

The change in factor VIII therapy in Germany - a follow-up retrospective data analysis from smart medication ScanDoc over five years

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Introduction

In July 2024 the new product class of high-sustained recombinant factor preparations (HSF) was introduced in Germany. Since then, HSF has displaced older product classes, particularly plasma derived (PD), standard half-life recombinant factor preparations (SHL) but also extended half-life recombinant factor VIII preparations (EHL), at a remarkable speed.

Starting in 9/2020 factor dispensing is documented in Germany in about 100 specialized hemophilia pharmacies with the smart medication ScanDoc software tool. The retrospective analysis of documentation shows the change over time in product classes in Germany. The aim of this ongoing study are to analyze the treatment changes in haemophilia A therapy in respect to the prescribed product classes and to identify trends and shifts between the product classes over time.

Method

With the introduction of the German “Act for more safety in the supply of medicines” (GSAV, Gesetz für mehr Sicherheit in der Arzneimittelversorgung) in 2019 with the elimination of the special distribution channel directly through hemophilia centers, factor preparations are provided to patients exclusively through pharmacies. The reporting obligation of the pharmacy to the prescribing physician regulated in in pharmacy operating regulations (ApBertrO) starting in 9/2020 has since been supported by the smart medication ScanDoc software tool and is used in about 100 pharmacies throughout Germany.

The present analysis covers a period of 5 years (9/2020 - 9/2025) with a total of more than 35.000 dispense records. In total 2772 distinct patients had been dispensed medicines for FVIII disorder treatment. In the analysis the number of distinct patients is reported. It has to be noted that patients who received different product classes within one year are counted in each product class. The analysis does include patients with on-demand as well as patients on prophylaxis therapy. Also patients with vWD could not be separated due to fact that diagnosis are not documented in the ScanDoc platform.

Results

Since 9/2020 the following changes of number of distinct patients could be observed (details see Fig.1):

- ❖ PD: decrease from 28% to 18% (- 10%)
- ❖ EHL: decrease from 22% to 20% (- 2%)
- ❖ SHL: decrease from 41% to 9% (- 32%)
- ❖ NF: increase from 8% to 21% (+ 13%)
- ❖ HSF: increase to 32% (+ 32%)

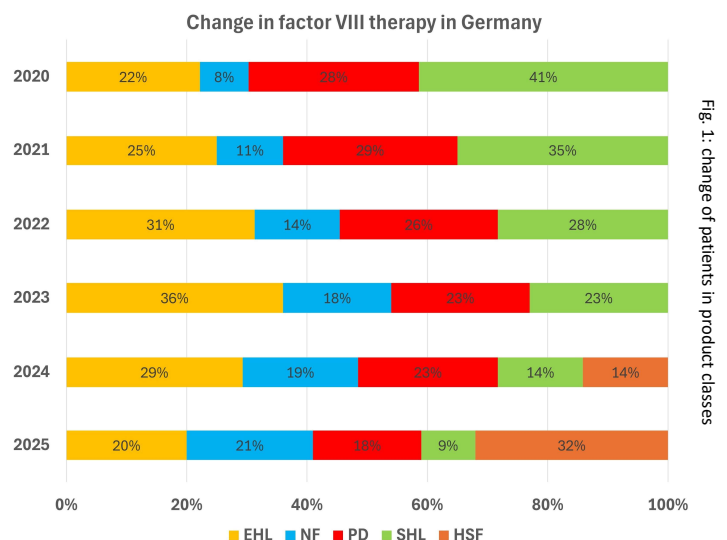


Fig. 1: change of patients in product classes

Conclusion

The retrospective data analysis shows that the modern therapy options (NF, HSF) have gradually replaced the previously established preparations (PD, SHL, EHL). Only NF, HSF show an increase of patients.

Patients using SHL declined by -32% and patients using PD by -10% over the observation period of five years. In contrast modern therapy options increased by +13% (NF) and +32% (HSF). Back in 2020 classical therapy options (PD, SHL, EHL) accounted for 91% of patients, while in 2025 modern therapy options (NF, HSF) already have already a share of 53% with a still increasing relevance.

