



## Review Article

## Legal requirements for optimal haemophilia treatment in Germany



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## ABSTRACT

The clinical benefits of early prophylaxis in the treatment of haemophilia have been unquestioned since publication of the results of the first randomized study. The question of whether or not prophylaxis is cost-effective remains to be proven. For European physicians treating haemophilia patients, and for German clinicians in particular, the law largely supports the use of prophylaxis in haemophilia, but many doctors are unaware of this. The aim of this review was therefore to describe the German legal framework and outline how it can be used to support appropriate clinical decision-making in the treatment of haemophilia and justify the use of prophylaxis to health insurers and third-party payers. The German Disability Equalisation Law and German Social Law Books V and IX outline legal requirements to prevent or ameliorate disability, and support the argument that all haemophilia patients, including adults, have the right to receive appropriate, adequate, and cost-effective treatment. “Appropriate” treatment means that it must be in accordance with state-of-the-art medical knowledge taking into account medical progress. “Adequate” treatment must be conducive to the goals of haemophilia management, which are to prevent bleeds, treat bleeding episodes, maintain and/or restore joint function, and integrate patients into a normal social life. This can only be achieved when long-term treatment is adequately dosed and regularly administered for as long as it is required. Thankfully, with the availability of virus-safe factor concentrates, the introduction of home treatment programmes, and the law on our side, we are in a very strong position to achieve these goals.

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## Introduction

The introduction of new management strategies over the last decades has led to significant improvements in the life expectancy and quality of life of people living with haemophilia. Historically, routine management

of haemophilia involved on-demand treatment, in which clotting factor concentrates are used to treat a bleeding episode or control bleeding during surgery. Prophylaxis, in which infusions are administered regularly to prevent bleeding episodes, has been introduced to improve the management of patients with severe haemophilia [1,2] with the aim of avoiding joint bleeding, thereby reducing, if not eliminating, progressive joint destruction.

Despite clear evidence for the long-term benefits of early prophylaxis [2–9], questions remain as to which patients should be

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treated prophylactically, when prophylaxis should begin, what dosing schedules should be used, and for how long treatment should continue. Recent evidence suggests that even sub-clinical bleeds may be associated with joint damage [8], raising the question as to whether children and adults with apparently milder phenotypes could benefit from prophylaxis, and whether our current prophylactic regimens are adequate.

The legal framework within Germany provides some assistance to clinicians wishing to initiate a prophylactic regimen for all haemophilia patients with severe or moderate haemophilia, including adults, legally entitled to receive adequate, appropriate, and cost-effective treatment. In this article, we outline how our clinical decision-making may be influenced by the national legal framework, which broadly supports the use of prophylaxis in the treatment of haemophilia. Interested readers are referred to other articles in this supplement reporting on the benefits of prophylaxis in paediatric (Kurnik et al.) and adult (Oldenburg and Brackmann) haemophilia patients.

### The German Social System – Historical Perspective

Germany has Europe's oldest national health insurance system, with origins dating back to Otto von Bismarck's social legislation, which included the Health Insurance Bill of 1883, the Accident Insurance Bill of 1884, the Old Age and Disability Insurance Bill of 1889, and the Pension Insurance Bill of 1891. Although originally applied only to low-income workers and some government employees [10], mandatory health insurance gradually expanded to cover virtually the entire population of Germany, and today, approximately 90% of the German population is covered by a basic health insurance plan provided by statute [11]. The remaining 10% select private health insurance. Today, the full picture of what was initiated by Bismarck is reflected by the Social Law Books [12].

### The German Disability Equalisation Law

The German Disability Equalisation Law came into effect in 1974 – a law that was supported by the Chancellor Willi Brandt – to ensure that all individuals receive consistent long-term treatment to prevent or remove the threat of disability and improve quality of care [13]. This law is particularly important for people with haemophilia and other bleeding disorders because **Paragraph 10** of the law states that: “The medical benefits for rehabilitation should comprise all types of support that are necessary to ensure that an imminent disability is prevented, to remove a disability, to improve a disability, or to prevent an aggravation, especially with regard to:

- (1) Medical and dental treatment
- (2) Medicinal products and dressings
- (3) Remedies including physiotherapy, exercise therapy, speech therapy, and occupational therapy
- (4) Equipment with body replacement parts, orthopaedic and other adjuvants, including necessary changes and repair, and the provision of replacement and education in the use of the devices
- (5) Testing of exposure and work therapy, including hospitals, cure establishments and special facilities as well as accommodation and catering.”

### The German Empire Health Act

Seven years after the adoption of the German Disability Equalisation Law, the Board of Enquiry and Remedies determined in 1981 that Paragraph 368e of the German Empire Health Act (Reichsversicherungsordnung) [14]: “The continuous substitution with factor VIII or factor IX, in cases of haemophilia A or haemophilia B, respectively, applies until the finalisation of growth and afterwards in the case of bleeds, operations, orthopaedic rehabilitation, as well as

extraordinary psychological challenges. The treatment of haemophilia patients with inhibitors using high doses of factor VIII or factor IX and the potential need for factor VIII inhibitor bypassing activity or other bypassing agents to treat bleeds in these patients is acknowledged.”

### The German Social Law Books

The Social Law Books are a 12-volume collection of books containing a summary of all social laws in Germany. The two books most relevant to the treatment of haemophilia are Social Law Book Volume V, which deals with statutory Health Insurance, and Social Law Book Volume IX, which covers the rehabilitation and integration of disabled individuals.

The Social Law Book V states in **Paragraph 1**: “The German health insurance system, as the local solidarity association, has the task to maintain, restore, and/or improve the health of the insured individuals. These individuals are responsible for their own health and for ensuring they lead a healthy lifestyle, including the early instigation of preventive measures and active participation during treatment and rehabilitation to prevent the onset of disease and disability and to overcome the consequences of such illness/disability. The health insurance companies must also provide support in education, consulting, and benefits, and how best to work towards and maintain healthy living conditions.”

The active participation of patients and their parents is critical to the successful treatment of haemophilia. Patients need to effectively self-manage their treatment while at home, ensure they attend regular hospital appointments, and optimize their joint health by staying active, avoiding risky sports or professions, and managing their weight.

#### *Social Law Book Volume V*

**Paragraph 11** of Social Law Book V states that insurants have the right to claim benefits:

- (1) For the prevention of diseases and their aggravation
- (2) For the early detection of diseases and for the treatment of disease
- (3) For medical rehabilitation as well as maintenance expense, support, or other additional benefits that are necessary to avert, remove, reduce, or balance disability or long-term care, to avoid their aggravation, or to reduce their consequences.

**Paragraph 23** of Social Law Book V deals with medical care services and states that insurants have the right to claim for medical treatment and the supply of medicines, bandages, and medical aids:

- (1) To correct weakened health, which, if not adequately treated, might result in disease in due course
- (2) To counteract the health hazards of a child's development
- (3) To prevent disease and/or to avoid their aggravation
- (4) To avoid the need for constant care.

**Paragraph 27** of Social Law Book V relates to medical treatment and states that insurants have the right to claim for treatment if it is necessary to detect disease, to heal, to prevent aggravation, or to reduce disease-related discomfort. The treatments covered include:

- (1) Medical treatment including psychotherapy
- (2) Dental treatment including supply with dental prostheses
- (3) Supply with medicinal products, bandages, remedies, or other supportive means
- (4) Home care and home help
- (5) Hospital treatment
- (6) Benefits for medical rehabilitation and complementary benefits.

#### *Social Law Book Volume IX*

Volume IX of the German Social Law Book relates to rehabilitation and integration of disabled individuals, with a special focus on preventing

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