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### Background

- In Germany, there is no general vaccination registry collecting data on vaccine coverage of the populations at risk. Since the majority of vaccines (other than COVID-19 vaccines) are administered in the doctor's office, a major source of vaccination data are the electronic medical record systems used by general practitioners and specialists.
- The aims of FluVac were
  - to use an electronic tool that allows live extraction of data from medical records
  - to determine influenza (flu) vaccination rates among PLWH (people living with HIV) in Germany
  - and to compare them with data on the vaccination coverage in the German general population

### Methods

#### Study population

- All PLWH from 6 participating study sites attending the centres for routine clinical care during flu season 2018/19 and/or flu season 2019/20 (i.e., quarters Q3/2018 – Q1/2019 and Q3/2019 – Q1/2020, respectively)
- Inclusion criteria for electronic data extraction
  - ✓ Availability of specific billing data for statutory or private health insurances in the respective observation period
  - ✓ Documentation of at least one HIV-related ICD code (B20 – B24 or Z21) during the observation period or in the patient's medical history

#### Anonymized data extraction from electronic patient files

- Data were extracted from medical records applying a software solution (cvSentinel, Clinovate NET) with interfaces adapted to the site-specific electronic patient management systems with different settings and features used in doctor's offices (such as vaccine management tools or HIV documentation tools [based on the HIV/AIDS quality assurance agreement in Germany]).

#### Regulatory issues

- For reasons of data protection, the extracted data files were stored locally in a site-specific database and anonymized prior to data transfer and data merger, as consented to by the ethics committee (BLAEK, Bayerische Landesärztekammer, Munich).

#### Variables of interest

- Date of flu vaccination and name of the administered vaccine (predefined by brand names as approved by the Paul Ehrlich Institute in accordance with the recommendations of the WHO and the assessment by the CHMP (Committee for Medicinal Products for Human Use)).
- Year of birth, gender, CD4 cell count, year of HIV diagnosis
- All ICD-10-GM\* codes for both acute and long-term diagnoses documented in the electronic patient records during the year prior to and through the end of each flu season
- ICD-10-GM codes/diagnoses associated with an indication for flu vaccination (other than HIV infection) were based on the recommendations of the German Standing Committee on Vaccination (STIKO) (e.g. asthma; chronic obstructive pulmonary disease; diabetes mellitus; cardiovascular, liver or kidney diseases, chronic neurological diseases such as multiple sclerosis)<sup>1</sup>

\*German modification of the 10<sup>th</sup> edition of the International Classification of Diseases and Related Health Problems

#### Quality assurance

- Source data verification was performed by the sites using random samples from the extracted and stored files.

### Results

#### Characteristics of the study population

- In total, 11,740 anonymized patient records (from 6 centres) were extracted (flu season 2018/19: 6,451; flu season 2019/20: 5,289; range across centres and seasons: 312 – 2,246).
- Characteristics of the study population are depicted in Table 1.

**Table 1. Characteristics of the study population**

	Flu season <sup>a</sup> 2018/19	Flu season <sup>a</sup> 2019/20
<b>Total number of patients per flu season</b>	6,451	5,289
<b>Age [years]; median (IQR)</b>	48 (38 – 55)	48 (39 – 56)
<b>Age ≥60 years; n (%)</b>	864 (13)	770 (15)
<b>Female; n (%)</b>	1238 (19)	926 (18)
<b>Time since HIV diagnosis [years]; median (IQR)</b>	11 (6 – 19)	11 (5 – 19)
<b>CD4 count (pre-vaccination or in Q4<sup>b</sup>) [cells/μL]; median (IQR)</b>	688 (500 – 910)	688 (505 – 893)
<b>CD4 count &lt;200 cells/μL (pre-vaccination or in Q4<sup>b</sup>); n (%)</b>	181 (3)	135 (3)
<b>Potential clinical indication for flu vaccination<sup>c</sup>; n (%)</b>	4122 (64)	3589 (68)

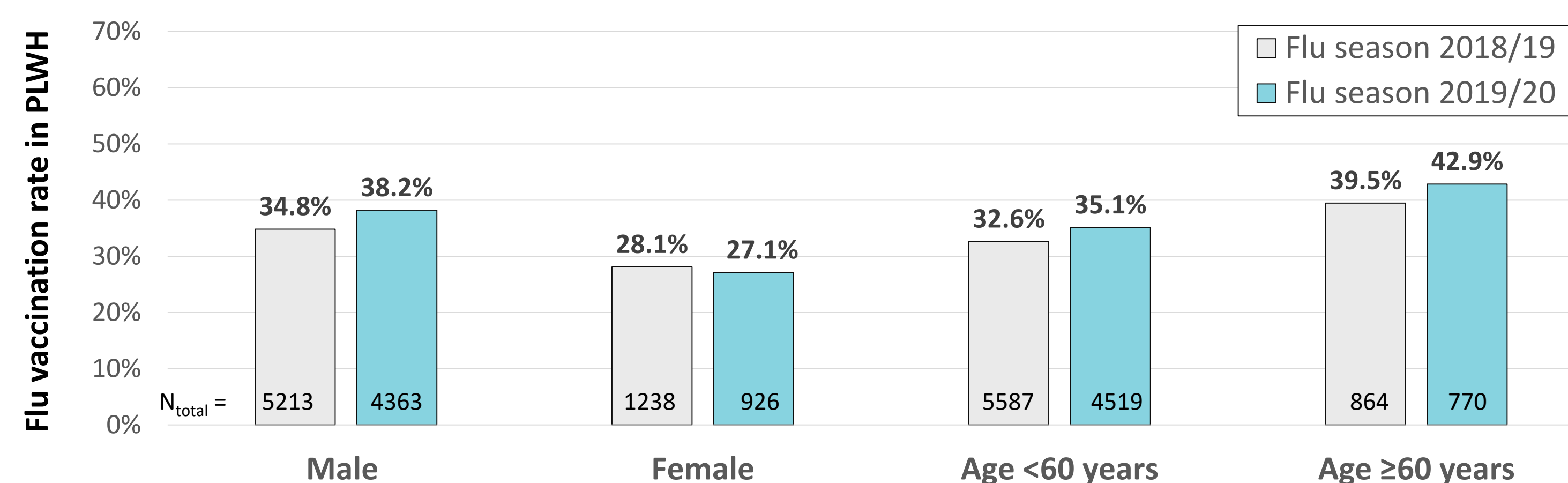
<sup>a</sup> between the 3<sup>rd</sup> quarter of a year and 1<sup>st</sup> quarter of the following year; <sup>b</sup> Q4, 4<sup>th</sup> quarter of the year; <sup>c</sup> based on ICD-10-GM codes associated with the STIKO recommendations<sup>1</sup>

#### Acknowledgement

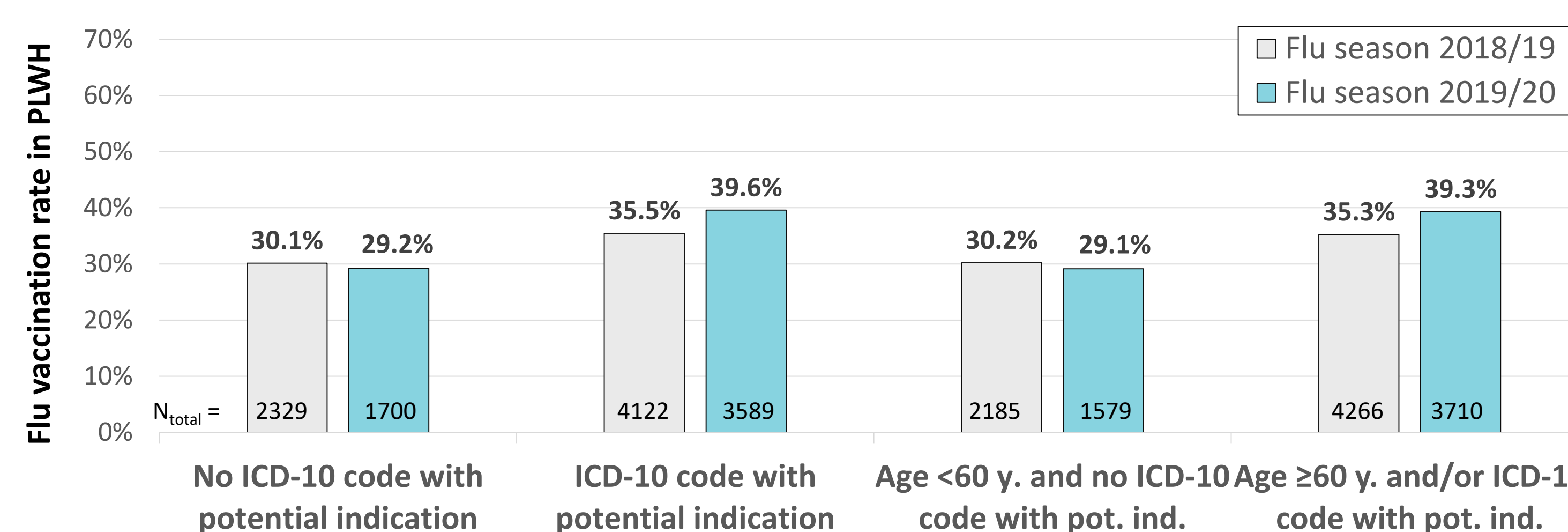
Financial support has been provided by Janssen-Cilag, Neuss, Germany. **Participating sites:** Practice Schwabstrasse 26, Stuttgart; MVZ München am Goetheplatz, Munich; prinzed, Munich; Practice Georgstrasse, Hannover; Private Practice Dr. Ines Ruck, Leipzig; MVZ Infektiologie Ärzteforum Seestrass, Berlin; all Germany. **Data management and statistics:** MUC Research, Munich, Germany. **Adaption of cvSentinel and data extraction:** Clinovate NET, Munich, Germany.

#### Flu vaccination rates in 2018/19 and 2019/20

- In 2018/19 (2019/20) flu vaccination was documented in 33.5% (36.3%) of PLWH (range across centres in 2018/19: 27.1% – 57.7%; 2019/20: 30.9% – 60.4%).
- Vaccination rates with respect to age, gender and clinical indication are shown in Figures 1a and 1b. Rates were slightly higher among men (vs. women; difference (Δ) 7 – 11 %-points), among PLWH aged 60+ (vs. younger; Δ 7 – 8 %-points) and among individuals with potential clinical indications (vs. without; Δ 5 – 10 %-points).

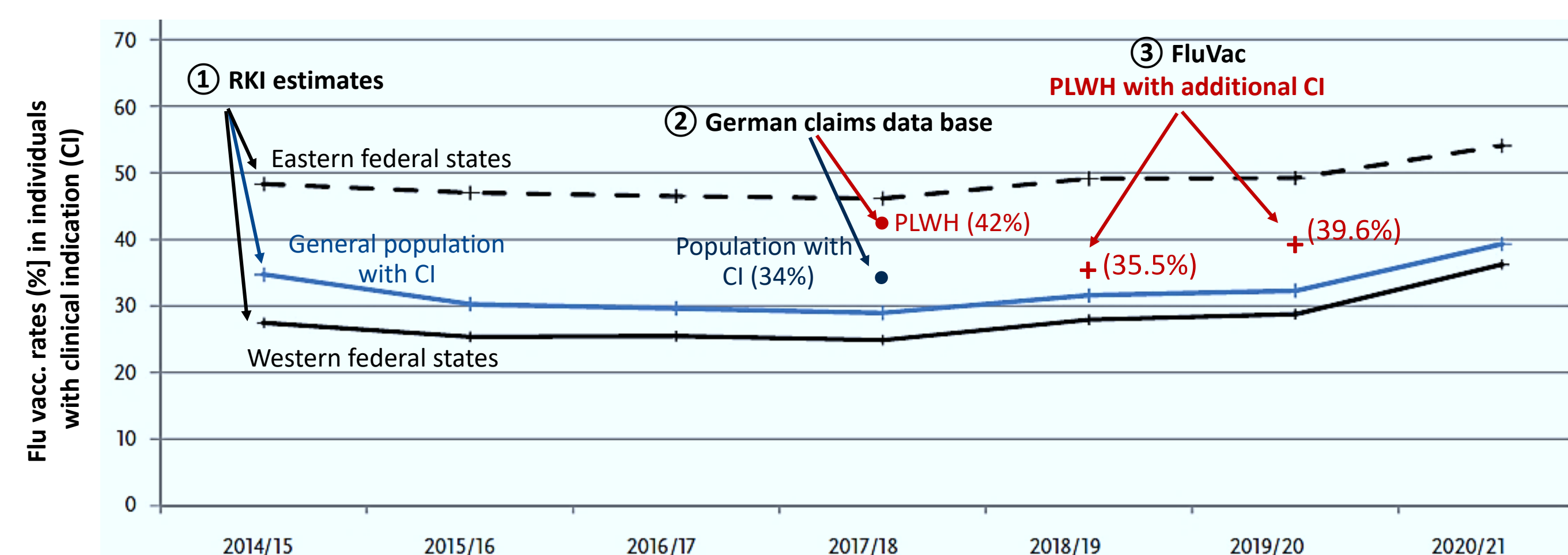


**Figure 1a: Flu vaccination rates in FluVac stratified by gender and age**



**Figure 1b: Flu vaccination rates in FluVac stratified by clinical indication for vaccination other than HIV infection (based on ICD-10 diagnoses corresponding to the STIKO recommendations)<sup>1</sup>**

#### Vaccination coverage when clinically indicated: PLWH compared to the German general population



**Figure 2: Flu vaccination coverage in populations with clinical indication (CI):** ① solid and dashed lines: estimates by the Robert Koch Institute for the adult general population with CI in the eastern [---] and western [—] federal states federal states of Germany and nationwide [—] according to the national vaccination surveillance system<sup>2</sup>; ② blue and red dots: rates according to statutory health insurance claims data for flu season 2017/18 in the general population with CI [•] and in PLWH [•]<sup>3</sup>; ③ red cross: PLWH with additional (potential) CI (other than HIV) in FluVac [•]<sup>4</sup>

#### Limitations

Missing vaccination data entries were classified as 'no vaccination' in this evaluation; however, 'no vaccination' might be a misclassification for a subset of PLWH vaccinated elsewhere, e.g. by a primary care physician (other than the HIV specialist) or company physician. In this case, vaccination status may be underreported by the HIV specialist leading to an underestimation of vaccination coverage.

### Conclusions

- In FluVac evaluating influenza vaccination in PLWH in Germany, the feasibility of using real-world data (RWD) extracted from routine electronic patient records has been demonstrated.
  - In the year prior to the SARS-CoV-2 pandemic, about one third of PLWH received flu vaccination.
  - For PLWH at increased risk for severe disease, i.e. individuals aged 60+ or with potential clinical indication other than HIV, vaccination rates were 5 to 10 %-points higher than in PLWH without additional criteria.
  - The overall flu vaccination coverage in PLWH with potential clinical indication (other than HIV infection) is comparable to the corresponding German general population with clinical indication; yet, in the general population there are marked differences between the eastern and western federal states.
- Prior to the SARS-CoV-2 pandemic, overall flu vaccination coverage in the key risk groups in Germany was still below the WHO and European Council target.<sup>4</sup>
- The development and use of interfaces to electronic health record systems are essential for generating real-world evidence.

#### References

<sup>1</sup>Robert Koch-Institut. Epidemiologisches Bulletin, 34/2020, 20.08.2020. <sup>2</sup>Robert Koch-Institut. Epidemiologisches Bulletin, 50/2021, 16.12.2021. <sup>3</sup>Akmatov MK, et al. Utilization of influenza vaccination among chronically ill individuals in Germany: A nationwide claims-based analysis. Vaccine 2021;39(6):952-960. <sup>4</sup>Council of the European Union. Council Recommendation of 22 December 2009 on seasonal influenza vaccination. Brussels; 2009.