Burden OF HCV In Iran

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Liver Disease Burden of Hepatitis C Virus Infection in Iran and the Potential Impact of Various Treatment Strategies on the Disease Burden

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Viral hepatitis

- Viral hepatitis is a leading cause of death and disability worldwide.

- Unlike most communicable diseases, between 1990 and 2013, viral hepatitis has increased in terms of both absolute burden and its relative rank.

- Together, viral hepatitis deaths from acute infection, cirrhosis and liver cancer were the 10th leading cause of death, globally, in 1990 (95% UI 10 – 12) and 7th leading cause in 2013 .

Viral hepatitis 2

- Viral hepatitis is one of the leading causes of death and disability worldwide, and causes at least as many deaths annually as tuberculosis, AIDS, or malaria.
- Viral hepatitis has risen in importance since the first GBD Study in 1990.
- WHO launches a major new effort to tackle viral hepatitis.

Global burden of Viral Hepatitis

Lancet July 2016 online

The global burden of viral hepatitis from 1990 to 2013: findings from the Global Burden of Disease Study 2013

Jeffrey D Stanaway, Abraham D Flaxman, Mohsen Naghavi, Christina Fitzmaurice, Theo Vos, Ibrahim Abubakar, Laith J Abu-Raddad, Reza Assadi, Neeraj Bhala, Benjamin Cowie, Mohammad H Forouzanfour, Justina Groeger, Khayriyyah Mohd Hanafiah, Kathryn H Jacobsen, Spencer L James, Jennifer MacLachlan, Reza Malekzadeh, Natasha K Martin, Ali A Mokdad, Ali H Mokdad, Christopher J L Murray, Dietrich Plass, Saleem Rana, David B Rein, Jan Hendrik Richardus, Juan Sanabria, Mete Saylan, Saeid Shahraz, Samuel So, Vasiliy V Vlassov, Elisabete Weiderpass, Steven T Wiersma, Mustafa Younis, Chuanhua Yu, Maysaa El Sayed Zaki, Graham S Cooke

Summary

Background With recent improvements in vaccines and treatments against viral hepatitis, an improved understanding of the burden of viral hepatitis is needed to inform global intervention strategies. We used data from the Global Burden of Disease (GBD) Study to estimate morbidity and mortality for acute viral hepatitis, and for cirrhosis and liver cancer caused by viral hepatitis, by age, sex, and country from 1990 to 2013.

Methods We estimated mortality using natural history models for acute hepatitis infections and GBD's cause-of-death ensemble model for cirrhosis and liver cancer. We used meta-regression to estimate total cirrhosis and total liver cancer prevalence, as well as the proportion of cirrhosis and liver cancer attributable to each cause. We then estimated cause-specific prevalence as the product of the total prevalence and the proportion attributable to a specific cause. Disability-adjusted life-years (DALYs) were calculated as the sum of years of life lost (YLLs) and years lived with disability (YLDs).

Findings Between 1990 and 2013, global viral hepatitis deaths increased from 0·89 million (95% uncertainty interval [UI] 0·86–0·94) to 1·45 million (1·38–1·54); YLLs from 31·0 million (29·6–32·6) to 41·6 million (39·1–44·7); YLDs from 0·65 million (0·45–0·89) to 0·87 million (0·61–1·18); and DALYs from 31·7 million (30·2–33·3) to 42·5 million (39·9–45·6). In 2013, viral hepatitis was the seventh (95% UI seventh to eighth) leading cause of death worldwide, compared with tenth (tenth to 12th) in 1990.

Interpretation Viral hepatitis is a leading cause of death and disability worldwide. Unlike most communicable diseases, the absolute burden and relative rank of viral hepatitis increased between 1990 and 2013. The enormous health loss attributable to viral hepatitis, and the availability of effective vaccines and treatments, suggests an important opportunity to improve public health.

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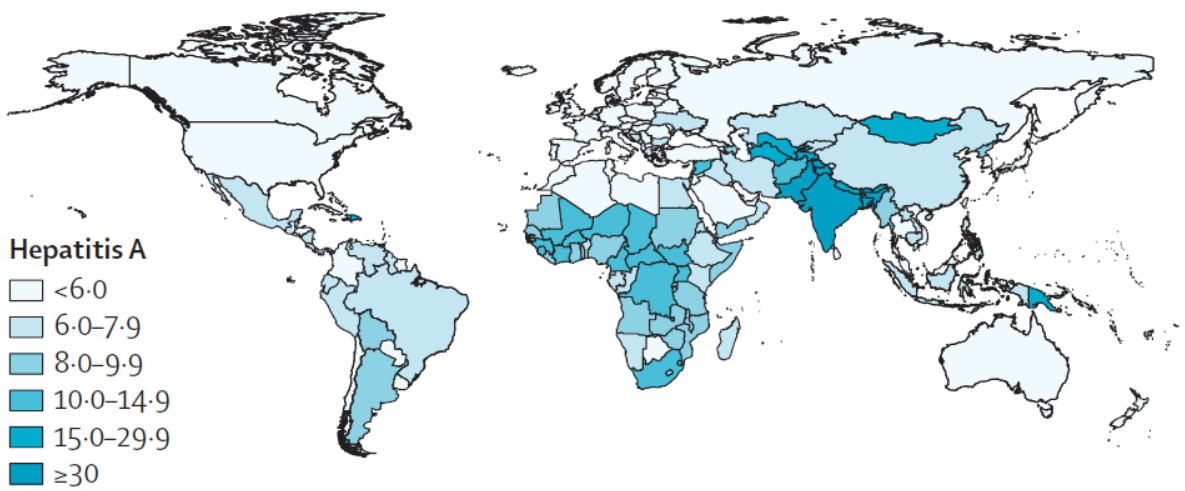
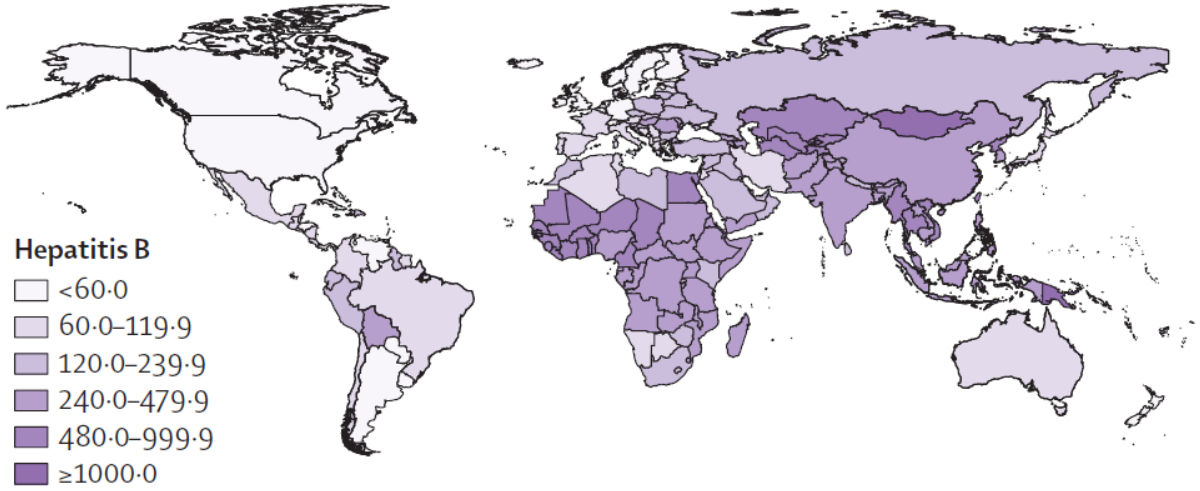
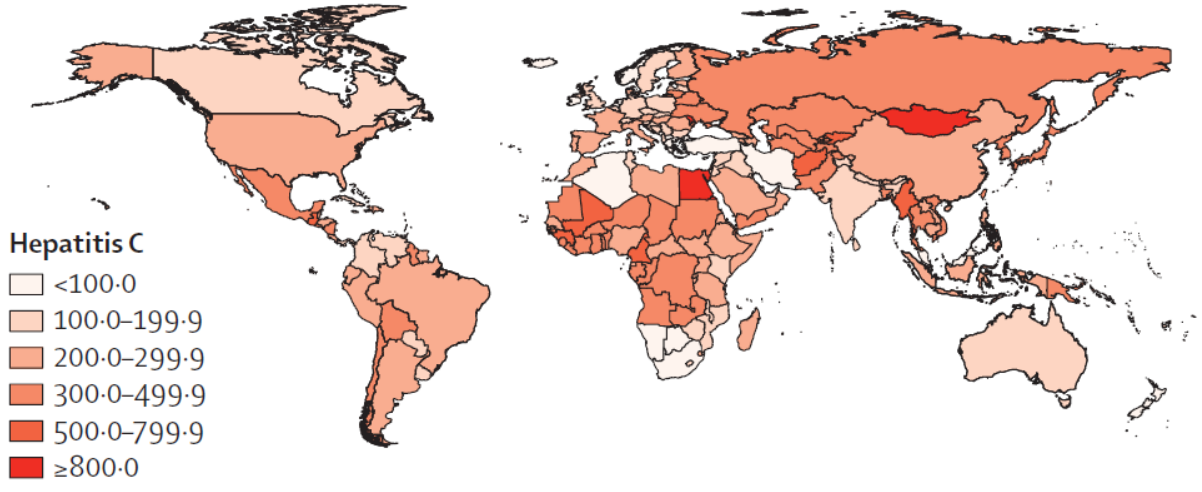
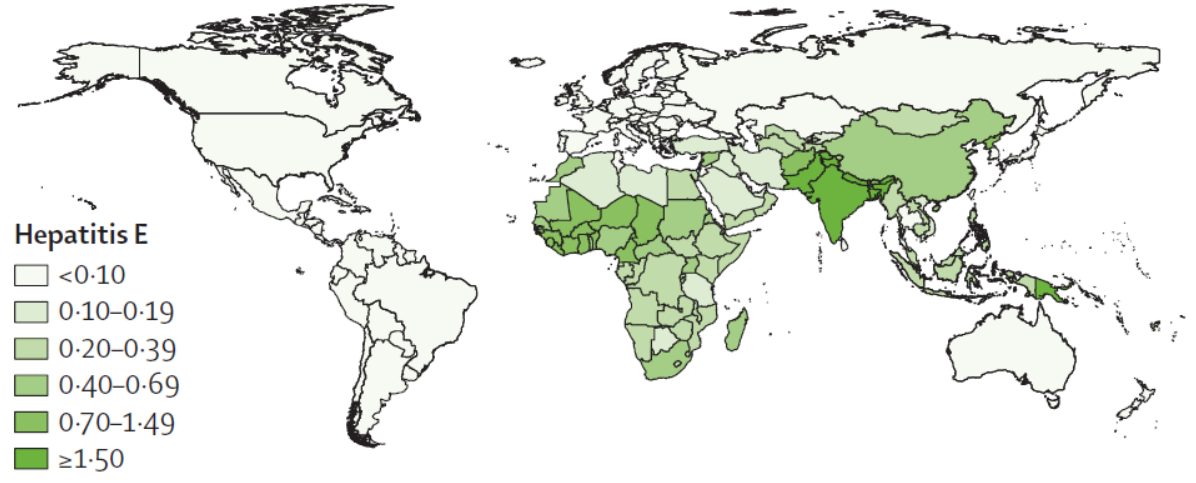
Institute for Health Metrics and Evaluation (J D Stanaway PhD, A D Flaxman PhD, Prof M Naghavi PhD, C Fitzmaurice MD, Prof T Vos PhD, M H Forouzanfour PhD, Prof A H Mokdad PhD, Prof C J L Murray DPhil) and Division of Hematology, Department of Medicine (C Fitzmaurice), University of Washington, Seattle, WA, USA; Institute for Global Health, University College London, London, UK (Prof I Abubakar PhD); Infectious Disease Epidemiology Group, Weill

Age-standardised disability-adjusted life-year rates to Hepatitis A, B, C, and E viruses in 2013, by country

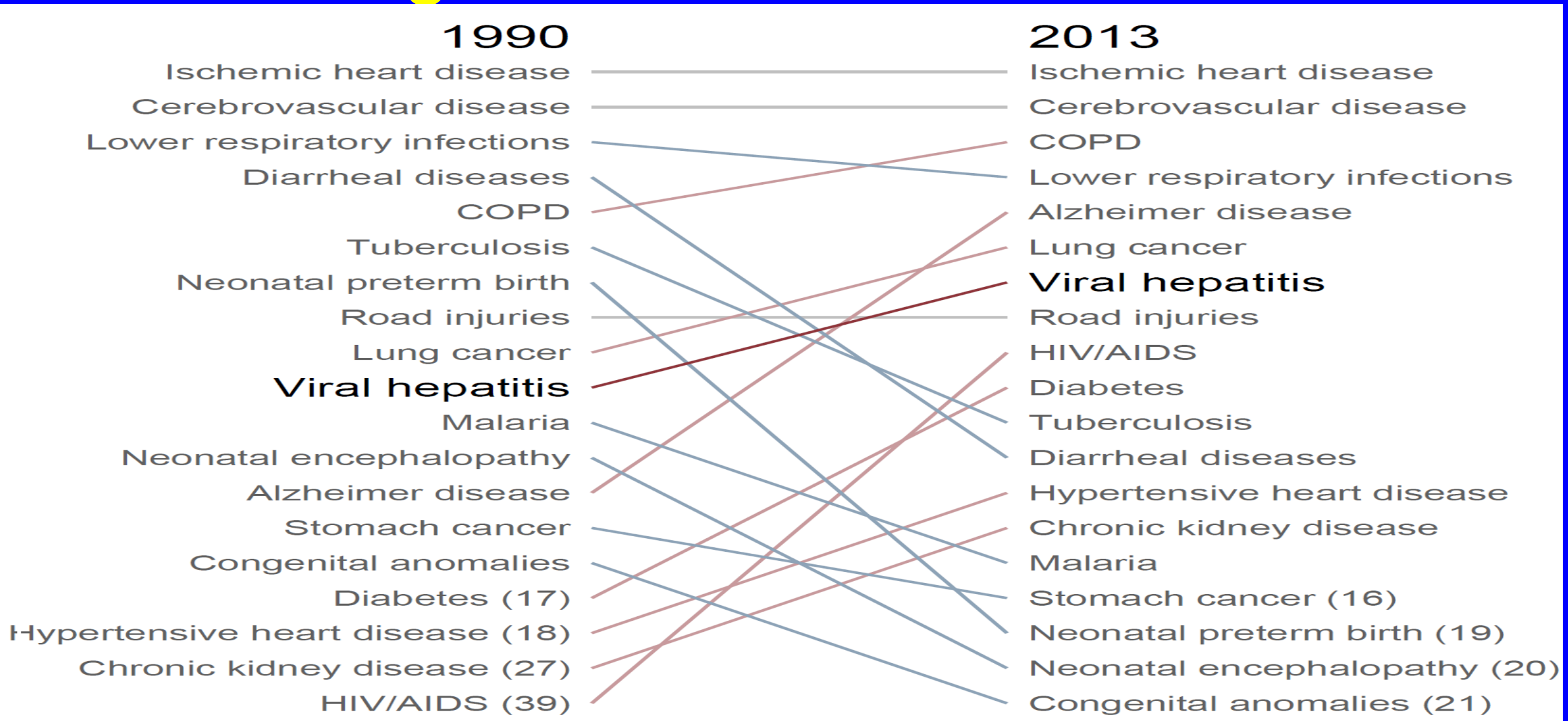




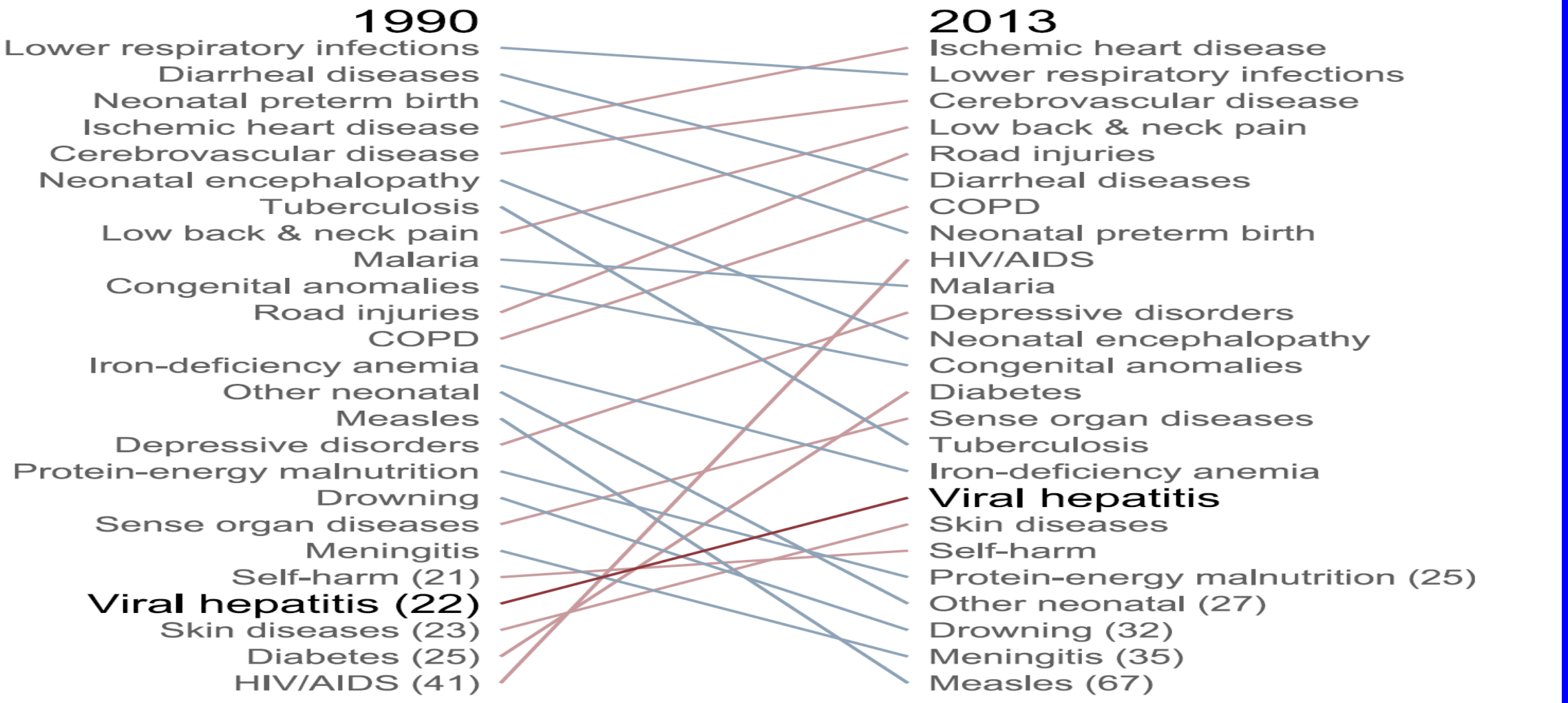




Among the Top 15 causes of mortality for 1990 and 2013 Viral hepatitis is the main infectious disease with increasing Burden



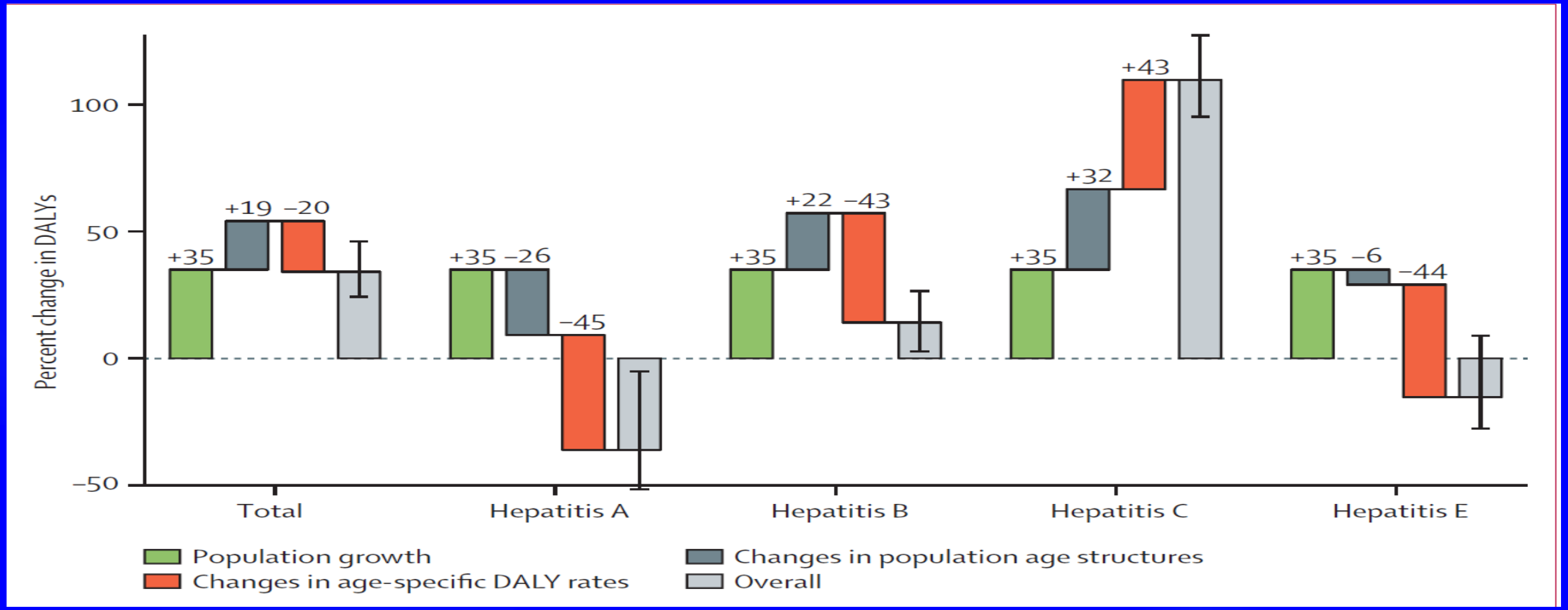
Among the Top 20 causes of DALYs for 1990 and 2013 Viral hepatitis is the main infectious disease with increasing Burden



Hepatitis C

- Hepatitis C is the only subtype for which we've seen an increase in age-specific rates; combined with increases due to both population growth and changing age structures'
- DALYs for hepatitis C have more than doubled since 1990.

HCV Burden increase more than all other viral hepatitis between 1990 and 2013, by virus type and for all hepatitis viruses combined



Population based seroprevalence and Spontaneous Hepatitis C Clearance

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Seroprevalence of hepatitis C virus: the first population-based study from Iran

Shahin Merat [a], Houri Rezvan [b], Mehdi Nouraie [a,c], Elham Jafari [a], Hassan Abolghasemi [d], Amir Reza Radmard [a], Hanieh Zaer-rezaii [a], Sedigheh Amini-Kafiabad [b], Mahtab Maghsudlu [b], Akram Pourshams [a], Reza Malekzadeh [a], Saeed Esmaili [a,*]

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SUMMARY

Objective: Early studies on blood donors point to a seroprevalence of approximately 0.25% for hepatitis C virus (HCV) infection in Iran. However, the true prevalence in the general population is unknown. The objective of this study was to determine the prevalence of HCV infection in the general population of Iran.

Methods: We randomly selected 6583 subjects from three provinces in Iran for inclusion in the study. Subjects were aged between 18 and 65 years. Anti-hepatitis C antibody was tested by a third-generation ELISA test. A recombinant immunoblot assay (RIBA) test was used to confirm the results. Risk factors were recorded and a multivariate analysis was performed.

Results: A total of 5684 plasma samples were tested. After confirmatory tests, we found 50 cases of HCV. The overall weighted prevalence of anti-HCV was 0.5%. The rate was significantly higher in men (1.0%) than in women (0.1%). In multivariate analysis, male sex, history of intravenous drug abuse, and imprisonment were significantly associated with anti-HCV.

Conclusions: We found the prevalence of HCV infection in Iran to be higher than previous estimates. It appears that the rate is rising, and in the future, hepatitis C will replace hepatitis B as the most common cause of chronic viral liver disease in Iran.

HCV-infected population in Iran

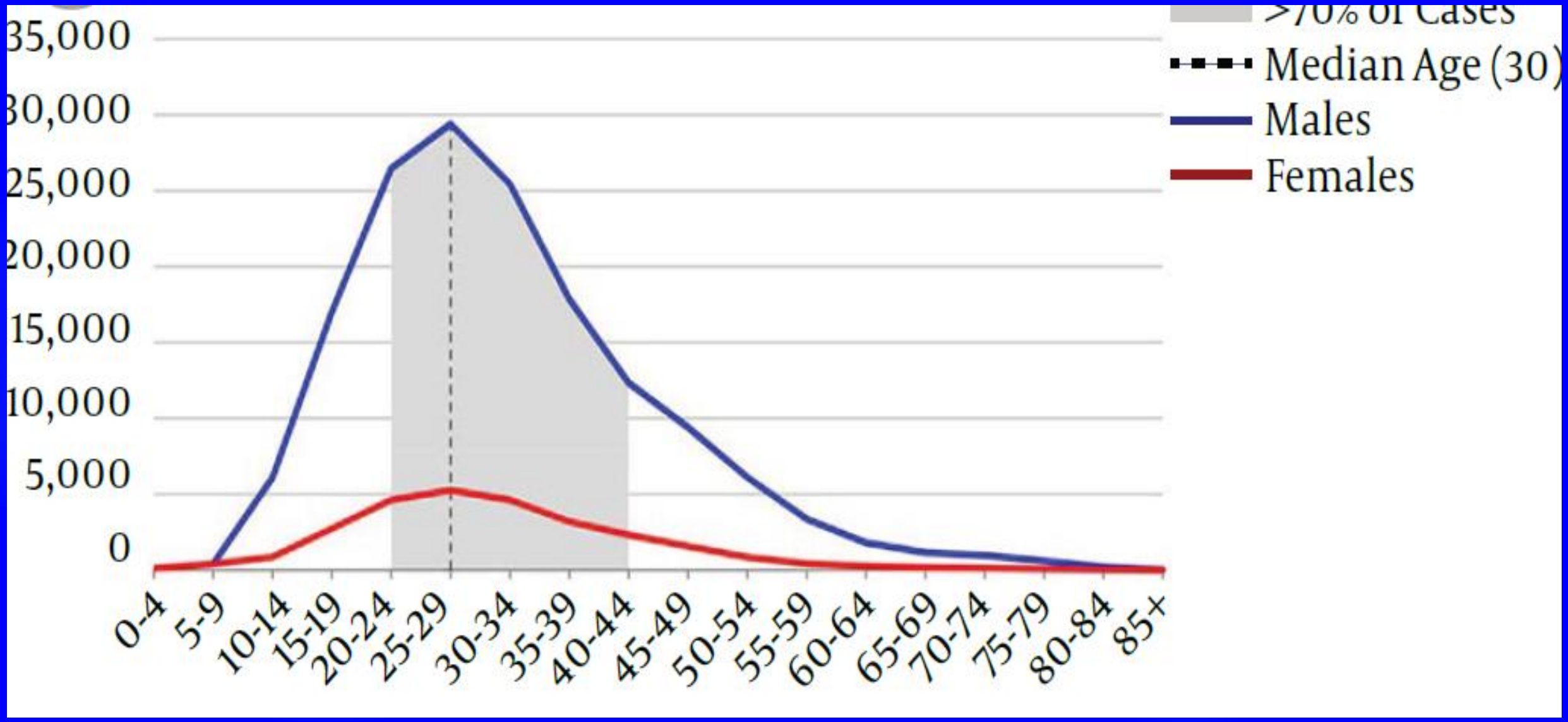
- A population-based study across three provinces estimated HCV Ab prevalence in adults aged 18–65 to be 0.5%

- Based on a another study from Iran a viremic prevalence of 0.2% (0.2–0.3%) representing approximately 170 000 (117 000– 223 000) viremic persons in Iran in 2006.

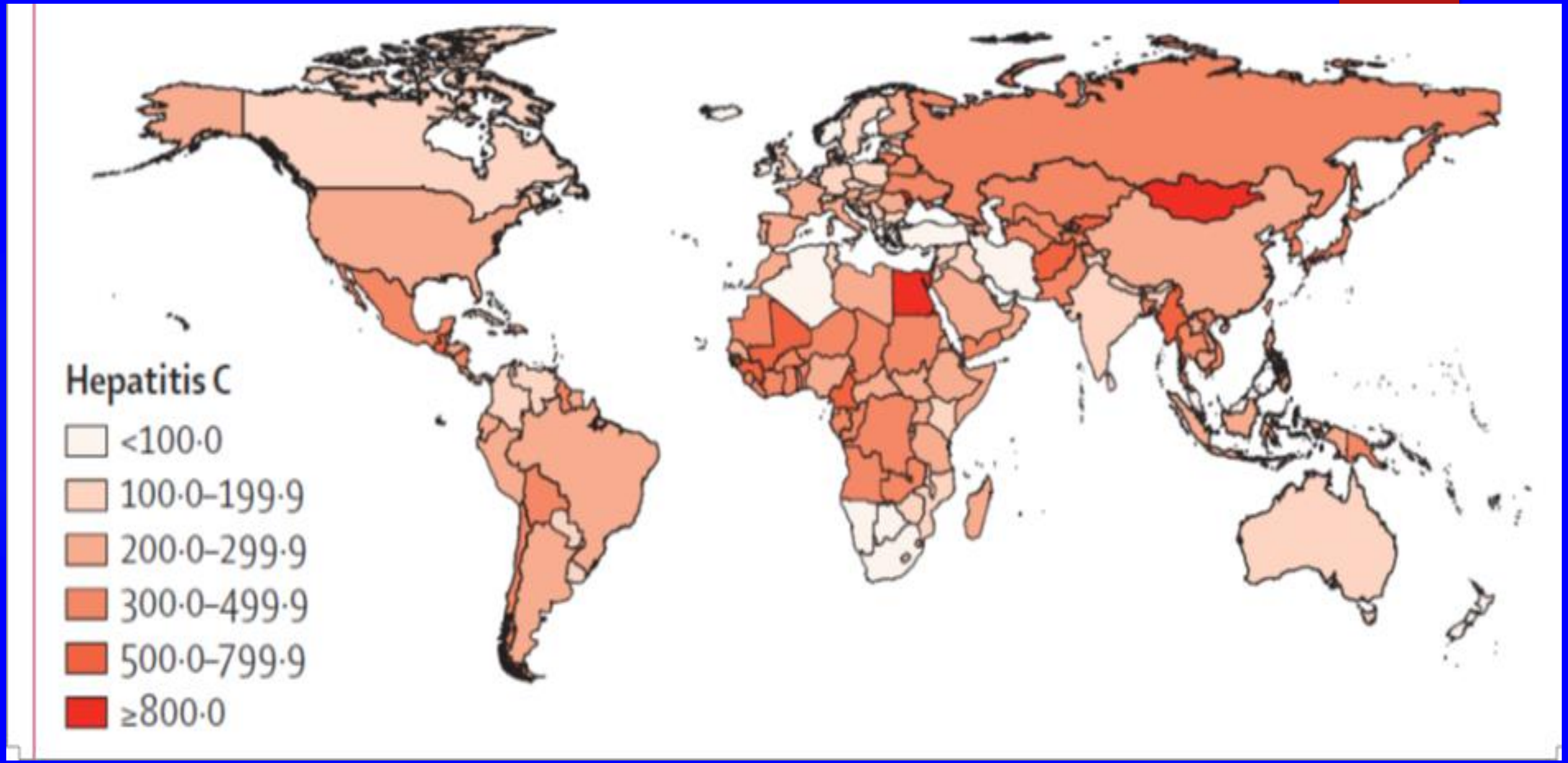
- It is estimated that there are 60 000 individuals diagnosed with HCV in Iran since 2013 with an annual diagnostic rate of 6000 with a maximum of 100 HCV liver transplant per year

Merat S…Malekzadeh R. Seroprevalence of hepatitis C virus:. Int J Infect Dis 2010; 14 (Suppl. 3): e113–e116.
Poustchi H,…malekzadeh The impact of illicit drug use on spontaneous hepatitis C clearance. PLoS ONE 2011; 6(8): e23830.

Age and Gender-Specific Distribution of Individuals Exposed and Living With HCV Infection



Iran: very low incidence area for HCV



Route of HCV infection Iran

- It was estimated that 75% of the infected population in Iran had been infected by IDU and 4% of all HCV cases were infected via transfusion procedures.

- The majority of new cases are due to IDU, which is reflected in the young age distribution.

HCV Genotype In Iran

- **Genotype 1a and 3a were predominant accounting for 47 and 36%, whereas 1b and 4 accounted for 8 and 7%.**

- **Subtype 1a was frequent in South Iran (70%), while 3a was more prevalent in North- West Iran (83%).**

- **Patients infected by blood products had more frequently subtype 1a (57%),while younger drug users had more frequently subtype 3a (54%).**

JSamimirad K ..Malekzadeh R. Med. Virol. 74:246–252, 2004.

Projection of HCV Morbidity and - 2030 by Diagnosis and Treatment Strategy

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Historical epidemiology of hepatitis C virus (HCV) in select countries – volume 3

V. Liakina,[1,2,‡] S. Hamid,[3,‡] J. Tanaka,[4,‡] S. Olafsson,[5,‡] A. I. Sharara,[6,‡] S. M. Alavian,[7,8,‡] L. Gheorghe,[9,‡] E. S. El Hassan,[10,‡] F. Abaalkhail,[11] Z. Abbas,[12] A. Abdou,[10] A. Abourached,[13,‡] F. Al Braiki,[14] F. Al Hosani,[15] K. Al Jaberi,[16] M. Al Khatry,[17] M. A. Al Mulla,[15] H. Al Quraishi,[18] A. Al Rifai,[19] Y. Al Serkal,[20] A. Alam,[21] H. I. Alashgar,[22] S. Alawadhi,[10] L. Al-Dabal,[23] P. Aldins,[24] F. Z. Alfaleh,[25,‡] A. S. Alghamdi,[26] R. Al-Hakeem,[27] A. A. Aljumah,[28] A. Almessabi,[14] A. N. Alqutub,[26] K. A. Alswat,[29] I. Altraif,[28] M. Alzaabi,[30,‡] N. Andrea,[31] A. M. Assiri,[27,‡] M. A. Babatin,[26] A. Baqir,[32] M. T. Barakat,[33] O. M. Bergmann,[34] A. R. Bizri,[35] S. Blach,[36] A. Chaudhry,[37] M. S. Choi,[38] T. Diab,[39] S. Djauzi,[40] S. El Khoury,[41] C. Estes,[36] S. Fakhry,[42] J. I. Farooqi.,[43,44] H. Fridjonsdottir,[45] R. A. Gani,[40] A. Ghafoor Khan,[46] A. Goldis,[47,‡] M. Gottfredsson,[48] S. Gregorcic,[49] B. Hajarizadeh,[50,51,‡] K. H. Han,[52,‡] I. Hasan,[40] A. Hashim,[53] G. Horvath,[54] B. Hunyady,[55,56,‡] R. Husni,[57] W. Jafri.,[58,‡] A. Jeruma,[59,60] J.G. Jonasson,[45,61,62] B. Karlsdottir,[63] D. Y. Kim,[52,‡] Y. S. Kim,[64] Z. Koutoubi,[65] L. A. Lesmana,[40,66,‡] Y. S. Lim,[67] A. Löve,[48,68] M. Maimets,[69] M. Makara,[70,‡] R. Malekzadeh,[71] M. Matičič,[49,‡] M. S. Memon,[72] S. Merat,[71] J. E. Mokhbat,[73] F. H. Mourad,[6] D. H. Muljono,[74,75] A. Nawaz,[76] N. Nugrahini,[77,‡] S. Priohutomo,[78] H. Qureshi,[79] P. Rassam,[41] H. Razavi,[36] D. Razavi-Shearer,[36] K. Razavi-Shearer,[36] B. Rozentale,[59,60] M. Sadik,[72] K. Saeed,[80] A. Salamat,[81] R. Salupere,[69,‡] F. M. Sanai,[25] A. Sanityoso Sulaiman,[40] R. A. Sayegh,[82] J. D. Schmelzer,[36] A. Sibley,[36] M. Siddiq,[83,84] A. M. Siddiqui,[85] G. Sigmundsdottir,[86] B. Sigurdardottir,[63] D. Speiciene,[1] A. Sulaiman,[40,87] M. A. Sultan,[88] M. Taha,[89] H. Tarifi,[90] G. Tayyab,[91,92] I. Tolmane,[59,60,‡] M. Ud din,[93] M. Umar,[94,95] J. Valantinas,[1,‡] J. Videčnik-Zorman,[49] C. Yaghi,[82] E. Yunihastuti,[96] M. A. Yusuf,[97] B. F. Zuberi[98] and J. Gunter[36]

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The present and future disease burden of hepatitis C virus infections with today's treatment paradigm – volume 3

A. Sibley,[1] K. H. Han,[2,*] A. Abourached,[3,*] L. A. Lesmana,[4,5,*] M. Makara,[6,*] W. Jafri,[7,*] R. Salupere,[8,*] A. M. Assiri,[9,*] A. Goldis,[10,*] F. Abaalkhail,[11] Z. Abbas,[12] A. Abdou,[13] F. Al Braiki,[14] F. Al Hosani,[15] K. Al Jaberi,[16] M. Al Khatry,[17] M. A. Al Mulla,[15] H. Al Quraishi,[18] A. Al Rifai,[19] Y. Al Serkal,[20] A. Alam,[21] S. M. Alavian,[22,23,*] H. I. Alashgar,[24] S. Alawadhi,[13] L. Al-Dabal,[25] P. Aldins,[26] F. Z. Alfaleh,[27,*] A. S. Alghamdi,[28] R. Al-Hakeem,[9] A. A. Aljumah,[29] A. Almessabi,[14] A. N. Alqutub,[28] K. A. Alswat,[30] I. Altraif,[29] M. Alzaabi,[31,*] N. Andrea,[32] M. A. Babatin,[28] A. Baqir,[33] M. T. Barakat,[34] O. M. Bergmann,[35] A. R. Bizri,[36] S. Blach,[1] A. Chaudhry,[37] M. S. Choi,[3] T. Diab,[39] S. Djauzi,[4] E. S. El Hassan,[13,*] S. El Khoury,[40] C. Estes,[1] S. Fakhry,[41] J. I. Farooqi,[42,43] H. Fridjonsdottir,[44] R. A. Gani,[4] A. Ghafoor Khan,[45] L. Gheorghe,[46,*] M. Gottfredsson,[47] S. Gregorcic,[48] J. Gunter,[1] B. Hajarizadeh,[49,50,*] S. Hamid,[51,*] I. Hasan A. Hashim,[52] G. Horvath,[53] B. Hunyady,[54,55,*] R. Husni,[56] A. Jeruma,[57,58] J. G. Jonasson,[44,59,60] B. Karlsdottir,[61] D. Y. Kim,[2,*] Y. S. Kim,[62] Z. Koutoubi,[63] V. Liakina,[64,65] Y. S. Lim,[66] A. Löve,[47,67] M. Maimets,[8] R. Malekzadeh,[68] M. Matičič,[48,*] M. S. Memon,[69] S. Merat,[68] J. E. Mokhbat,[70] F. H. Mourad,[71] D. H. Muljono,[72,73] A. Nawaz,[74] N. Nugrahini,[75,*] S. Olafsson,[76,*] S. Priohutomo,[77] H. Qureshi,[78] P. Rassam,[4] H. Razavi,[1] D. Razavi-Shearer,[1] K. Razavi-Shearer,[1] B. Rozentale,[57,58] M. Sadik,[69] K. Saeed,[79] A. Salamat,[80] F. M. Sanai,[27] A. Sanityoso Sulaiman,[4] R. A. Sayegh,[81] A. I. Sharara,[71,*] M. Siddiq,[82,83] A. M. Siddiqui,[84] G. Sigmundsdottir,[85] B. Sigurdardottir,[6] D. Speiciene,[64,*] A. Sulaiman,[4,86] M. A. Sultan,[87] M. Taha,[88] J. Tanaka,[89,*] H. Tarifi,[90] G. Tayyab,[91,92] I. Tolmane,[57,58,*] M. Ud din,[93] M. Umar,[94,95] J. Valantinas,[64,*] J. Videčnik Zorman,[48] C. Yaghi,[81] E. Yunihastuti,[96] M. A. Yusuf,[97] B. F. Zuberi[98] and J. D. Schmelzer

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Strategies to manage hepatitis C virus infection disease burden – volume 3

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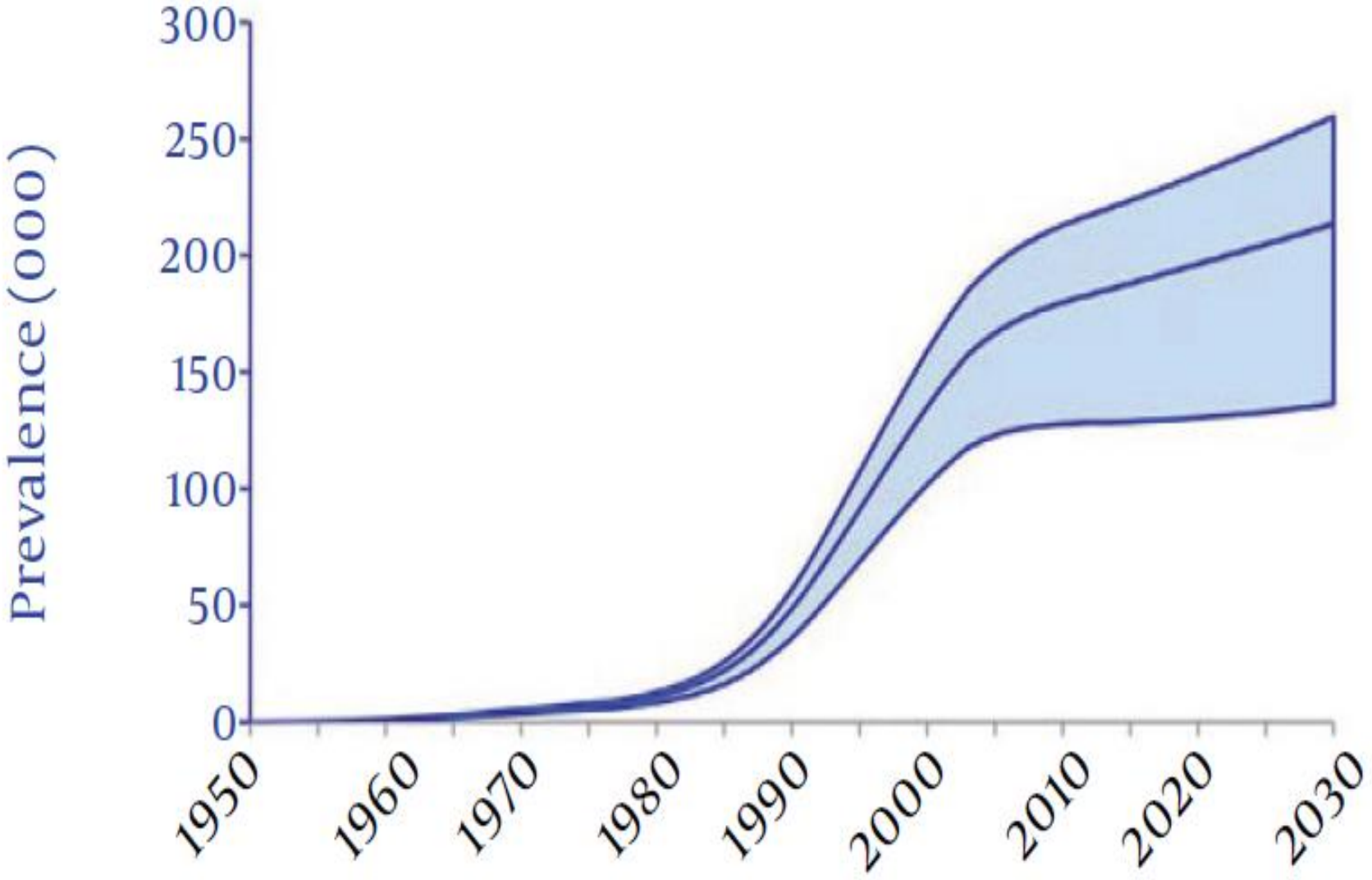
HCV in Iran In 2030

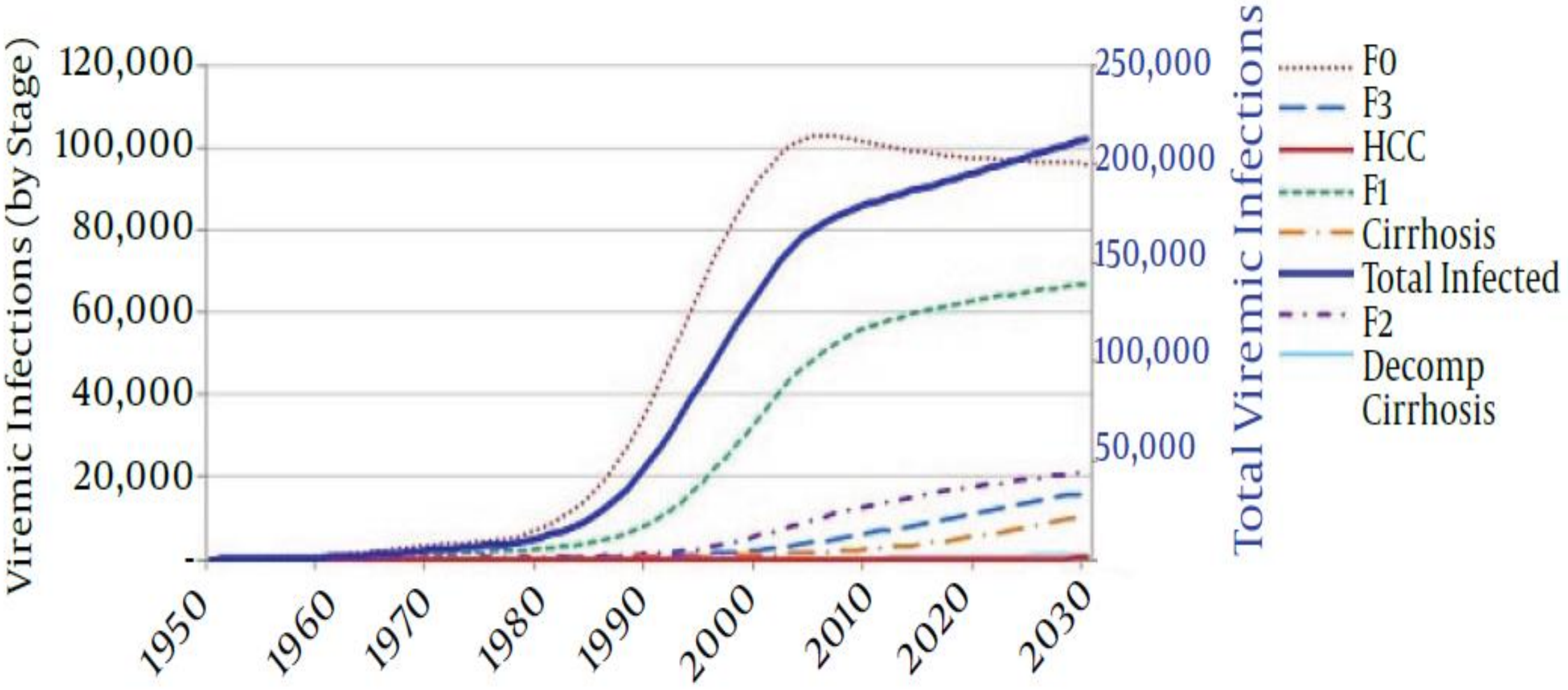
- In 2014, an estimated 186,500 individuals are living with HCV infection in Iran (median age: 30 years).

- By 2030, this number will increase to 213,700, while three to four folds increase is expected in the case numbers of decompensated cirrhosis (DC, n = 620),hepatocellular carcinoma (HCC, n = 510), and liver disease death (n = 400), assuming the current diagnosis/treatment settings.

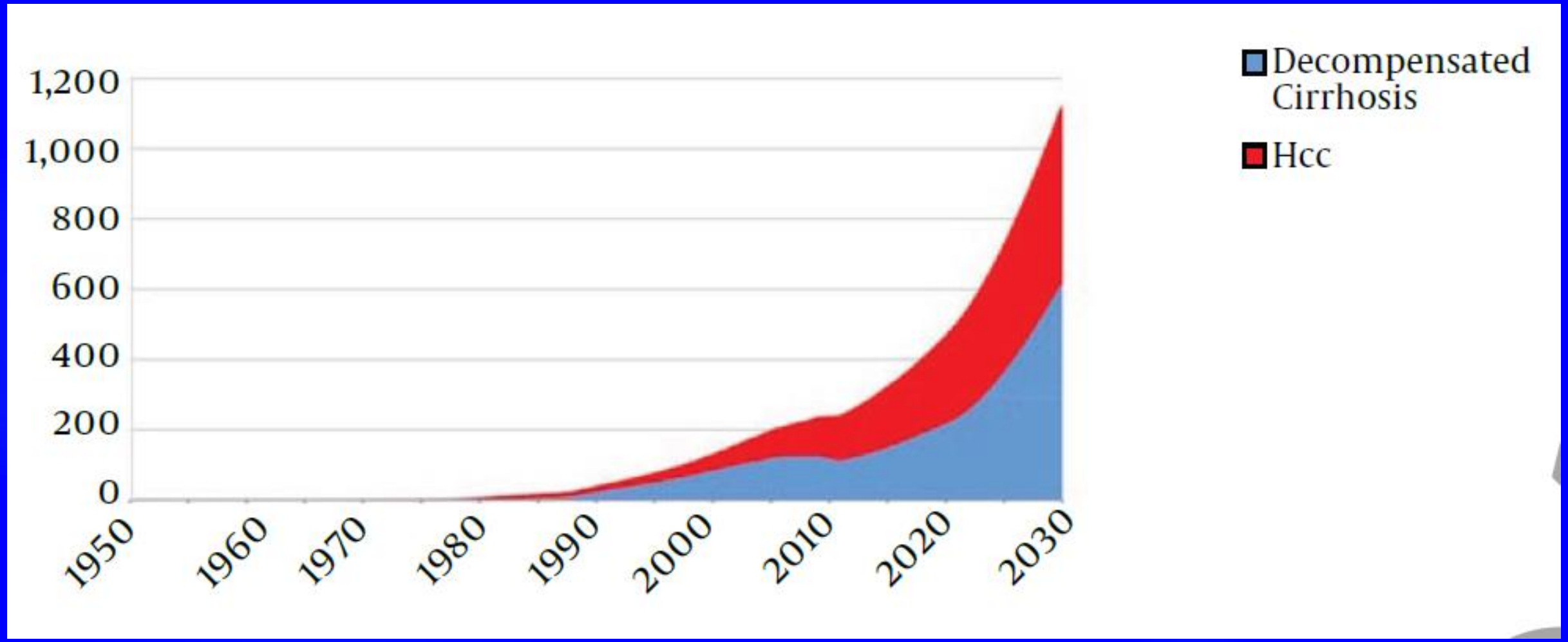
Estimated HCV Disease Burden in Iran During 1950 – 2030 Total number of individuals living with HCV



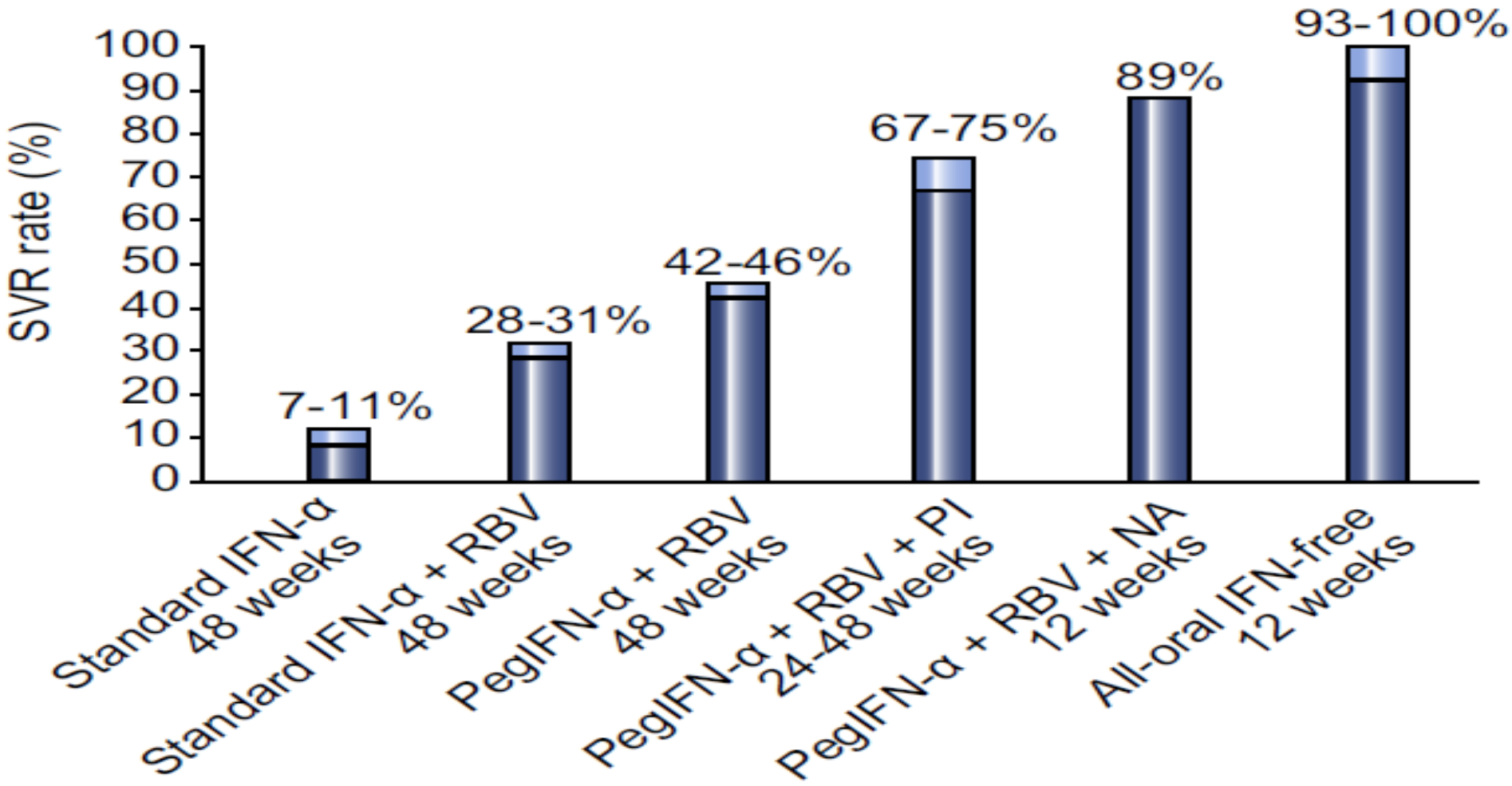
Number of individuals living with HCV infection in total and by liver fibrosis and disease stage



Number of individuals with HCV related cirrhosis and hepatocellular carcinoma



Progress in therapy of chronic hepatitis C genotype 1 as shown by SVR rates with different antiviral regimens.



DDRI Supporting production of Peg interferon in Iran

Pegaferon in hepatitis C: Results of a Multicenter Study

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ABSTRACT

BACKGROUND

Chronic hepatitis C (CHC) is a major contributor to cirrhosis and hepatocellular carcinoma and major global public health problem that causes mortality in both developed and developing countries.For the past decade, treatment with pegylated interferon (peg interferon α) and ribavirin (RBV) has been associated with rates of sustained virologic response of ≤ 66% among patients with hepatitis C virus (HCV) infection. In this study, we report the response rate of Iranian treatment-naïve CHC patients to Pegaferon, a locally developed pegylated interferon-α2a (PEG-IFNα2a).

METHODS

Patients diagnosed with CHC who referred to two university based outpatient clinics in Tehran from December 2007 to May 2011 were enrolled in a single-group, open-labeled experimental design. Eligible patients were above 15 years of age and had HCV infection with evidence of chronic hepatitis. Exclusion criteria included the presence of a debilitating disease, decompensated cirrhosis or refusal to participate in the study. Patients were treated with 180µg Pegaferon weekly in addition to 800-1200 mg daily, weight-based RBV for 24 or 48 weeks depending on genotype. Viral response and adverse effects were recorded.

RESULTS

A total of 216 patients were enrolled in the study of which 83.3% were male and 16.7% were female. In 93 (43.1%) patients, the HCV RNA viral load was ≥ 800,000 IU/ml before starting treatment. "As-treated analysis" indicated that a total of 168 (77.8%) patients achieved sustained viral response (SVR, undetectable plasma HCV RNA 24 weeks after the last planned dose of study treatment).

CONCLUSION

This study, with a larger number of participants, confirms the results of a previous study by the authors that Pegaferon, a PEG-IFNα 2a locally produced in Iran, is effective in treatment-naïve CHC patients.

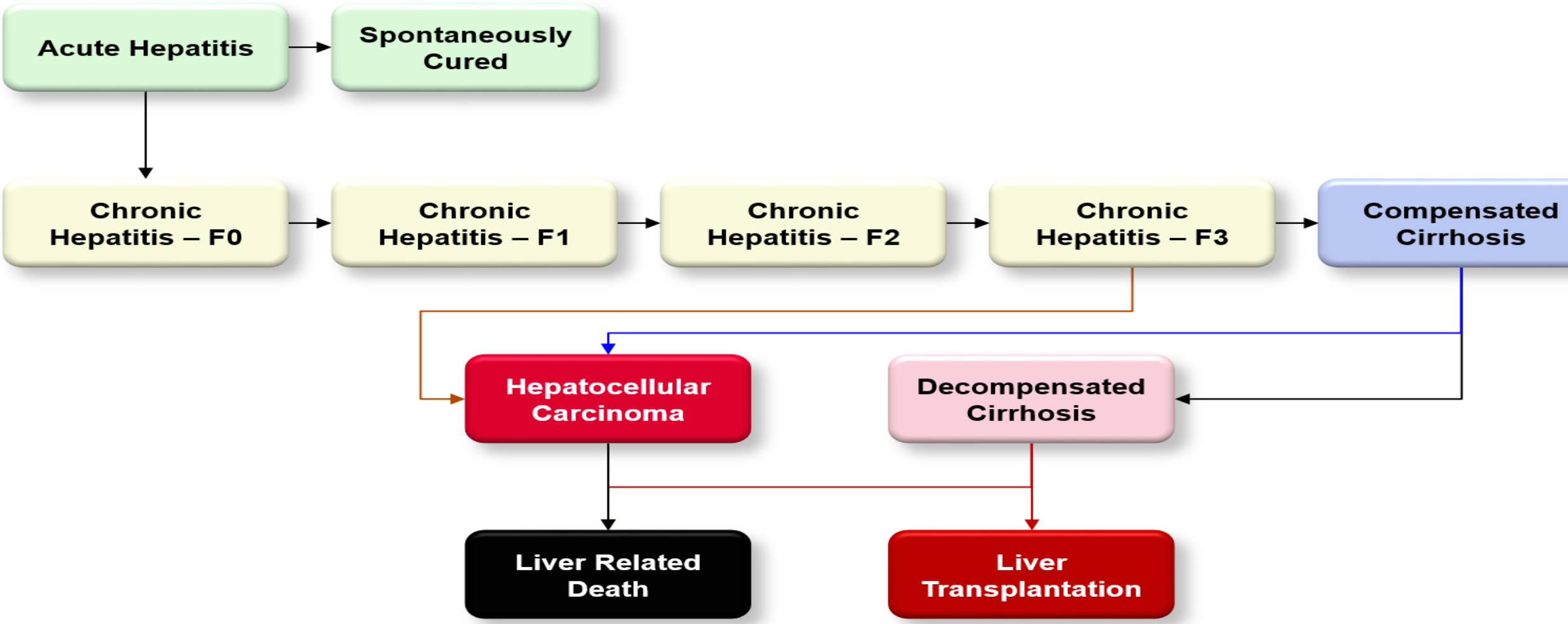
KEYWORDS

Hepatitis C virus; Pegylated interferon; Pegaferon; Ribavirin

Case Scenario with eradication

- As compared with the base case scenario, scenarios 1 and 2 will have a limited impact on HCV disease burden, while scenarios 3 and 4
- will result in 45% - 49% decrease in the number of individuals living with HCV infection and 60% - 69% decrease in DC, HCC and liver disease deaths by 2030.
- For at least 90% reduction in HCV infections by 2030 (scenario 5), diagnosis and treatment rates should be increased to 12,000 and 9,000 individuals per year in 2016, respectively and to 24,000 and 18,000 individuals per year, respectively in 2018 onward

HCV Infection – Disease Progression (simplified)



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PLoS one

The Impact of Illicit Drug Use on Spontaneous Hepatitis C Clearance: Experience from a Large Cohort Population Study

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Abstract

Background and Aims: Acute hepatitis C infection usually ends in chronic infection, while in a minority of patients it is spontaneously cleared. The current population-based study is performed on a large cohort in Golestan province of Iran to examine the demographic correlates of Spontaneous Hepatitis C Clearance.

Methods: Serum samples used in this study had been stored in biorepository of Golestan Cohort Study. These samples were evaluated for anti hepatitis C Virus by third generation Enzyme-linked immunosorbent assay (ELISA). Subjects who tested positive were then invited and tested by Recombinant Immunoblot Assay (RIBA) and Ribonucleic Acid Polymerase Chain Reaction test (PCR). If tested positive for RIBA, subjects were recalled and the two tests were re-done after 6 months. Those subjects who again tested positive for RIBA but negative for PCR were marked as cases of spontaneous clearance.

Results: 49,338 serum samples were evaluated. The prevalence of Chronic Hepatitis C Virus (CHCV) infection based on PCR results was 0.31%. Among those who had acquired hepatitis C, the rate of SC was 38%. In multivariate analysis, illicit drug use both Injecting Use (OR = 3.271, 95% CI: 1.784–6.000, p-value$<$0.001) and Non-Injecting Use (OR = 1.901, 95% CI: 1.068–

Spontaneous Hepatitis C Clearance in Iran

- Among those who had acquired hepatitis C, in Golestan Iran the rate of SC was 38%.

- Illicit drug use whether intravenous or non-intravenous is the only significant correlate of Chronic HCV due to repeated contacts with hepatitis C antigen.

Utilizing an aggressive treatment and diagnosis strategy, there would be a 90% reduction in the total number of viremic individuals.

- **There would be 26 700 fewer viremic individuals in 2030, a 13% reduction as compared to the base case.**
- **The number of HCC cases in 2030 was estimated at 300 cases, a 7% decrease from the base case.**
- **The number of liver-related deaths would decrease by 7% from the base, with 400 deaths in 2030.**
- **Decompensated and compensated cirrhosis would decrease by 10% and 7% from the base, with 590 and 10 100 cases in 2030.**

Prevalence of risk factors in HCV positivity

	HCV negative	HCV positive	P-value
Blood Transfusion	8.6%	16.2%	0.004
Accident	7.3%	19.4%	<0.001
War Injury	1.8%	7.7%	<0.001
Imprisonment	8.3%	38.5%	<0.001
Body Piercing	57.3%	35.2%	<0.001
Illicite Drug Use	17.7%	62.8%	<0.001
IV Drug Use	4.4%	15.6%	0.019

Sovodak :Eradicate all genotypes of HCV covered by IR Insurance system

Thank you!

Questions?