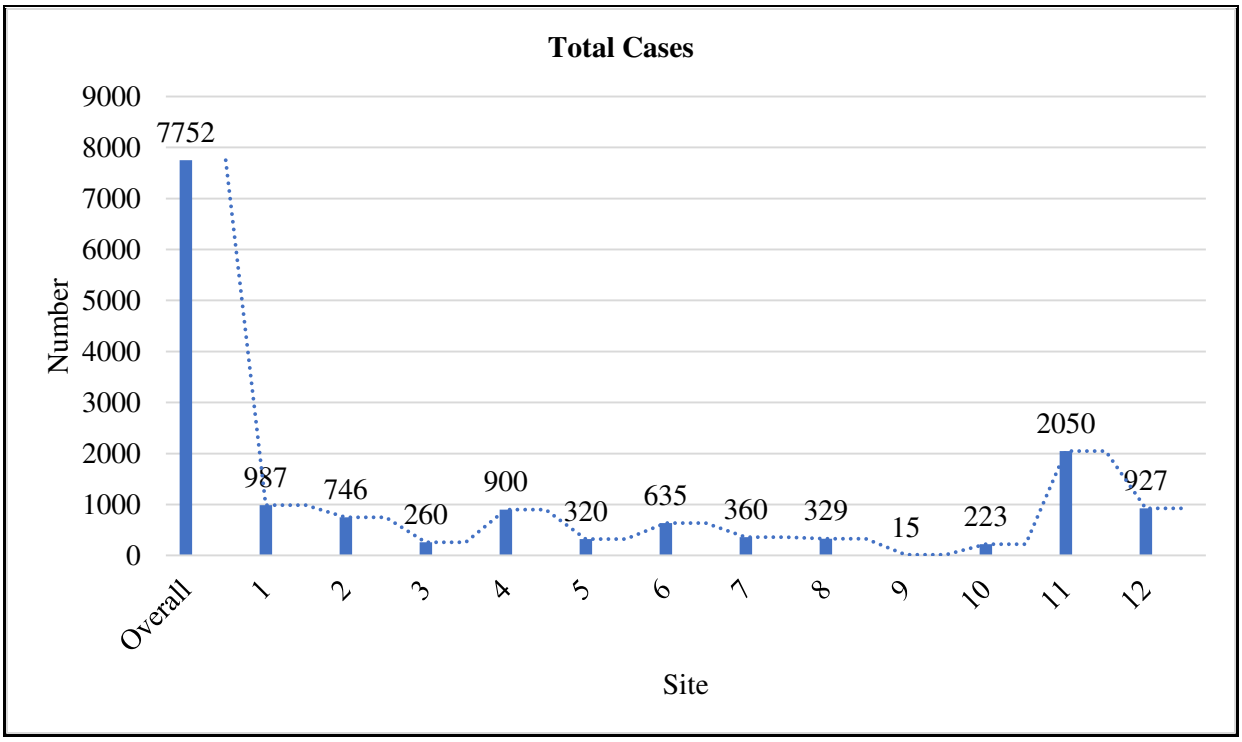
Research sample comprised of 7752 patients who were managed under the said program at twelve various sites. In the sample population six-month treatment was completed by 3440 patients (45.4%); whereas, only 1686 employed polymerase chain reaction test (49%) at the end of 6 months. The infection was not diagnosed in the time of six months

in 1133 out of 1686 cases (67%); whereas, no response was observed in 553 cases (33%). Inclusion criteria was completed by a total of 454 cases and management of the disease was carried out in 85 cases (18.72%), complete treatment in 9 cases (10.58%), 3 cases were positive for HBV (3.52%) for clearance of antigen and anti-HBe production.

A detailed outcomes analysis of the research has been shown in Table I & II and respective figures.

Table – I: Evaluation for Hepatitis C virus

HCV - sites		Total Cases	Nos. Fulfilling inclusion criteria (Adults, No sign of decompensation HCV & PCR +ve)	Treatment Completed	End Point - End of Six months ETR PCR Done at Six months. (49%)	Non-Responder: (PCR positive) (32.7%)	Responders: (PCR negative)
Overall	**N**	7752	7572	3440	1686	553	1133
	%		97		100	52	67
1	**N**	987	982	133	3	1	48
	%		99				48
2	**N**	746	727	278	50	3	2
	%		97				67
3	**N**	260	244	216	602	164	47
	%		94				82
4	**N**	900	871	871	311	72	438
	%		97				73
5	**N**	320	320	320	14	14	229
	%		100				74
6	**N**	635	538	14	71	12	-
	%		85				
7	**N**	360	360	354	115	32	59
	%		100				83
8	**N**	329	329	329	-	-	83
	%		100				72
9	**N**	15	6	5	16	2	-
	%		40				
10	**N**	223	222	114	-	-	14
	%		99				75
11	**N**	2050	2046	-	404	201	-
	%		99				
12	**N**	927	927	806	-	-	203
	%		100				50


Total Cases
Number
9000
8000
7000
6000
5000
4000
3000
2000
1000
0
7752
987
746
260
900
320
635
360
329
15
223
2050
927
Overall
1
2
3
4
5
6
7
8
9
10
11
12
Site

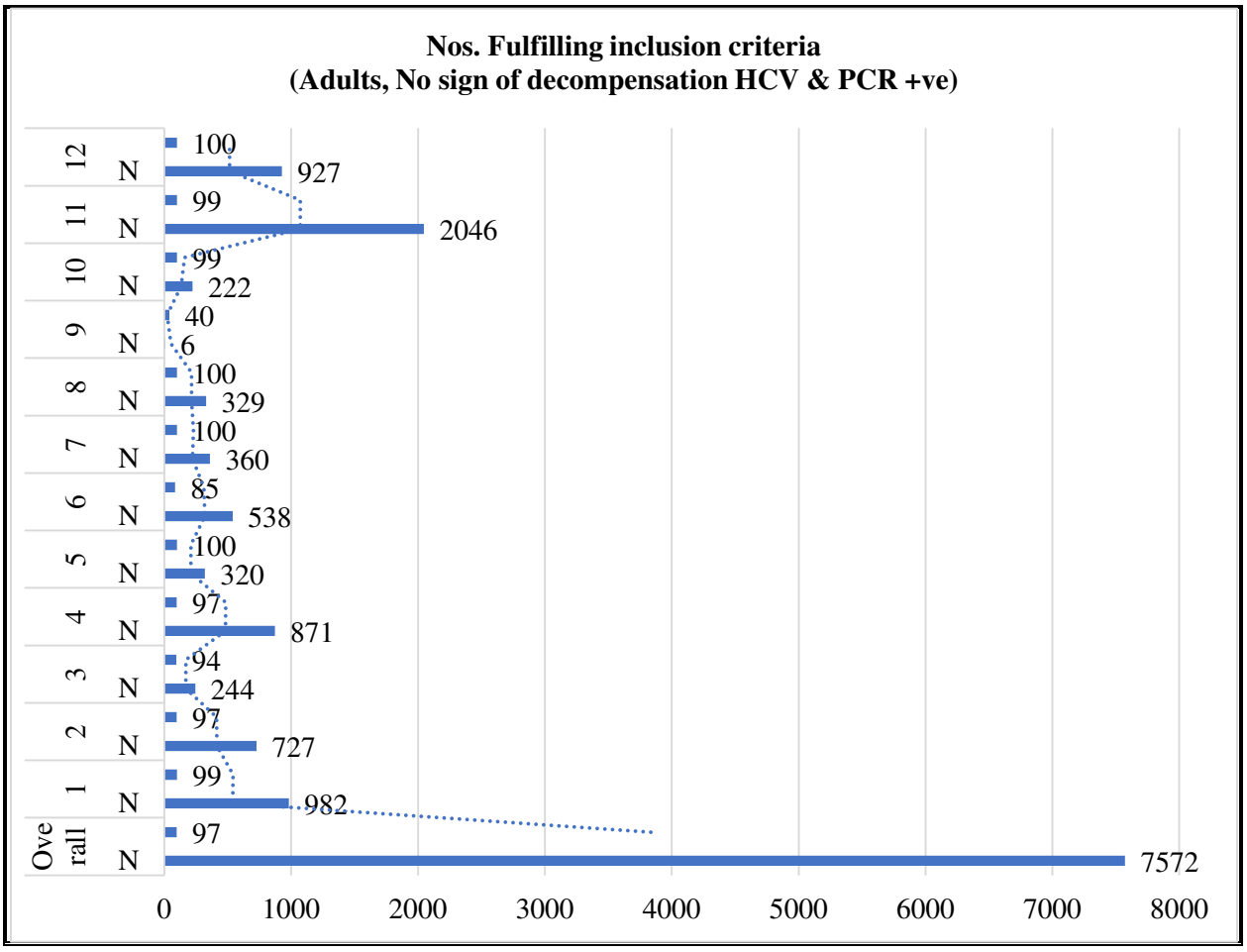
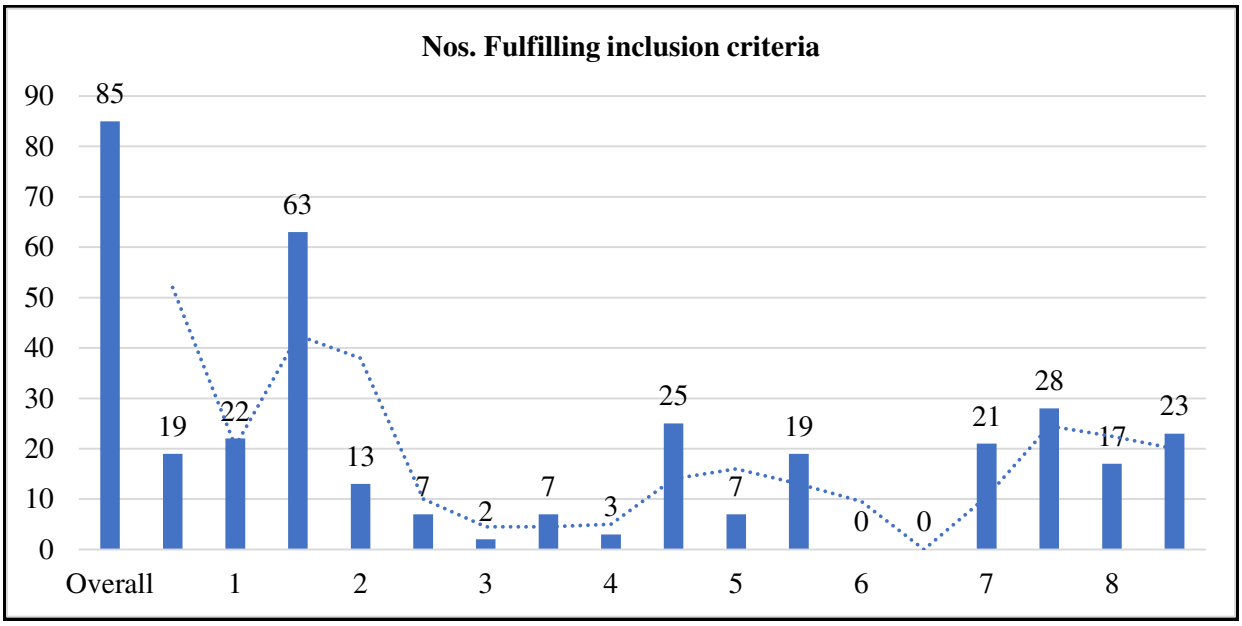

Nos. Fulfilling inclusion criteria
(Adults, No sign of decompensation HCV & PCR +ve)
Overall N 97 7572
1 N 99 982
2 N 97 727
3 N 94 244
4 N 97 871
5 N 100 320
6 N 85 538
7 N 100 360
8 N 100 329
9 N 40 6
10 N 99 222
11 N 99 2046
12 N 100 927
0
1000
2000
3000
4000
5000
6000
7000
8000

Table – II: Evaluation for Hepatitis B virus

HBV - sites	Overall		1		2		3		4		5		6		7		8	
	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Total Cases	454		35		175		30		12		37		16		76		73	
Nos. Fulfilling inclusion criteria	85	19	22	63	13	7	2	7	3	25	7	19	0	0	21	28	17	23
Group I (Wild type) HBeAg +ve HBV DNA +ve	54		11		8		2		3		5		-		13		12	
Group II (Pre_core mutant) HBeAg -ve, HBV DNA +ve	31		11		5		-		-		2		-		8		5	
Treatment: Completed (ETR)	9		6		0		2		-		-		-		1		-	
HBV DNA negative, ALT normal at 1 year	3	33	2	33	-		-		-		-		-		1	100	-	



DISCUSSION:

In the total sample of 7752 HCV cases and HBV as 454 cases were reviewed in this research. An overall response for Hepatitis C in the period of six months was observed in 1133 out of 1686 cases (67%) and no response was observed in 553 cases, exclusion and inclusion was based on the follow-up and non-adherence of the treatment. We did not check SVR in this project.

In the best cases the response rate was observed in the range of 60 – 70 percent [16 – 20]. The report states that clearance failure in the intervention of interferon was in the range of 10 – 15 percent as pegylated interferon was three to four times expensive [15]. It is therefore suggested to include eligible cases for the purpose of review.

In the scarcity of resources, the effort was commendable on the part of government and health department in response to the chronic Hepatitis B & C [21]. This program helped the underprivileged who were unable to afford the costly treatment of these two infections. All the failure cases who did not abide by the regulations need to be treated and made accountable.

The cost of the program was relatively less than the overall actual treatment cost which was quarter of prevalent market rate as one case for a period of six months receives the treatment of amounting nine thousand and for total population the cost is about sixty-eight million in Hepatitis C cases; whereas, in the case of HBV a tablet price is estimated twenty-five rupees and one-month expenditure is 1050 rupees which becomes for one year as 12600 per patients.

Commitment lack was also observed at the part of the site managers as they lost almost fifty percent of the recruited cases. Failure was attributed to managerial issues, poor compliance, por patient's enrollment which requires timely rectification. Program can be improved through the eradication of non-justified discontinuation and termination of follow-up.

Selected HBV cases were recommended to be treated with nucleoside with analogues lamivudine [22]. The overall response is dependent on the accurate selection, duration of treatment, compliance to treatment and proper drug intake [23]. We also observed that a number of cases were treated without viral replications markers which added in
the drug-resistant pool. The misuse of drugs can be discouraged in future through selected centers for HBV treatment which will accelerate the development in the resistant patients.

Early management of the HCV and HBV can reduce or eliminate the developmental chances of hepatocellular carcinoma and liver cirrhosis and ultimately save the economic burden. This will make the availability of services for poor.

Preventive interventions need focus in these kinds of programs instead of treatment efforts. Awareness about the disease management will help a lot in this concern. In the context of Pakistan, the community pressure is felt for the infection disease management at every level of administration whether at district or provincial level. Escalating HCV and HBV incidence can be minimized through necessary interventional approaches which will halt the disease progression. We need to promote safe practice of injections and vaccination against the infection of Hepatitis B.

CONCLUSION:

The inappropriate record keeping and poor incidence of follow-up in biochemical/ serological tests was observed as the loop hole in both the infected cases including HBV and HCV. This resulted in the wastage of financial and manpower resources as there was an obvious ill planning and factor of accountability was also missing.

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