### **Supplementary materials**

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# Supplementary material 1: Composition of research team and expert panel.

#### 1. Research team

NAME	COUNTRY/ORGANISATION	
1. Jef Vanhamel	Belgium (ITM Antwerp)	
2. Eline Wijstma	Belgium (ITM Antwerp)	
3. Jessika Deblonde	Belgium (Sciensano Brussels)	
4. Marie Laga	Belgium (ITM Antwerp)	
5. Bea Vuylsteke	Belgium (ITM Antwerp)	
6. Christiana Nöstlinger	Belgium (ITM Antwerp)	

#### 2. Expert panel

NAME	COUNTRY/ORGANISATION
1. Jessika Deblonde	Belgium
2. Josip Begovac	Croatia
3. Anna Kubátová	Czech Republic
4. Henrikki Brummer-Korvenkontio	Finland
5. Jean-Michel Molina	France
6. Jérémy Zeggagh	France
7. Uwe Koppe	Germany
8. Binod Mahanty	Germany

9.	Daniel Schmidt	Germany	
10.	Ioannis Mameletzis	Greece	
11.	Caroline Hurley	Ireland	
12.	Fiona Lyons	Ireland	
	Carole Devaux	Luxembourg	
14.	Valeska Padovese	Malta	
15.	Silke David	Netherlands	
16.	Elske Hoornenborg	Netherlands	
17.	Birgit Van Benthem	Netherlands/STI CC	
18.	Alma Cicic	Montenegro	
19.	Milena Stevanovikj	North Macedonia	
20.	Arild Johan Myrberg	Norway	
21.	Justyna Kowalska	Poland	
22.	Milosz Parczewski	Poland	
23.	Margarida Tavares	Portugal	
24.	Claudia Estcourt	Scotland	
25.	Janez Tomažič	Slovenia	
26.	Julia Del Amo	Spain	
27.	Asuncion Diaz	Spain	
28.	Pep Coll	Spain	
29.	Finn Filen	Sweden	
30.	Benjamin Hampel	Switzerland	
31.	Natalie Messerli	Switzerland	
32.	Matthias Reinacher	Switzerland	
33.	Olga Denisiuk	Ukraine	
34.	Ann Sullivan	EACS	
35.	Antons Mozalevskis	WHO Regional Office for Europe	
36.	Rosalind Coleman	UNAIDS	
37.	Raj Patel	IUSTI	
38.	Andrew Winter	IUSTI	
39.	Jürgen Rockstroh	EACS	
40.	Daniela Rojas Castro	Coalition Plus	
41.	Gus Cairns	EATG	
42.	Zoran Dominković	IZORAK	

### 3. Steering group

NAME	COUNTRY/ORGANISATION	
1. Jef Vanhamel	Belgium (ITM Antwerp)	
2. Eline Wijstma	Belgium (ITM Antwerp)	
3. Jessika Deblonde	Belgium (Sciensano Brussels)	
4. Marie Laga	Belgium (ITM Antwerp)	
5. Bea Vuylsteke	Belgium (ITM Antwerp)	
6. Christiana Nöstlinger	Belgium (ITM Antwerp)	
7. Teymur Noori	ECDC	
8. Claudia Estcourt	IUSTI	
9. Ann Sullivan	EACS	
10. Zoran Dominković	IZKORAK	
11. Uwe Koppe	Germany (RKI)	
12. Silke David	The Netherlands (RIVM)	

## **Supplementary material 2: Rapid online country survey.**

	1. UPDATE COUNTRY CASE STUDY*				
cou	This section aims to capture the latest updates regarding the status of PrEP implementation in your country. You will find the country case study that you submitted previously <u>here</u> , to assist you to fill in this section. If more options are possible, please tick all that apply.				
LICK	What is the current status of PrEP implementation in your country?				
	□National program with co-payments				
Α	□National program without co-payments				
	□Private prescription and online purchase				
	□Ongoing pilot or research project				
	□Other: please specify				
	Are there any major changes in the main service delivery approach for PrEP [i.e. type of provider and delivery setting of PrEP], compared to the country case study? If yes, please specify. If no, please proceed to section 2.				
	setting of Filer, compared to the country case study: If yes, please specify. If no, please proceed to section 2.				
В					

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In this section we will focus on available data on **people who initiate PrEP** (i.e. first-time PrEP users or 'PrEP starters') in your country.

How many people have started PrEP (i.e. have received PrEP for the first time in their lives) in the year 2019<sup>1</sup> in your country? Please specify how this number was produced.

If no estimate on national level can be provided, please provide any other (more peripheral) available data on PrEP starters and specify the source(s). If no data at all are available, please proceed to question C.

Α

Please specify for each level (i.e. national/regional, and facility-level), <u>all possible available data sources</u> that you are currently aware of and that could inform the number of PrEP starters in your country. If any (ongoing) research is available that could inform this number, please specify.

- Possible sources can include (but are not limited to): (sub-)national surveillance, clinical record data (i.e. patient data), pharmacy data (e.g. boxes of TDF/FTC sold), claims data (e.g. reimbursed prescriptions/consultations for PrEP), etc.
- (Sub-)national or regional level concerns the availability of data covering the entire country (or county/region for sub-national level), either through central data collection systems, or through the reporting of peripherally collected data (i.e. at facility-level) to a (sub-)national focal point.
- Facility-level concerns the availability of data at the specific facility or site where they are collected and/or registered (i.e. at pharmacy or at certain clinics).

B Level (national/regional, facility) and research data

1. National or regional (if applicable)

2. Facility level

3. Research data (or ongoing research projects) Please specify.

Data sources (e.g. surveillance, clinical records, pharmacy data, claims data, other?). Please specify.

3. Research data (or ongoing research projects) Please specify.

<sup>&</sup>lt;sup>1</sup> We request data on the year 2019 as data on the reporting year of 2020 might not be available yet in some settings and/or COVID-19 might have caused considerable disruptions in data collection/registration compared to regular reporting years. However, if only data outside the requested time span are available, then please provide these data and specify the reporting period.

	What are some of the main challenges you currently encounter with regard to monitoring the number of PrEP initiations in your country? [i.e. potential for over- versus under-reporting (accuracy), possibility that certain groups or regions are not included (coverage) etc.] Please explain briefly.				
С					
	you		ou explain br	nformation on PrEP starters is – to your knowledge – a riefly (e.g. data sources, national/regional and facility-lealable?	
	Cate	egory	Available?	Can you specify? (e.g. available data sources, facility vs. national/regional level etc.)	If available, estimate for 2019 <sup>1</sup> .
	Sex		□YES □NO □ Don't know		
	Age (group)		□YES □NO □ Don't know		
	Country of birth		□YES □NO □ Don't know		
D		MSM	□YES □NO □ Don't know		
	20	Transgender people □ YES □ NO □ Don't			
	KEY POPULATION	Sex workers	□YES □NO □ Don't know		
		People who inject drugs	□YES □NO □ Don't know		
		Prisoners	□YES □NO □ Don't know		

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	TIONAL DATA RELATED TO PrEP	
us on additional PrEP d	a (other than 'PrEP starters') currently available in yo	our country.
e, are any data on ti	following topics related to PrEP available in yo	our country? If yes,
or used and its data	ource, and provide an estimate if possible/ava	ilable.
Available?	Specify (e.g. indicator used + data source)	If available
		estimate for 2019 <sup>1</sup> .
ligible		2019
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□NO		
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know		
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know		
use? N/A		
1.4/.		
4. FUTURE P	RSPECTIVES FOR MONITORING PREP	
e, are there any (otl	r) potential data sources that are currently und	exploited/under-us
	the monitoring of PrEP in the future?	

 $\square {\tt YES}$ 

 $\square$ NO

 $\ \square \ Don't$ 

PrEP regimen (daily versus

event-driven)

	According to you, what are key priorities for improving the monitoring of PrEP in your country? (please list at least three in descending order of importance, i.e. number 1 being the most important one)
В	1.
	2.
	3.
	What are your expectations/wishes from this project? What kind of output/tool would add the most value
	to you at this stage of monitoring PrEP rollout in your country?
С	

#### 5. FINAL COMMENTS

Please share below any other information, comments and/or suggestions that could be relevant regarding the topic of monitoring PrEP (either for your country or at the EU/EEA level).

Α

# Supplementary material 3: list of candidate indicators and accompanying definitions, and a list of useful data sources for PrEP monitoring.

Indicator name	Description
1. PrEP service availability	The number of PrEP providers in a given area or per 100.000 population.
2. PrEP awareness	The number of people who report being aware of the existence of PrEP as an HIV prevention option, regardless of whether or not it is available to them.
3. Willingness to use PrEP	The number of people who report being willing to use PrEP if it were offered/available to them.
4. Discussed PrEP with provider	The proportion of PrEP-eligible people that discussed PrEP with a provider, e.g. requested or received information on PrEP.
5. PrEP eligibility	The number of people that are (estimated to be) eligible for PrEP, according to local PrEP eligibility criteria.

<sup>\*</sup> This survey was sent out to representatives of 16 different EU/EEA countries: Belgium, Croatia, Czech Republic, England, France, Germany, Ireland, Malta, The Netherlands, Norway, Poland, Scotland, Slovenia, Spain, Sweden and Switzerland. We received 11 completed questionnaires, from: Belgium, Croatia, England, France, Germany, Ireland, Malta, The Netherlands, Scotland and Spain.

6. Number of sexual health service attendees	The number of people that attended a sexual health service (SHS) in the reporting period (e.g. 12 months).
7. Current PrEP use	The number of people who used PrEP <b>at least once</b> during the reporting period (e.g. last 12 months).
8. New PrEP initiations	The number of people who initiated PrEP for the first time in their lives (i.e. who were previously naïve to the use of ARVs for the purpose of HIV prevention) during the reporting period (e.g. the last 12 months).
9. Profile of current PrEP users	The number of people who used PrEP <b>at least once</b> during the reporting period (e.g. last 12 months), disaggregated by some key characteristics of these users.
	Disaggregations: sex, age, key population (MSM, transgender persons, PWID, sex workers, prisoners), nationality, country of birth, socio-economic status, place of residence.
10. PrEP coverage	The number of people who used PrEP at least once during the reporting period (e.g. 12 months), divided by the size of the total PrEP-eligible population.
11. PrEP product use	The number of people who used PrEP at least once during the reporting period, stratified by specific PrEP product choice (i.e. oral TDF/FTC, oral TDF/3TC, oral TDF, or – in the future – injectable Cabotegravir or oral Islatavir).
12. PrEP dosing regimen	The proportion of people taking PrEP on a daily versus event-driven basis during the reporting period.
13. PrEP-to-need ratio	The number of people who used PrEP at least once during the reporting period in a given area (e.g. 12 months), divided by the number of new HIV diagnoses during the reporting period (e.g. 12 months).
14. Adherence	The proportion of PrEP users with sufficient or good adherence to the chosen PrEP dosing regimen (i.e. who take pills as directed to have protective drug levels in the blood during condomless intercourse).
15. PrEP continuation	The proportion of people who initiated PrEP and continued taking PrEP until a certain time point.
16. PrEP discontinuation	The number of people who are reported to have stopped PrEP OR who did not return for a follow-up visit during the reporting period (and who still received PrEP in the previous reporting period).
17. Retention in care	The number of HIV tests performed among all PrEP users during the reporting period (e.g. 12 months), divided by the number of HIV tests expected to have been performed among all PrEP users during the reporting period (e.g. 12 months).
18. HIV seroconversions among PrEP users	The number of new HIV diagnoses among people prescribed PrEP at least once during the reporting period and who had at least one follow-up HIV test.
19. PrEP safety	The number and type of (serious) adverse events that occur among PrEP users during the reporting period and are related to PrEP use.
20. STI diagnoses	The number of new diagnoses of chlamydia, gonorrhoea and syphilis among PrEP users during the reporting period.
21. ARV resistance	The proportion of blood specimens from PrEP users or people with a history of PrEP use and diagnosed with HIV that were tested and which show genetic mutations associated with (ineffective) PrEP use.

Table 1. List of useful data sources for monitoring programmatic PrEP indicators, as identified in this scoping review and rapid country survey.

Data source	PrEP indicators that can be constructed using this data source	Reported Benefits	Reported Challenges	Comments
Pharmacy prescription database	Number of PrEP users; Number of PrEP initiations (if UICs available);	Algorithms applied to the specified databases can identify TDF/FTC prescriptions for PrEP with high	1) Databases not exhaustive (e.g., unavailability of data from prescriptions through closed health systems)	Provides estimates on prescriptions written
Pharmacy dispensation database	PrEP continuation (if UICs available); PrEP adherence as the proportion of days covered by a prescription (if UICs available);	sensitivity and high specificity (after excluding indications for HIV infection, HBV infection or TDF/FTC for PEP)	2) Possible lack of insight into the proportion of missing data or whether missingness is differential	Provides estimates on prescriptions filled
Medical claims database	Number of PrEP users; Number of PrEP initiations (if UICs available); PrEP continuation (if UICs available); Retention in PrEP services (i.e. through HIV testing as proxy measure); HIV infection (e.g., through HIV testing followed by ART prescription) PrEP adherence as the proportion of days covered by a prescription (if UICs available);	Readily available data     Population-level data	3) Limited sociodemographic data (e.g., on sex, age and place of residence, but not KP)	Provides estimates on prescriptions filled
PrEP facility/clinic registries	PrEP need (i.e. proportion of clinic attendants who report behaviour consistent with PrEP-eligibility) Number of PrEP initiations; Number of PrEP users; Sociodemographic data (including KP) Dosing regimen; PrEP adherence, as self-reported or as the proportion of days covered by a prescription; Continuation; Discontinuation and reasons; Retention in PrEP services; New STI diagnoses	Not approximations, but records.     Data can be kept at the client-level	1) Incomplete data if administrative burden on facility staff is high	Using standardized service codes facilitates aggregation of local data for national estimates

National HIV surveillance	New HIV diagnoses among total population;	1) Population-level data	1) Limited sociodemographic characteristics	/
	New HIV diagnoses among PrEP users (if data can be linked to PrEP databases)		2) Unique identifier codes are needed to link HIV diagnoses to PrEP use.	
	Proxy for PrEP need (i.e. denominator for PrEP-to-need ratio)			
Repeated surveys	PrEP awareness; Willingness to use PrEP; PrEP need (i.e. proportion of respondents who report behaviour consistent with PrEP	Survey questions are adaptable to local contexts      Behaviour, knowledge and	Surveys likely comprise convenience samples, and results may consequently not be generalizable to the total population	To date, large-scale behavioural surveys to monitor PrEP have focused on MSM.
	eligibility); Estimates of PrEP use prevalence (among respondents); Trends in the profile of PrEP users	attitudes cannot be not captured by other data sources	2) Self-reported outcomes are susceptible to information bias, including recall bias and social desirability bias	Different sampling methods (e.g., venue-based or internet-based) may yield characteristically different population samples.
	(although surveys likely target only 1 KP); Estimates of dosing regimen; Estimates of adherence; Estimates of continuation; Estimates of discontinuation and reasons; Changes in behaviour after PrEP initiation; Trends in STI diagnoses;		3) Financial and human resources are required to disseminate, (administer), and analyze surveys	Generally, internet-based surveys are more timely and lower cost than in-person surveys and have a broader geographic scope.

#### Supplementary material 4: methodological details of the Delphi process.

#### 1. The Delphi technique

In order to facilitate the process of ultimately finding the most reliable consensus on indicators suitable to include in a practical monitoring tool for PrEP programmes in the EU/EEA, we used a modified Delphi method as an overall guiding approach<sup>2</sup>. The Delphi technique has been characterized as "a method for structuring a group communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with a complex problem". Key advantages of using the technique are (1) the ability to build consensus in areas where scientific evidence is insufficient and/or conflicting, (2) the possibility to involve a wide range of experts from many countries at distance, with their indirect interaction being mediated by the study team, and (3) the ability to 'level-out' the influence of relatively dominant voices when using regular discussion groups. The modified Delphi method applied in this project existed of two phases, and combined a comprehensive review of existing evidence on the topic of PrEP monitoring (phase 1) with the collective judgement of a multidisciplinary expert panel (phase 2).

To this extent, an international expert panel was established with support of ECDC, consisting of 42 members. This panel included people from different backgrounds (clinical, research, and community), yet all with practice-based experience with the implementation and/or monitoring of PrEP or related programmes, and representing different EU/EEA Member States (see supplementary material 1 for the full list of experts). This expert panel committed to participating to the entire consensus-building process.

#### 2. Consensus-building process

The data collection phase consisted of two online survey rounds, with an online meeting of the expert panel in-between survey rounds. Data collection took place between September and November 2021. We used Formsite as online survey platform, and Webex as online videoconference tool. The first Delphi survey was conducted in September 2021 and consisted of the 21 candidate indicators identified through the evidence review phase. Expert panelists were asked to rate the perceived importance and feasibility of implementing the candidate indicators in their respective contexts on a 7-point Likert scale (1=not important or not feasible at all; 7=very important or very feasible). Experts were asked to base their ratings on the accompanying evidence summary tables (see Table 1 and Table 2), combined with their personal opinion and experience. Participating experts had the opportunity to provide additional qualitative comments for each indicator, to clarify their ratings or to express particular concerns they might have had. A link to the online survey can be found here.

In total, 30 out of 42 invited experts completed the first online survey. For each candidate indicator, we calculated the experts' median rating for importance and feasibility, and the percentage of experts rating on either extremes of the scale (i.e. 6-7 as top rating, and 1-3 as bottom rating).

Based on the ratings of the experts, the research team categorized the candidate indicators into their likelihood of being included in a future monitoring tool. The following algorithm was used to distinguish between indicators that could be (1) included without further discussion, (2) for which inclusion was uncertain, or (3) indicators that would be eligible for exclusion due to poor ratings of importance and feasibility:

<sup>&</sup>lt;sup>2</sup> McCorry NK, O'Connor S, Leemans K, et al. Quality indicators for Palliative Day Services: A modified Delphi study. *Palliative Medicine*. 2019;33(2):197-205. doi:10.1177/0269216318810601.

<sup>&</sup>lt;sup>3</sup> Chitu Okoli, Suzanne D. Pawlowski. The Delphi method as a research tool: an example, design considerations and applications. Information & Management. 2004; 42 (1): 15-29. doi.org/10.1016/j.im.2003.11.002.

- INCLUDE WITH NO DISCUSSION: Median importance rating of 6-7 with NO DISAGREEMENT
  - Disagreement = 25% or more experts rated 1-3 on importance scale OR expressed substantial reservations in the qualitative comments
- UNCERTAIN: Median importance rating of 3-5 (regardless of agreement) OR median importance rating of 6-7 WITH DISAGREEMENT
  - Disagreement = 25% or more experts rated 1-3 on importance scale OR expressed substantial reservations in qualitative comments
- EXCLUDE: median importance rating of 1-2 (regardless of agreement) OR indicators from uncertain category that remain unresolved after discussion

The online meeting with the expert panel was held on 9 November 2021. The aim of the meeting was to:

- 1. Agree to include those indicators in the monitoring tool that have a high median score of importance (6-7) with no disagreement.
- 2. Agree to discard indicators deemed of insufficient importance (median importance score of 1-2).
- 3. Discuss the appropriateness of including those indicators in the monitoring tool that fall under the 'uncertainty' category.
- 4. Discuss which indicators could be part of a minimum common 'core set' of indicators to be collected and reported across the EU/EEA.

After plenary discussion, during which indicators were refined to make them more accurate and adapted to the EU context, attending panellists were asked to vote for final inclusion or exclusion of the (refined) indicator in the monitoring tool, distinguishing between inclusion in a common 'core set' to be reported across EU/EEA MSs and relevant indicators to adapt on a country-level basis. The cut-off to include indicators in the final tool was set as follows:

- INCLUDE: if 75% or more of panellists voted for either inclusion or inclusion of a modified indicator (and provided suggestions for modification).
- EXCLUDE: if >25% of panellists votes for exclusion of indicator.

See supplementary material 4 for a synthesis of expert panellists' ratings.

Pending issues were resolved in a steering group consisting of the research team, the ECDC coordinator and 5 expert panellists (see Supplementary Material 1). These panellists were selected based on their particular expertise with designing programmatic PrEP monitoring indicators (i.e. one expert led a previous publication on the topic), the status of PrEP implementation and monitoring in the country (including both representation from countries more advanced in PrEP monitoring as well as "starters"), and representation from different professional backgrounds (clinical, public health

surveillance, and civil society) in addition to those of the research team (epidemiological, social sciences and M&E).

## Supplementary material 5: synthesis of the expert panel's ratings for both Delphi survey rounds.

Indicator name	Description	Number of panellists who rated the <i>importance</i> of monitoring the specified indicator as 1 to 7, during the <u>first</u> Delphi survey  1=not at all important; 7=extremely	Percentage of panellists who voted to include or exclude the specified indicator in a monitoring tool, during the <a href="mailto:second">second</a> Delphi survey (after plenary discussion)  (N of participating panellists = 31)				
		important Median score is indicated by the red bar  (N of participating panellists = 30)	As supplementary indicator  (= implementation up to individual EU/EEA MSs)	As core indicator  (= to be collected systematically by all EU/EEA MSs)			
1. Current PrEP use	The number of people who used PrEP at least once during the reporting period (e.g. last 12 months)	20 15 10 5 0 1 2 3 4 5 6 7	N/A	Include as defined 82.6 % Include modified 17.4 % indicator Exclude 0.0 % Outcome: retained as core indicator.			
2. New PrEP initiations	The number of people who initiated PrEP for the first time in their lives (i.e., who were previously naïve to the use of ARVs for the purpose of HIV prevention) during the reporting period (e.g. the last 12 months).	20 15 10 5 0 1 2 3 4 5 6 7	N/A	Include as defined 87.5 % Include modified 8.3 % indicator Exclude 4.2 % Outcome: retained as core indicator.			

3. PrEP product use	The number of people who used PrEP at least once during the reporting period, stratified by specific PrEP product choice (i.e. oral TDF/FTC, oral TDF/3TC, oral TDF, or – in the future – injectable Cabotegravir or oral Islatavir).	20 15 10 5 0 1 2 3 4 5 6 7	Include as defined 52.0 % Include modified* 20.0 % indicator Exclude 28.0 % *Only if relevant in the specific context (i.e., if multiple PrEP products are available)  Outcome: excluded as separate indicator; PrEP product added as relevant disaggregator for PrEP use (i.e. PrEP use by product).	N/A
4. PrEP dosing regimen	The proportion of people taking PrEP on a daily versus event-driven basis during the reporting period.	20 15 10 5 0 1 2 3 4 5 6 7	Include as defined 37.0 % Include modified* 33.3 % indicator Exclude 29.6 %  *The proportion of people taking PrEP on a daily versus non-daily basis during the reporting period.  Outcome: excluded as separate indicator; dosing regimen added as relevant disaggregator for PrEP use at start (i.e. chosen PrEP dosing regimen at initiation).	N/A
5. Number of sexual health service attendees	The number of people that attended a sexual health service (SHS) in the reporting period (e.g. 12 months)	20 15 10 5 0 1 2 3 4 5 6 7	Outcome: Excluded as separate in Delphi session 2 – specified proxy unsuitable in many (non-UK) cont	for PrEP need perceived to be

6. PrEP coverage	The number of people who used PrEP at least once during the reporting period (e.g. 12 months), divided by the size of the total PrEP-eligible population.	20	Include as defined 22.7 % Include modified* 9.1 % indicator Exclude 68.2 %
		0 1 2 3 4 5 6 7	*For the denominator: define 'PrEP-eligibility' according to local criteria; monitor PrEP coverage only if it is expected that valid estimates of the population in need of PrEP can be made  Outcome: retained as supplementary indicator given context-dependent challenges defining denominator (i.e. eligible population).
7. PrEP-to-need ratio	The number of people who used PrEP at least once during the reporting period in a given area (e.g. 12 months), divided by the number of new HIV diagnoses during the reporting period (e.g. 12 months).	20 15 10 5 0 1 2 3 4 5 6 7	Include as defined 45.5 % Include modified* 45.5 % indicator Exclude 9.1 %  *Advise to estimate the PrEP-to-need ratio across the EU/EEA in research first; If outcomes are meaningful and helpful, reconsider incorporating this indicator in routine monitoring.  Outcome: retained as alternative supplementary indicator for PrEP coverage

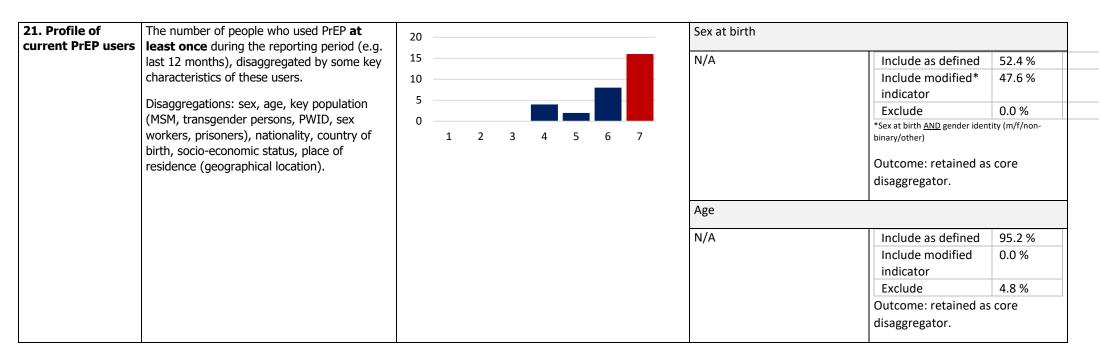
8. Adherence	The proportion of PrEP users with sufficient or good adherence to the chosen PrEP dosing regimen (i.e. who take pills as directed to have protective drug levels in the blood during condomless intercourse).	20 15 10 5 0	1	2	3	4	5	6	7	Include as defined Include modified indicator Exclude  Outcome: excluded a indicator as panel pe more as a clinical mo indicator (not progra	rceived it nitoring	Include as defined Include modified indicator Exclude	9.5 % 4.8 % 85.7 %
9. PrEP continuation	The proportion of people who initiated PrEP and continued taking PrEP until a certain time point.	20 15 10 5	1	2	3	4	5	6	7	Include as defined Include modified* indicator Exclude *Align continuation indicator of follow-up guidelines Outcome: retained as supplementary indicator	5	Include as defined Include modified* indicator Exclude	19.0 % 14.3 % 66.7 %
10. PrEP discontinuation	The number of people who are reported to have stopped PrEP OR who did not return for a follow-up visit during the reporting period (and who still received PrEP in the previous reporting period).	20 15 10 5 0	1	2	3	4	5	6	7	Include as defined Include modified* indicator Exclude *Disaggregated by whether ar lost-to-follow-up, and/or the r discontinuation. Outcome: excluded a indicator; merged wit continuation" indicat	eason for PrEP s separate th "PrEP	Include as defined Include modified indicator Exclude	40.9 % 0.0 % 59.1 %

11. Retention in care	The number of HIV tests performed among all PrEP users during the reporting period (e.g. 12 months), divided by the number of HIV tests expected to have been performed among all PrEP users during the reporting period (e.g. 12 months).	20 15 10 5 0 1 2 3 4 5 6 7	Include as defined 34.8 % Include modified* 26.1 % indicator Exclude 39.1 %  *Preference to base retention on follow-up visit attendance, rather than HIV testing adherence  Outcome: excluded as separate indicator due to lack of accuracy and relevance.	Include as defined 35.0 % Include modified* 10.0 % indicator Exclude 55.0 %  *Preference to base retention on follow-up visit attendance, rather than HIV testing adherence
12. New HIV diagnoses among PrEP users	The number of new HIV diagnoses among people prescribed PrEP at least once during the reporting period and who had at least one follow-up HIV test.	30	N/A	Include as defined 54.2 % Include modified* 41.7 % indicator Exclude 4.2 %  *New HIV diagnoses among people who ever used PrEP, disaggregated whether or not the individual recently used PrEP (i.e., in the last 12 months)  Outcome: refined indicator retained as core indicator.
13. STI diagnoses	The number of new diagnoses of chlamydia, gonorrhoea and syphilis among PrEP users during the reporting period.	20 15 10 5 0 1 2 3 4 5 6 7	N/A	Include as defined 59.1 % Include modified* 22.7 % indicator Exclude 18.2 % *Number of PrEP users newly diagnosed with chlamydia, gonorrhoea, syphilis or Hepatitis C during the reporting period.  Outcome: excluded as separate indicator due to outside scope of PrEP monitoring tool as such;

14. PrEP safety	The number and type of (serious) adverse events that occur among PrEP users during the reporting period and are related to PrEP use.	20 — 15 — 10 — 5 — 0	1	2	3	4	5	6	7	D		-	suggestion included to integrate PrEP monitoring with STI monitoring systems.  dicator; not discussed during general pharmacovigilance
15. ARV resistance	The proportion of blood specimens from PrEP users or people with a history of PrEP use and diagnosed with HIV that were tested and which show genetic mutations associated with (ineffective) PrEP use.	15 —	1	2	3	4	5	6	7			-	ndicator; not discussed during general HIV monitoring
16. PrEP service availability	The number of PrEP providers in a given area or per 100.000 population.	20 — 15 — 10 — 5 — 0 •	1	2	3	4	5	6	7	0	Include as defined Include modified indicator Exclude Outcome: indicator re		N/A

17. PrEP awareness Via surveys - research	The number of people who report being aware of the existence of PrEP as an HIV prevention option, regardless of whether or not it is available to them.	20 15 10 5 0	1	2	3	4	5	6	7	Include as defined Include modified indicator Exclude  Outcome: indicator is optional indicator give routine surveillance for special surveys).	ven outside	N/A
18. Willingness to use PrEP Via surveys - research	The number of people who report being willing to use PrEP if it were offered/available to them.		1				5	6	7	Include as defined Include modified indicator Exclude  Outcome: indicator in optional indicator give routine surveillance for special surveys).	ven outside (e.g. need	N/A
19. Discussed PrEP with provider Via surveys – research (or facility data)	The proportion of PrEP-eligible people that discussed PrEP with a provider, e.g. requested or received information on PrEP.	20 15 10 5 0	1	2	3	4	5	6	7	Include as defined Include modified indicator Exclude  Outcome: excluded a indicator due to lack relevance and feasib	of	N/A

The number of people that are (estimated to be) eligible for PrEP, according to local PrEP eligibility criteria.	1 2 3 4 5 6 7	Include as defined 15.8 % Include modified* 52.6 % indicator Exclude 31.6 % *Devise a (nationally relevant) algorithm or proxy to predict the size of the PrEP-eligible population based on data of – among other possible predictors- STI incidence and HIV incidence.  Outcome: excluded as separate indicator; integrated in denominator of "PrEP coverage" indicator.	
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		Belonging to the KP of MSM			
		N/A	Include as defined	85.7 %	
			Include modified indicator	9.5%	
			Exclude	4.8 %	
Profile of current PrEP users,			Outcome: retained as disaggregator.	s core	
continued		Belonging to the KP of transge	nder people (TGP)		
		N/A	Include as defined	38.1 %	
			Include modified* indicator	52.4 %	
			Exclude	9.5 %	
			*do not 'collect' separately, bu sex at birth and gender identit transgender men and transger	y; disaggregate by	
			Outcome: exclude as	separate	
			indicator; derive from	n combining	
			disaggregators "gender" and "sex at birth"		
		Belonging to the KP of people			
		N/A	Include as defined	66.7 %	
		,	Include modified* indicator	23.8 %	
			Exclude	9.5 %	
			*use of any drug (including ch		
			Outcome: retain as su disaggregator.	upplementar	
		Belonging to the KP of sex wor	kers (SW)		

		N/A		Include as defined	45.0 %
		11/7			
				Include modified*	30.0 %
				indicator	
				Exclude	25.0 %
				*report PrEP use among male separately	MSW and FSW
				Outcome: retain as su	upplement
				disaggragator.	
		Belonging to the KP o	f prisoners	3	
		Include as defined	42.3 %	N/A	
		Include modified*	0.0 %		
		indicator			
		Exclude	57.7 %		
		Outcome: retained as			
		supplementary disagg			
		oapp.c	5. 00		
		Country of birth (as ir	ndicator fo	r migration status)	
		Include as defined	96.3 %	Include as defined	95.2 %
		Include modified*	0.0 %	Include modified*	0.0 %
		indicator		indicator	
		Exclude	3.7 %	Exclude	4.8 %
				Outcome: retained as	
				disaggregator.	
		Nationality		1	
	h	Include as defined	22.2 %	N/A	
		Include modified*	7.4 %		
		indicator	,		
		Exclude	70.4 %		
		Outcome: retained as			
		Ourcome: retained as	•		
		supplementary disagg			

(in case country of birth no available).	t
available).	
Place of residence (geogra	hical location)
	0% N/A
Include modified* 14.	3%
indicator	
Exclude 22.	. %
Outcome: retained as	
supplementary disaggrega	or.
Socioeconomic status (SES	
Include as defined 12.	% N/A
Include modified* 67.	' %
indicator	
Exclude 19.	%
*Replace SES with 'highest completed	
education'	
Outcome: excluded as	
	_
separate indicator; no sing	
best SES disaggregator, to	oe
judged in context which SI	5
indicator is most relevant	0
report.	