

## BACKGROUND MEDIA INFORMATION

### Fast facts about liver disease

**Liver, or hepatic, disease comprises a wide range of complex conditions that affect the liver.**

- Liver diseases are extremely costly in terms of human suffering, doctor/hospital visits, and premature loss of productivity<sup>1</sup>
- Approximately 29 million people in the European (EU) region suffer from a chronic liver condition<sup>2</sup> and more than 30 million Americans have liver disease<sup>3</sup>
- The most common causes of liver disease worldwide are chronic Hepatitis B and C virus, alcohol, and non-alcoholic steatohepatitis associated with obesity and metabolic syndrome<sup>1</sup>

#### Cirrhosis

***Cirrhosis is the late, symptomatic stage of chronic liver disease which occurs when scar tissue (fibrosis) largely replaces healthy liver tissue, compromising the function of the organ and predisposing to liver cancer.***<sup>4</sup>

- Complications of cirrhosis are serious and include, among others, the accumulation of fluid in the abdominal cavity (ascites), jaundice, gastrointestinal bleeding (rupture of gastroesophageal varices), severe bacterial infections, and hepatic encephalopathy
- It is estimated that in 2013, liver cirrhosis resulted in 170,000 deaths in Europe<sup>1</sup>
- In 2010, liver cirrhosis, as a result of alcoholic liver disease (ALD), was responsible for 493,300 deaths (156,900 female and 336,400 male deaths) worldwide<sup>5</sup>
- The complications of cirrhosis are the leading cause of adult liver transplants in Europe with 67,208 carried out between 1988 and 2015<sup>6</sup>

#### Liver cancer

***Liver cancer is a frequent tumour that starts in the main types of liver cells. The most common primary liver cancer is hepatocellular carcinoma (HCC), which starts in the hepatocytes.***<sup>7</sup>

- Worldwide, liver cancer is the sixth most common cancer<sup>8</sup>
  - In 2012, 63,500 new cases of liver cancer were diagnosed in Europe<sup>8</sup>
- Liver cancer is the second most common cause of cancer death worldwide, preceded only by lung cancer. There were 788,000 deaths due to liver cancer in 2015<sup>9</sup>
- HCC is one of the most serious outcomes of cirrhosis and is responsible for 70 to 90% of cases of primary liver cancer<sup>2</sup>
- Non-alcoholic fatty liver disease (NAFLD) associated with HCC is rapidly increasing<sup>10</sup>

#### Viral Hepatitis

***Viral hepatitis is caused by viruses that infect and damage liver tissue. Some of these viral infections can become chronic and lead to cirrhosis. Viral hepatitis kills 1.4 million people worldwide each year.***<sup>11</sup>

#### Hepatitis A

***Hepatitis A is caused by the Hepatitis A virus. It is most commonly spread by eating food contaminated by the stools of an infected person and can result in mild to severe illness.***<sup>12</sup>

- Globally, there are an estimated 1.4 million cases of Hepatitis A every year<sup>13</sup>
- Hepatitis A infection does not cause chronic liver disease and is rarely fatal, but it can cause debilitating symptoms and acute liver failure, which is associated with high mortality<sup>12</sup>

## Hepatitis B

***Hepatitis B is transmitted through contact with infected blood or other bodily fluids, and can result in acute or chronic liver disease, ranging in severity from a mild condition lasting a few weeks to a serious, lifelong illness progressing to cirrhosis and HCC.<sup>14</sup>***

- Sexual contact is the most common way of transmitting Hepatitis B
- A highly effective vaccine against Hepatitis B virus is available and protects from transmission
- Approximately one third of the world's population has serological evidence of past or present infection with Hepatitis B<sup>15</sup>
- In the World Health Organization (WHO) EU region, it is estimated that 13.3 million people have chronic Hepatitis B<sup>16</sup>
- An estimated 240 million people worldwide have chronic Hepatitis B<sup>14</sup>
- More than 686,000 people die every year worldwide due to complications of Hepatitis B, including cirrhosis and liver cancer.<sup>14</sup> Hepatitis B results in an estimated 36,000 deaths each year in Europe<sup>16</sup>

## Hepatitis C

***Hepatitis C is transmitted through contact with infected blood or other bodily fluids, and can result in acute or chronic disease, ranging in severity from a mild condition lasting a few weeks to a serious, lifelong illness.<sup>17</sup>***

- Hepatitis C is found worldwide, through the most affected regions are Central and East Asia and North Africa<sup>17</sup>
- The number of people chronically infected with the Hepatitis C virus worldwide is estimated to be about 180 million, but most are unaware of their infection<sup>18</sup>
- Approximately 700,000 people die each year from Hepatitis C-related liver diseases<sup>17</sup>
- In the WHO EU region, it is estimated that 15 million people have Hepatitis C, resulting in approximately 86,000 deaths each year<sup>16</sup>
- No vaccine is available against the Hepatitis C virus

## Hepatitis D

***Hepatitis D is caused by the hepatitis delta virus, and is transmitted through contact with infected blood or other bodily fluids. This form of hepatitis only occurs in people who are also infected with Hepatitis B.<sup>19</sup>***

- Hepatitis D is present worldwide and current estimates suggest that 15 to 20 million people have been exposed to the hepatitis delta virus<sup>20</sup>
- Hepatitis D occurs more commonly in areas such as the Mediterranean, Middle East, Pakistan, Central and Northern Asia, Japan, Taiwan, Greenland, parts of Africa, the Amazon Basin and certain areas of the Pacific. Prevalence is low in North America, Northern Europe, South Africa and Eastern Asia<sup>19</sup>
- The majority of patients infected with the Hepatitis D virus have a progressive disease which over time eventually evolves into cirrhosis<sup>20</sup>

## Hepatitis E

***Hepatitis E is caused by the Hepatitis E virus and is mainly transmitted via contaminated water or raw swine meat.<sup>21</sup>***

- Hepatitis E is found worldwide, but the prevalence is highest in East and South Asia<sup>21</sup>
- It is usually self-limiting but (like Hepatitis A) it may develop into acute liver failure<sup>21</sup>
- Every year there are an estimated 20 million Hepatitis E infections, over three million symptomatic cases of Hepatitis E and 56,600 Hepatitis E-related deaths<sup>21</sup>

## Alcoholic liver disease (ALD)

**Alcoholic liver disease or alcohol-related liver disease is damage to the liver caused by excessive alcohol consumption, resulting in serious and life-threatening complications.**<sup>22</sup>

- Europe is the heaviest drinking region in the world in terms of the prevalence of alcohol consumption; therefore, ALD is an important issue for Europe to address<sup>23</sup>
- It is also the most common cause of cirrhosis in the West and in Europe, and one of the ten most common causes of death<sup>23,24</sup>

## Non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH)

**NAFLD is a condition in which fat builds up in the liver. It is often associated with obesity and diabetes. In some people NAFLD can progress to non-alcohol related steatohepatitis (NASH), a more aggressive form that can lead to cirrhosis, which can seriously impair the liver's ability to function, and to primary liver cancer.**<sup>25</sup>

- NAFLD is the most common liver disorder in Western countries<sup>26</sup>
- NAFLD affects approximately 20% of the population worldwide<sup>27</sup>
  - The prevalence in Western countries is estimated to be between 17 and 46% of the general population<sup>26</sup>
  - As many as 116 million people in the EU may suffer from some form of NAFLD<sup>1</sup>
  - Two large European studies reported prevalence rates between 46 and 70% in adults with type 2 diabetes<sup>2</sup>
- Between 10 and 30% of patients with NAFLD have NASH that can progress to cirrhosis<sup>28</sup>

## Autoimmune, cholestatic and drug-induced liver diseases

**Liver diseases that affect bile secretion are termed 'cholestatic' and they can be caused by drugs, genetic defects, developmental disorders and autoimmune damage of the bile ducts. Autoimmune liver diseases may also affect the liver cells (autoimmune hepatitis).**

### Autoimmune and cholestatic liver disease

- Autoimmune and cholestatic liver diseases are relatively rare compared with viral hepatitis and fatty liver disease, but are associated with a significant societal and economic burden<sup>1</sup>
- The diseases account for 10% of liver transplants performed in Europe over the last 20 years<sup>1</sup>
- Despite recent advances in understanding of the diseases and available treatments, there remain significant areas of unmet clinical need in each of the autoimmune liver diseases<sup>29</sup>

### Drug-induced liver disease

- Drug-induced liver injury is the most common cause of acute liver failure in Western countries<sup>30</sup>
- The incidence and seriousness of drug-induced hepatitis are largely underestimated in the general population<sup>31</sup>

## Liver transplant

**A liver transplant is a surgical procedure to remove a diseased liver and replace it with a healthy liver from a donor.**<sup>32</sup>

- It is estimated that over 26,000 liver transplants were conducted globally in 2014<sup>33</sup>
- More than 5,500 liver transplants are performed each year in Europe<sup>2</sup>
- In terms of survival post transplantation, more than 90% of people are alive after one year, around 80% live at least five years, and many people live for 20 years or more<sup>32</sup>

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