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0 SUMMARY

Drug-related deaths

According to the German Federal Criminal Police Office (Bundeskriminalamt, BKA), in 2017 1,272 people died as a result of the use of illicit drugs. This represented a decrease in the number of drug-related deaths for the first time in five years. It was a decrease of 4.6 % against the previous year; however the figure remains higher than 2015. 84.6 % of the drug deaths were male, the average age was 39 years old. Opioid poisoning (mono or poly drug) continues to be the most frequent cause of death, accounting for a proportion of over 55 %. However, the share has fallen in recent years. There is no current data from the general mortality register.

Drug-related, non-fatal emergencies

In 2016, there were 23,589 cases of drug-related intoxication and poisoning in Germany, which were treated on an inpatient basis. The number sharply increased over a ten-year period up to 2015 (2006: 12,249 admissions) and has now remained relatively stable for one year. Whether this indicates a longer term stabilisation is currently unclear. Toxicological indications from admissions must be interpreted cautiously due to large inaccuracies in coding.

In the area of inpatient admissions, poisoning through "other opioids" predominates, however the numbers have been decreasing since 2011. The next largest group is cannabinoids (however with significantly lower total numbers). In the acute intoxications group, the most commonly coded diagnosis, by some margin, is intoxication through multiple substance use or the use of other psychotropic substances. The numbers for these types of inpatient admissions case have steeply increased over the past ten years and account for a large part of the total increase in all drug-related emergencies admitted to in-patient hospital treatment in the last decade. The cannabinoid category of substances (incl. synthetic cannabinoids), sedatives / hypnotics, stimulants (excl. cocaine) and opioids account for between 2,000 and 3,000 cases with considerable, similarly sized proportions. The proportion of cannabinoids is tending to rise, while that of sedatives / hypnotics is tending to decrease.

Drug-related infectious diseases

There is no HIV reporting data for 2017.

The Robert Koch-Institut (RKI) reports 3,622 HBV infections for 2017. Information on the mode of transmission was only stated in 163 cases, and of those injecting drug use represented the third most commonly stated mode of transmission (23 %).

For 2017, a total of 4,798 cases of newly diagnosed hepatitis C were reported to the RKI. Evaluable indications as to the probable mode of transmission were made in 1,129 (24 %) of the newly diagnosed cases. Injecting drug use, which has a high probability of being causally related to a diagnosis of hepatitis C, was once again the most common mode of transmission and was reported for 879 newly diagnosed cases (78 %). The value has been around 80 %

since 2012, with some fluctuations. This mode of transmission accounted for 82 % of the entries for men (n=711/872) and 65 % of those for women (n=165/253). The more detailed specification of "injecting drug use in prison" was recorded for 47 of the males (5.4 %) and 5 of the females (2.0 %) for whom "injecting drug use" was recorded. The number of reported newly diagnosed cases for which injecting drug use was recorded has decreased in comparison to the previous three years. One reason for this could be that according to the old case definition infections that had already been cured were often recorded as well whereas they do not meet the new case definition. It is also possible that drug users were indeed regularly screened for HCV antibodies, however potentially a secondary diagnosis was not always carried out in addition.

Harm reduction interventions

Measures for harm reduction constitute one of the four levels of the National Strategy on Drug and Addiction Policy. Since 2016, the BIS 2030 strategy of the German Federal Government has also been available, which has the objective of substantially reducing HIV, hepatitis B and C as well as other sexually transmitted infections by 2030. Injecting drug users are explicitly named as one of the specific target groups of this strategy.

Additionally, recommendations on the basis of the DRUCK study demonstrate ways in which infectious diseases can be treated among drug users. The evaluation of the Berlin drug consumption rooms has also revealed indications as to how the provision of such rooms might be improved.

Health aspects of drug use are addressed both in the scope of specific services offered to drug users as well as within the framework of general healthcare. There is no uniform financing. The costs of most facilities are borne by the municipalities, however there is also some financing from the Federal Government and the *Laender*. The availability of harm reduction measures varies greatly in Germany. Overall, it is better in cities and heavily populated regions than in rural areas. Provision in prisons is clearly in need of improvement (see Workbook Prison).

In order to counteract opioid overdoses, emergency training is offered in several cities on the use of the emergency medicine naloxone by laypeople. The target groups are drug users and people in their environment. The availability to date is very limited; currently there are programmes in Berlin, several cities in North Rhine-Westphalia, Munich and, since December 2017 in Saarbrücken. In Bavaria, a *Land* funded pilot project is being planned which is intended to start in five cities at the end of 2018.

Drug consumption rooms continue to play a crucial role in harm reduction among injecting drug users. To date, 22 fixed sites and two mobile drug use facilities are available across 6 *Laender*. One other *Land* is in the process of adopting an ordinance to enable the operation of drug consumption rooms; specific plans for the opening are currently being drawn up in one city in that *Land*. There are still no drug consumption rooms in nine *Laender*. Saarland is the second *Land* after North Rhine-Westphalia (NRW) to open its drug consumption rooms for substituting clients.

Syringe provision programmes currently exist in the form of 172 syringe vending machines in 9 *Laender*, as well as the provision of loose syringes in numerous projects nationally. Safer-use services in prisons continue to lag far behind what is possible, however: only one of the 180 prisons in Germany has a syringe vending machine.

The chances of curing hepatitis C among drug users have significantly improved due to the introduction of new medicines onto the market which improve the chances of recovery whilst having a more favourable side-effect profile. The effectiveness of medicinal drugs for drug users is again confirmed by a study. Chances of recovery were about 85 %. In addition, there are findings that the expected explosion in costs on the basis of high prices of new medicinal drugs did not occur; it remains unclear however how many drug users are able to benefit from these new therapy options because of the difficulties to identify affected individuals.

1 NATIONAL PROFILE

1.1 Drug-related deaths

1.1.1 Drug-related deaths: Overdose deaths

In Germany, there are two general, comprehensive systems for recording cases of drug-related deaths, which differ from one another in various aspects. These are the police data from the "Drugs data file" (Falldatei Rauschgift) and the "Statistical report on the causes of death" (Todesursachenstatistik) from the German Federal Statistical Office. Both data collection systems are described in more detail in section 5.2.1 and only briefly characterised here:

The data collected by the BKA, the so called "Drugs data file" shows long-term secondary diseases, suicides and accidents that have come to the attention of the police. Since the data year 2012, the BKA has used a new table in which the individual causes of death can be better differentiated and overlaps can be better identified in many cases.

The "Statistical report on the causes of death", the general mortality register (Allgemeine Sterberegister) of the German Federal Statistical Office are used for comparisons with other European countries as this register largely follows common European standards. Data from the police register is of great significance for long-term comparisons of national trends and provides important information as to categories of substances involved in overdoses. However, it is less suitable for Europe-wide comparisons due to differences in selection criteria and reported age groups.

Neither of the two methods used records all drug-related deaths. In each method, a certain number of relevant cases is not recognised, is unreported or is wrongly assigned. However, a long-term comparison of the two registers reveals similar developments and trends (whereby the trends in the systems are of different strengths, see section 1.1.4), which can be seen as a sort of cross-validation of the two estimation methods. An empirical analysis of the question as to the extent to which the two systems record the same cases and how far the target groups overlap has not as yet been performed.

Current police data on drug-related deaths

The reliability of information on drug-related deaths strongly depends on whether autopsies and toxicological reports have been utilised to validate the initial estimate of whether a particular death is drug-related. The autopsy rate for all drug-related deaths in the Drugs Data File (Falldatei Rauschgift, FDR) of the BKA in the reporting year 2017 was 59.0 % (2016: 57.7 %) (Bundeskriminalamt, 2018a; Bundeskriminalamt, 2018b).

In 2017 there was a decrease in the number of drug-related deaths for the first time in five years. A total of 1,272 people died as a result of using illicit drugs (2016: 1,333, 2015: 1,226), which corresponds to a reduction of approximately 4.6 %; however the number remains higher than 2015. 84.6 % of the drug deaths were males, the average age was 39 years old.

In terms of the number of inhabitants, the relatively small *Land* of Saarland was – apart from the city states of Berlin, Hamburg and Bremen – the most impacted, as it was in the previous year (2.7 drug deaths per 100,000 inhabitants), followed by Bavaria, the *Land* with the second largest population (2.4 drug deaths per 100,000 inhabitants; 24 % of all drug deaths in Germany). 16 % of drug deaths were in the *Land* with the largest population, North Rhine-Westphalia (1.1 drug deaths per 100,000 inhabitants). The city state of Berlin was again the most affected major city in 2017, with a respective figure of 4.7, followed by Cologne (4.6), Nuremberg (3.7), Frankfurt (3.6), Mannheim (3.3) and Munich (3.0) (Bundeskriminalamt, 2018b). When interpreting these numbers, it must be taken into account that the autopsy rate of the individual *Laender* can sometimes vary widely making comparisons between *Laender* more difficult.

Current data from the general mortality register

No data is available for 2016 due to a delay in data delivery to the general mortality register. The 2015 data can be found in last year's workbook (Dammer et al., 2017).

Comparison of the data from the general mortality register with the police data

In 2015, the general mortality register included more cases overall than the parallel BKA register; the difference between the two in the data year 2015 was 80 cases. A more up to date comparison is not possible due to the fact that no data has been provided. Both registers do exhibit similar trends over recent years (which are described in more detail in section 1.1.4), even though the reference populations and case definitions for the two registers are not identical. One problematic factor which persists is that the exact number of overdoses in the Register on the causes of death produced by the Federal Statistical Office is not stated, as it remains the situation that too few cases are specifically coded with respect to the acute cause of death and a multicausal code has not yet become established nationwide. Thus, despite the changes of the WHO coding rules which took effect in 2006, the national mortality register is still seen as less meaningful in respect of the analysis of the substance classes which acutely led to deaths in the case of intoxications than the categorisation of the causes of death (as revised in 2012) in the BKA figures.

1.1.2 Toxicology of overdose deaths

Police data on drug-related deaths

Overdosing on heroin / morphine (including poisoning by heroin / morphine in conjunction with other substances) was recorded for 409 cases (2016: 511), thus remaining the most common cause of death (32 %). This proportion is, however, 13 per cent lower than two years previously (2016: 38 %; 2015 and 2014: 45 %). The proportion of drug-related deaths in which substitution drugs were detected, alone or in combination with other drugs as main substance, was at 17 %, the same as the previous year (218 cases). Poisoning through substances other than opiates, especially through cocaine / crack and amphetamine /

methamphetamine was the cause of death in 18 % of cases (see Table 1) (Bundeskriminalamt, 2018b).

It is possible that the numbers of mixed intoxications ("poly drug poisonings") could be underestimated in the representation of substance involvement due to a lack of precise toxicological information.

Table 1 Drug-related deaths 2017 by substance

Causes of death	% of Total		No.
	2016	2017	2017
Monodrug poisoning from opioids	20.8	20.8	264
Heroin / Morphine	14.4	13.0	165
Opiate-substitution drugs	3.2	2.5	32
– of which: Methadone / Polamidone	2.8	2.4	30
– of which: Buprenorphine (i.a. subutex)	0.3	0.2	2
– of which: Other	0.1	0	0
Opiate-based medicines	2.9	3.4	43
– of which: Fentanyl	2.6	3.3	42
Synthetic opioids (i.a. fentanyl derivatives)	0.3	1.9	24
poly drug poisonings from opioids¹	38.4	34.8	443
Heroin/morphine in connection with other substances (i.c.w.o.s.)	23.9	19.2	244
Opiate-substitution drugs i.c.w.o.s.	14.2	14.6	186
– of which: Methadone / Polamidone i.c.w.o.s.	11.2	11.6	147
– of which: Buprenorphine (i.a. Subutex) i.c.w.o.s.	1.6	1.7	22
– of which: Other i.c.w.o.s.	2.0	2.6	33
Opiate-based medicines	5.9	6.6	84
– of which: Fentanyl	4.5	5.3	68
Synthetic opioids (i.a. fentanyl derivatives) i.c.w.o.s.	1.4	1.8	23
Monodrug poisonings from substances other than opioids / opiates	7.5	7.3	93
Cocaine / Crack	2.4	3.2	41
Amphetamine / Methamphetamine	2.0	2.4	30
– of which: Amphetamine	1.6	1.8	23
– of which: Methamphetamine	0.5	0.6	7

Amphetamine derivatives	0.2	0.3	4
New Psychoactive Substances (NPS)	2.6	0.7	9
Other (not. incl. psychoactive medicinal drugs)	0.3	0.7	9
poly drug poisonings from substances other than opioids / opiates¹	11.6	11.1	141
Cocaine / Crack i.c.w.o.s.	2.9	3.6	46
Amphetamine / Methamphetamine i.c.w.o.s.	5.7	6.3	80
– of which: Amphetamine i.c.w.o.s.	5.1	5.3	68
– of which: Methamphetamine i.c.w.o.s.	1.5	1.7	21
Amphetamine derivatives i.c.w.o.s.	1.2	1.3	16
New Psychoactive Substances (NPS) i.c.w.o.s.	3.1	1.5	19
Psychoactive medicinal drugs i.c.w.o.s.	2.6	1.9	24
Other i.c.w.o.s.	1.7	1.7	22
Other causes of death			
Intoxications from psychoactive medical substances only (where applicable, in connection with alcohol)	1.4	1.5	19
Not specified / unknown poisonings	2.6	3.6	46
Suicides	6.5	6.7	85
– of which: Suicide by way of intoxication (already included in the causes mentioned above)	3.2	2.0	26
– of which: Suicide through means other than intoxication	3.2	4.6	59
Long-term harms:	11.6	14.0	178
– of which: Long-term harms in combination with intoxication consequences	5.7	2.7	34
Accidents	2.5	1.6	20
Other cases	0.6	0.7	9
Total (N)²	1,333		1,272

(Bundeskriminalamt, 2018b)

¹ In the subcategories, multiple counting is possible.

² The total number is formed from the sum of all monodrug and poly drug poisonings plus all suicides not caused by intoxications as well as all long-term impacts, accidents and other cases.

Data from the general mortality register

There is no data for 2016. Evaluations of trends in the coded causes of death can be found in section 1.1.4.

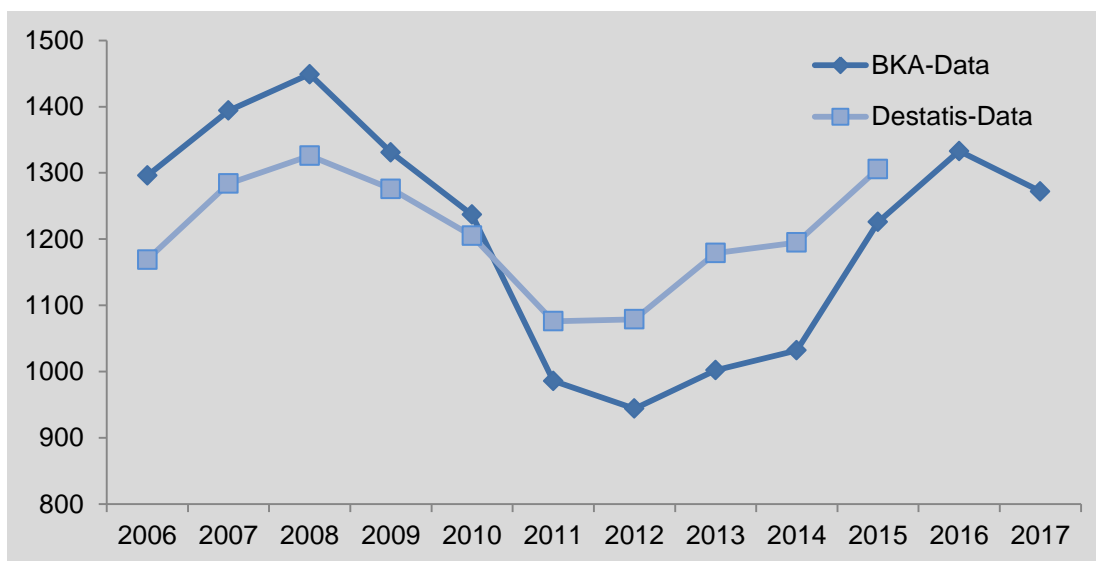
1.1.3 Mortality cohort studies

There is no overview available on mortality in the overall population of drug users, nor are there any known current regional cohort studies.

1.1.4 Trends

The long term trend in the total numbers of drug-related deaths in Germany has been very similar for both registration systems between 2006 and 2015. Between 2008 and 2012, the number of drug-related deaths fell significantly in both systems; since 2012, however, the numbers have been increasing again. It is noticeable that the trends of the most recent comparable years are somewhat steeper in the police data than in the data of the general mortality register (see Figure 1). In 2017, the numbers in the BKA data fell slightly for the first time; whether this trend will be confirmed in the coming years and whether it will also be reflected in this form in the Destatis data remains to be seen.

As no current data is available from the general mortality register, no trends will be reported (the trends from the previous year can be found in the previous year's workbook).



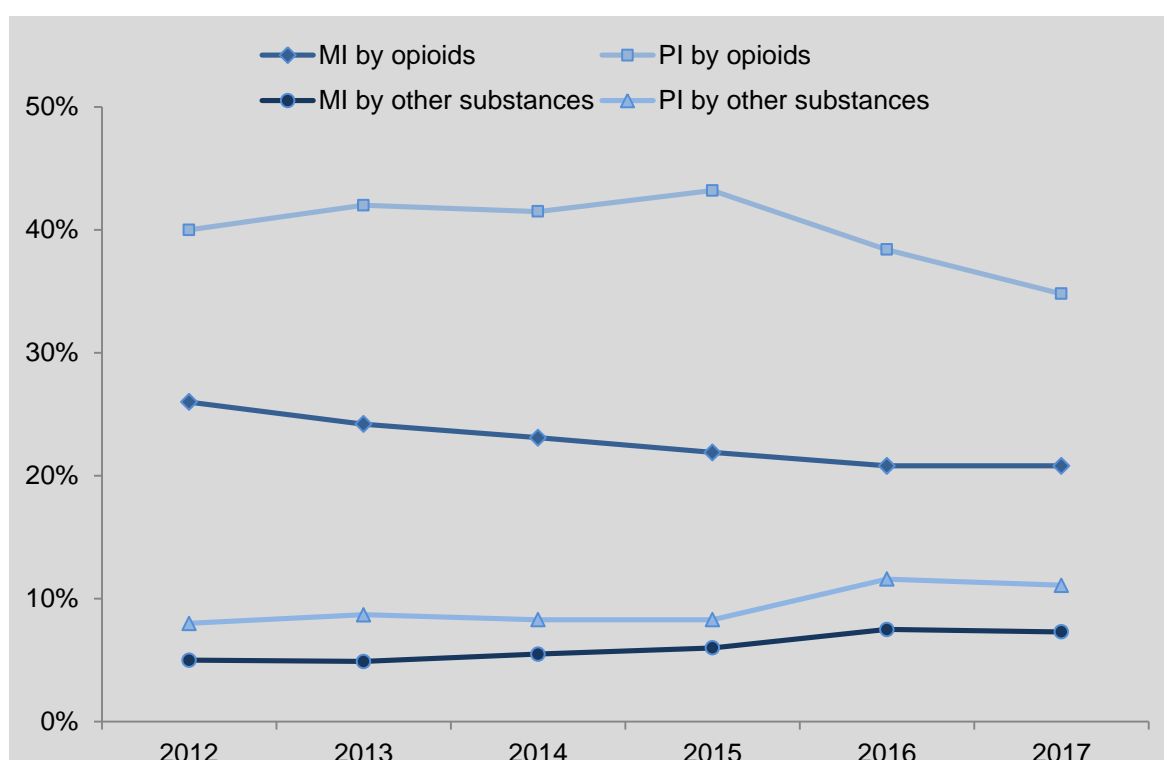
(Statistisches Bundesamt, 2018; BKA, 2018)

Figure 1 Trends in the number of drug-related deaths: Comparison of BKA and Destatis data, 2006 to 2017

Police data on drug-related deaths

Drawing comparisons between previous years is only possible under reservations, as the data recording system of the BKA was changed in 2012. For that reason the trend since 2012 is shown in Figure 2. Poisonings from opioids are the main causes of death in that register also. Unlike in the general mortality register, a distinction is drawn between monodrug and poly drug poisonings (see Figure 2). The proportion of monodrug opioid poisonings continuously fell from 2012 to 2016, from 26.0 % to 20.8 %, and has stagnated at

this level in 2017. Polydrug opioid poisonings remain the most common cause of death, however at 34.8 % it represents a smaller proportion than in previous years. Monodrug as well as poly drug poisonings from other substances have remained stable between 2012 and 2015 at 5 - 6 % and 8 - 9 % respectively; for 2016 they increased to around 7 % and around 11 % respectively. In 2017 the number has stabilised at this slightly higher level. The proportion of long-term harm (not shown in the Figure) rose for the first time; between 2012 and 2016 it was between 9 % and 11 % with slight fluctuations, in 2017 it rose to 14 % for the first time.



(BKA, 2018)

MD = monodrug poisoning, PD = poly drug poisoning

Figure 2 Causes of death, BKA data 2012 – 2017

1.1.5 Additional information on drug-related deaths

In a study by the IFT Munich funded by the German Federal Ministry of Health (Bundesminister für Gesundheit, BMG) the data from the FDR for the years 2012 to 2016 were more closely analysed (Kraus et al., 2018). Unlike the annual BKA reporting, the "free text entries" made by the police were also analysed. These contain, as well as the substances concerned (the analysis of which does not significantly differ from already reported data, as the basis for the data is, while not exactly the same, very similar) the circumstances surrounding the drug-related death, i.e. whether third parties were present, if resuscitation attempts were made, if there had been any crises prior to the drug death, whether previous comorbidities were known of or if social contacts existed.

Knowledge of substitution was present in around 10 % of deaths involving a drug overdose. In addition, in around 7 - 15 % of overdose cases third parties were present, in 20 % of cases attempts had been made to resuscitate, with the proportion increasing over time, and for around 6 % there was knowledge of a reduced tolerance inferred from situations such as the ending of drug therapy or release from prison immediately before the overdose. There was at least one mention of the presence of third parties or of resuscitation attempts in about 17 % of opioid overdoses. Indications of comorbid disorders were present in 11 - 13 % of drug-related deaths, with hepatitis being the most frequent, present in an average of a quarter of cases (predominantly hepatitis C). This rate is, however, significantly below the rate determined for example in the DRUCK study of injecting drug users (average prevalence of potentially infectious hepatitis C 44 %, chronic hepatitis C 66 % (RKI, 2016)). One can assume that there is a significant under-representation of the presence of comorbid disorders in the FDR, as these are not the focus of police investigations. On average, lung disease, heart disease or liver cirrhosis was present in over 10 % of cases with comorbid disorders. A psychological disorder was recorded in 21 % of cases with comorbid disorders; this number also appears to be very low in comparison to comorbid psychological disorders for drug users in Germany usually stated in the literature (Marschall, 2010; Wittchen et al., 2011). Presumably, one can also assume in this case that this information represents an underestimation due to the objectives of the FDR. As far as deaths as a consequence of long term drug use, the proportion of comorbid disorders was the highest and the people who dies had also reached the highest age relatively speaking. Crises prior to death were reported between 2 % and 5 % of drug-related deaths over time.

The main limitation of the study is the sometimes high number of blank entries. For example, it is impossible to distinguish whether a person who died actually had no physical disorders or whether this was not documented (for instance because the police themselves were not aware or categorised it as irrelevant). In addition, there are large differences in the documentation of individual *Laender*. Accordingly, the authors conclude that the further development and standardisation of the documentation on the use situation and the circumstances of death in individual *Laender* are recommended, as well as generally carrying out autopsies and in particular the creation of toxicological reports. Only in this way could developments and changes to the attendant circumstances be observed over time on a sound basis, including the substances used by the deceased person, and statements made about known risk factors.

1.2 Drug-related acute emergencies

1.2.1 Drug-related acute emergencies

As an approximation of the number of drug related, non-fatal emergencies, there is nationwide data available on acute intoxications (ICD-10 diagnoses F1x.0) and poisonings (ICD-10-diagnoses T40.X) treated on an inpatient basis in hospitals from the Statistical Report on Hospital Diagnoses 2016 (Krankenhausdiagnosestatistik) as well as the special reports of the German Federal Statistical Office (see Table 2). It should be noted that the

cases of poisoning (ICD-10 T40.X) can include both overdoses as well as mistaken administration or ingestion of the wrong substances. Moreover, cases of opioid poisoning, for example, could be caused by (accidental or intentional) overdoses of prescribed medications containing opioids and not by the consumption of illicit drugs. In addition, this data only allows conclusions to be drawn in respect of drug-related, non-fatal emergencies admitted to hospital on an inpatient basis. Emergency cases, which are not treated at all or are treated by other facilities (poison information centres, see section 1.2.2, but also by practice-based doctors, emergency medical treatment with no subsequent inpatient treatment), are not covered here. Further, it is not clear from the data how seriously pronounced or dangerous the symptoms were and how long the respective treatment lasted; very short term cases are also included. The data should therefore only be interpreted with caution.

A further approximation of the number of drug-related emergencies can be taken from the data of the Poison Information and Poison Control Centres (Giftinformationszentrale, Giftnotrufzentrale, GIZ). That data provides information about emergencies that did not lead to hospital admission and will be presented below (see section 1.2.2).

1.2.2 Toxicology of drug-related acute emergencies

Table 2 Number of acute intoxication and poisoning cases, Statistical Report on Hospital Diagnoses, 2016

ICD-10 Diagnosis	Total	Age in years				
		<15	15 - 24	25 - 45	45 - 65	65+
Acute intoxication [acute inebriation] (F11.0 to F16.0, F18.0, F19.0)	21,934	397	6,432	10,660	3,623	822
from opioids (F11.0)	2,086	11	204	1,186	456	229
from cannabinoids (F12.0)	2,623	169	1,535	791	118	10
from sedatives / hypnotics (F13.0)	2,347	32	368	893	681	373
from cocaine (F14.0)	599	5	129	396	67	2
from other stimulants (F15.0)	2,121	50	911	1,043	109	8
from hallucinogens (F16.0)	491	17	266	186	21	1
from volatile substances (F18.0)	58	4	13	32	7	2
from multiple substance use or use of other psychotropic substances (F19.0)	11,609	109	3,006	6,133	2,164	197
Poisoning by narcotic drug and psychodysleptics (hallucinogens) (T40.X)	1,655	75	319	503	326	432
from opium (T40.0)	83	2	3	13	32	33

from heroin (T40.1)	126	1	8	89	28	0
from other opioids (T40.2)	836	34	67	158	198	379
from methadone (T40.3)	66	0	4	39	22	1
from other synthetic narcotics (T40.4)	30	2	7	12	4	5
from cocaine (T40.5)	101	5	25	60	11	0
from other and non-specified narcotics (T40.6)	44	4	7	12	10	11
from cannabis (derivatives) (T40.7)	284	23	159	88	12	2
from lysergide (LSD) (T40.8)	27	0	17	9	1	0
from other and non-specified psychodysleptics (T40.9)	58	4	22	23	8	1

(Statistisches Bundesamt, special calculations)

From the data of the GIZ:

Data is available from four of the eight poison information centres¹ on the documented enquiries on the basis of acute poisoning cases in connection with drugs (not including medicinal drugs, which are recorded separately) from 2016 (Abteilung für klinische Toxikologie & Giftnotruf München der Klinik und Poliklinik für Innere Medizin II, 2017; Gif tinformationszentrum-Nord (GIZ-Nord), 2017b; Informations- und Behandlungszentrum für Vergiftungen Homburg/Saar, 2017; Informationszentrale gegen Vergiftungen des Landes Nordrhein-Westfalen, 2017).

In these four institutions, a total of 103,432 enquiries on the basis of suspected cases of human poisoning were registered in 2016, of which 2,236 were due to actual or suspected consumption of illicit drugs. The proportion of drug cases is thus 2.16 % and remains, as in previous years, stable at a low level. From this information, however, one cannot ascertain whether the overdoses were as a result of unintended consumption or wilful drug use. Some of the poison information centres also classify cases by substance, as well as by other variables such as age, in their documentation systems.

The GIZ Nord² documented a total of 33,986 cases of suspected human poisonings in 2016, of which 2.3 % (N = 768) concerned enquiries related to the main group, illicit drugs. No cases of death were documented. 64 of the suspected cases were classified as severe poisoning (8.3 %), 281 (36.6 %) came under the medium level of severity, 183 (23.8 %) were classed as slight poisoning. 29 suspected cases (3.8 %) were asymptomatic. In 205

¹ <https://www.klinitox.de/3.0.html> [Accessed: 28 Aug. 2018].

² Responsible for enquiries from Bremen, Hamburg, Lower Saxony and Schleswig-Holstein.

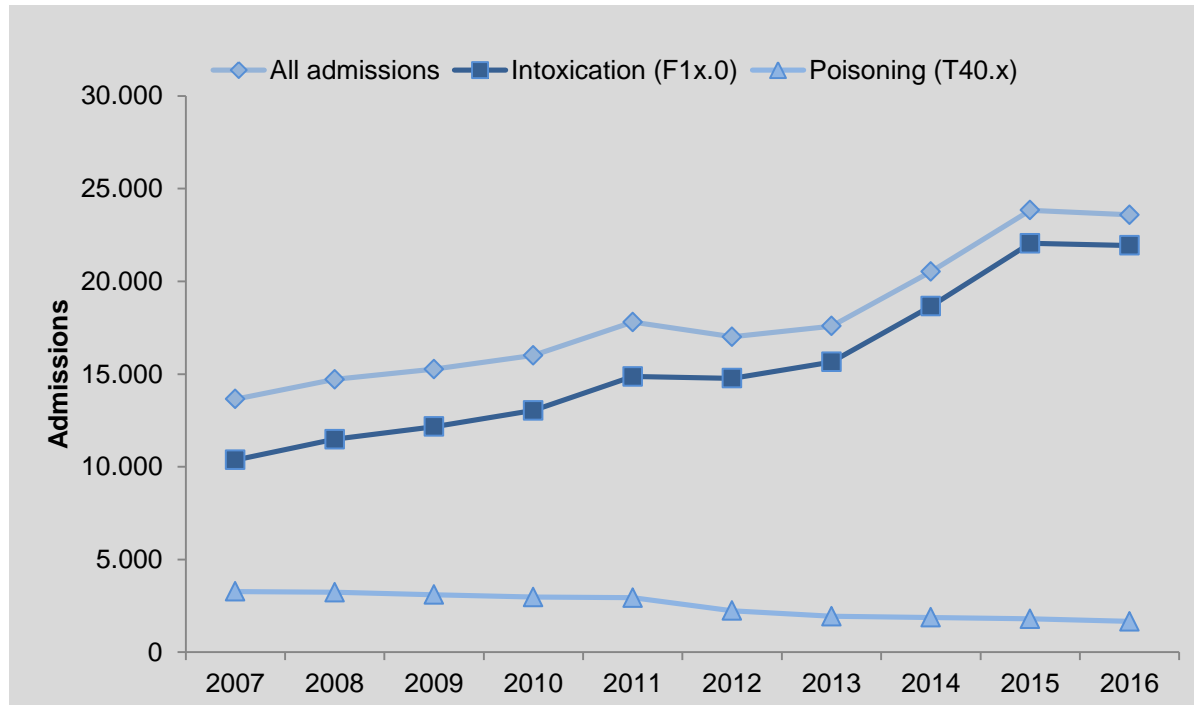
suspected cases (26.7) the severity of the poisoning could not be determined, in 6 cases the documentation was missing (GIZ Nord, 2017a).

Information on substance groups is available: 36.6 % of the calls (N = 281) were made due to the consumption of amphetamine type substances. 17.6 % (N = 135) were related to the use of cannabinoids, of which the most frequent reason for calling, accounting for just over half of the enquiries, was in relation to synthetic cannabinoids (N = 73). This proportion has now fallen, following an increase in the previous year, but is nevertheless significant if one takes into account the significantly lower prevalence numbers for synthetic cannabinoids in relation to conventional forms of cannabis. Cocaine (derivatives) accounted for 16.2 % of calls (N = 125), opioids 8.2 % (N = 63), of which the majority of cases was heroin (51).

Of the 64 poisonings classified as severe, 31 were due to amphetamine-type stimulants, 10 due to cocaine, 9 due to opioids and 6 were due to cannabinoids (5 of those were synthetic cannabinoids).

1.2.3 Trends

The following trend is based on the nationwide data available on acute intoxication and poisoning cases treated on an inpatient basis in hospitals (ICD-10 diagnoses) from the annual Statistical Report on Hospital Diagnoses of the German Federal Statistical Office (Statistisches Bundesamt, special calculations). This data should be interpreted with great caution; the limitations are explained above (see section 1.2.1).

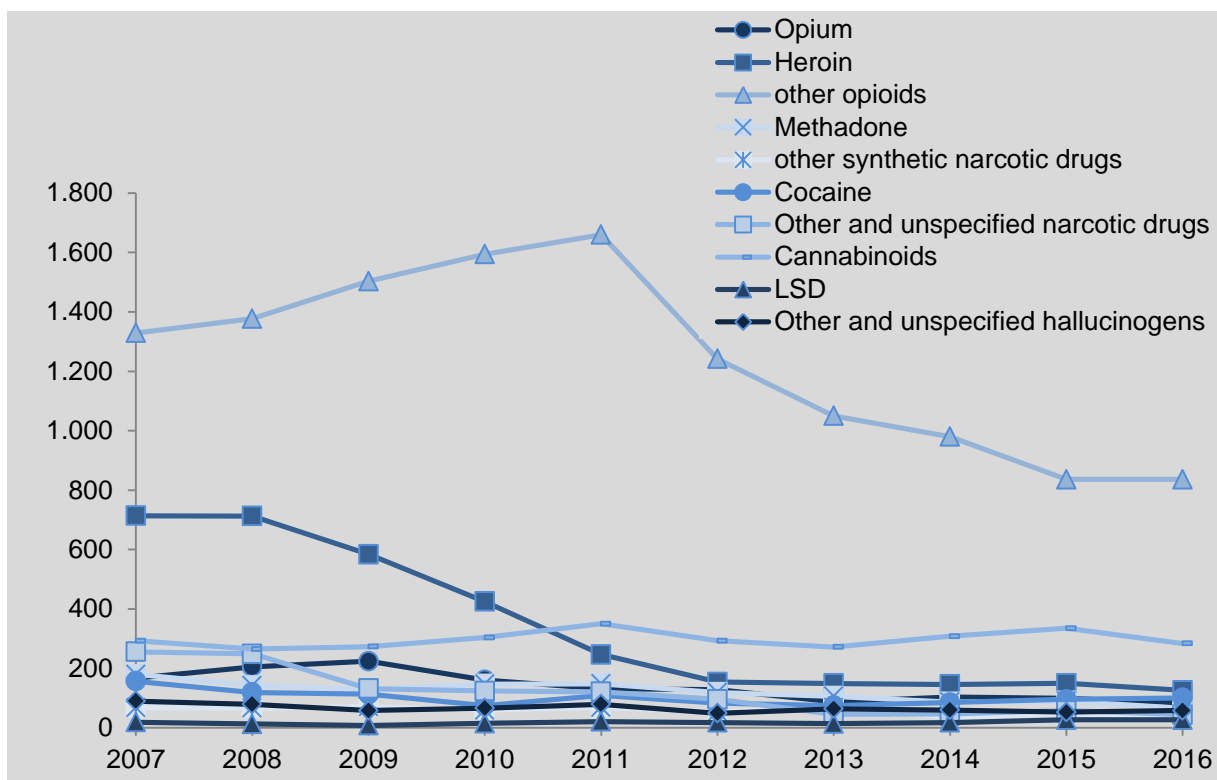


(Statistisches Bundesamt, special calculations)

Figure 3 Trend in acute drug-related emergencies admitted to inpatient treatment 2007 - 2016

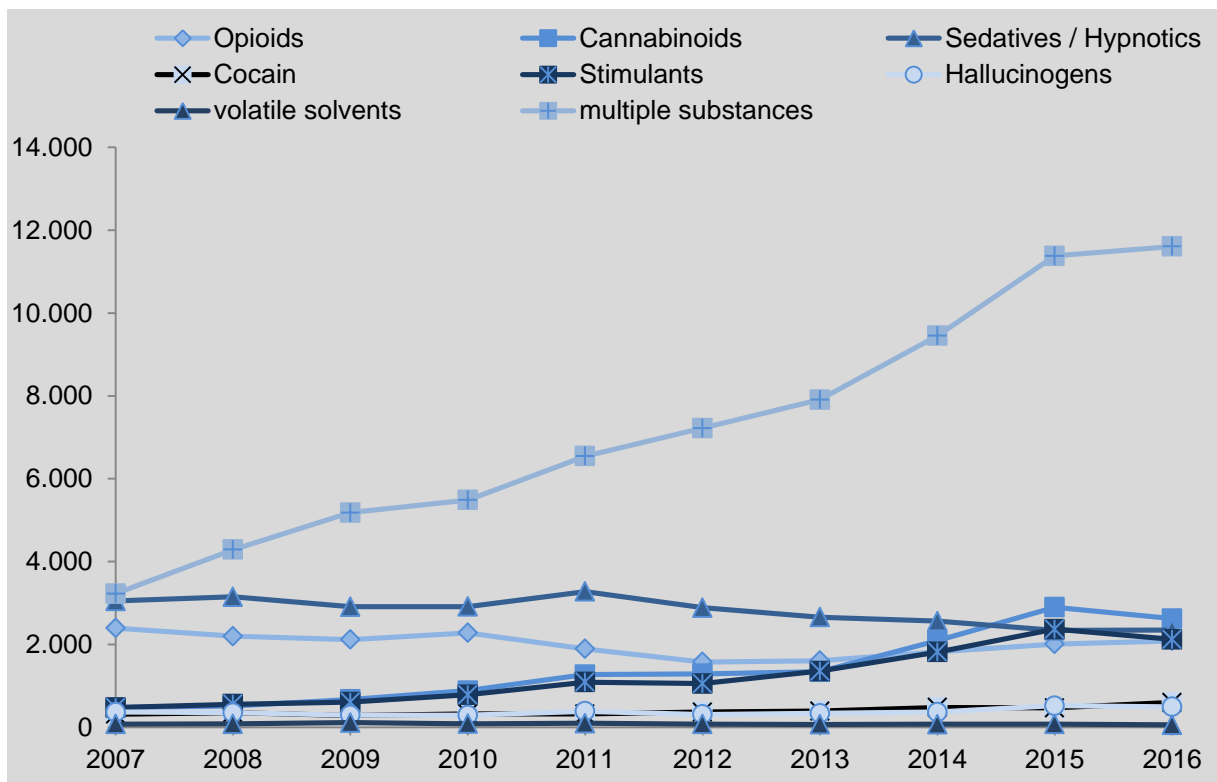
Overall, a continuous increase in non-fatal drug-related emergencies admitted to inpatient treatment can be seen in the ten years to 2015, with the number rising from 12,249 admissions in 2006 to 23,839 in 2015 (see Figure 3). In 2016 the number of admissions was at a similar level to the previous year (23,589). Whether this indicates a longer term stabilisation is currently unclear. The increase in recent years is due to the increase in coded acute intoxication cases, which for 2016 totalled 21,934 cases. The number of cases of poisoning, which were already coded at a much lower level in 2006, has fallen even further in the last 10 years, with 1,655 cases in 2016. It remains unclear whether this can be explained through coding practices or whether in fact there really were fewer cases of poisoning and more cases of intoxication recorded.

If poisoning and intoxication are considered separately, poisoning through "other opioids" (T40.2) clearly predominates among inpatient admissions for poisoning (T 40.x codes, see Figure 4) in the last 10 years. After a considerable increase up to 2011 (1,660 cases), the numbers have since considerably decreased again (2016: 836 cases). For a long time, poisoning from heroin (T40.1) was the second most common diagnosis in this group, however the number of cases has been decreasing almost constantly for over 10 years and today comprises a relatively small proportion of poisonings (2016: 126 cases). Since 2011, cannabinoid poisoning (T40.7) has then been the second most commonly coded cause of hospital admission, after poisoning by other opioids. However, the trend has stabilised in the last ten years, with slight fluctuations, and at 284 cases in 2016, the level is considerably lower than that of opioid poisoning. All other substances, including the other / unspecified narcotics, play only a minor role, with up to 100 reported cases.



(Statistisches Bundesamt, special calculations)

Figure 4 Trend in acute drug-related emergencies admitted to inpatient treatment: poisonings (T40.x-codes) 2007 - 2016



(Statistisches Bundesamt, special calculations)

Figure 5 Trend in acute drug-related emergencies admitted to inpatient treatment: acute intoxications (F1x.0-Codes) 2007 - 2016

In the acute intoxications group, the most commonly coded diagnosis, by some margin, is intoxication due to multiple substance use or use of other psychoactive substances (F19.0) (see Figure 5). The numbers of cases for these types of inpatient admissions have steeply increased over the past ten years and account for a large part of the total increase in all drug-related emergencies admitted to in-patient hospital treatment in the last decade. With 11,609 cases in 2016, this group makes up almost half of all acute drug-related emergencies admitted to inpatient treatment. There is sadly no information available on the individual substances which have been coded under "multiple use" or "other psychotropic substances", so no precise conclusions can be made as to the use behaviour.

The categories of substances, cannabinoids (incl. synthetic cannabinoids), sedatives / hypnotics, stimulants (excl. cocaine) and opioids account for between 2,000 and 3,000 cases with considerable, similarly large proportions. Over time, the significance of individual substance categories has significantly changed:

Since 2015, intoxication due to cannabinoids (including synthetic cannabinoids) has been the second most commonly coded cause. In the last ten years, the numbers recorded for this type of poisoning have increased more than five-fold (475 cases in 2007, 2,623 cases in 2016), although the 2016 number is once again somewhat lower than the previous year. A similar trend can be seen for stimulants (excl. cocaine), which, at 2,121 cases in 2016, has been coded four times more often than ten years previously; a slight year on year decrease has also been recorded in this category, however. In contrast, the number of intoxications from the substance group of sedatives / hypnotics, which up to the previous year had always been the second most common, has fallen overall in the last ten years (2007: 3,049 cases; 2016: 2,347 cases). Intoxication due to opioids has fluctuated over the last ten years by around 2,000 cases per year; no clear trend can be discerned here. Overall, in the area of acute intoxications, a trend towards multiple substance use and an increasing significance of cannabinoids and stimulants is apparent, whereas sedatives / hypnotics in comparison are rather losing significance.

1.2.4 Additional information on drug-related acute emergencies

No additional information is available on this.

1.3 Drug-related infectious diseases

Throughout Germany, all data on infectious illnesses, the reporting of which is mandatory under the German Protection Against Infection Act (Infektionsschutzgesetz, IfSG), is reported to the RKI and analysed there. This therefore also includes reports of HIV and hepatitis infections. In addition, data is available from the Statistical Report on Substance Abuse Treatment in Germany (Deutsche Suchthilfestatistik, DSHS), however this should only be interpreted with extreme caution due to a very high rate of missing information. Data from other sources provides additional insight into the problems of specific, often regional, populations of drug users (e.g. consumption room users and clients of outpatient addiction support facilities) with HIV and hepatitis. In this respect, special mention should be made of

the DRUCK study, which from 2011 to 2015 analysed the prevalence of hepatitis B and hepatitis C as well as HIV, unsafe-use behaviours, knowledge about the infections as well as safer use practices among injecting drug users in eight German cities, the results of which were reported in detail in the reports of the last two years.

More precise information on the data sources for drug-related infectious diseases can be found in section 5.1.2.

1.3.1 Main drug-related infectious diseases among drug users – HIV, HBV, HCV

No HIV data could be reported for 2017, as this was not yet available due to a change to the database for HIV cases reported to the RKI at the time of finalising this report. In 2016, 3,419 newly diagnosed HIV infections were reported. Persons who are assumed to have contracted their HIV infection through injecting (i.v.) drug use make up, at 127 persons, the third largest group as has been the case in recent years (5 % of all new infections where information was recorded on the mode of transmission). Of these 127 persons, 38 lived in Bavaria. After a record low in 2010-2012 in new HIV diagnoses where injecting drug use was the mode of transmission, (77 - 80 new diagnoses per year) following a period of continuously declining numbers, HIV-diagnoses associated with this mode of transmission have since been rising (from 80 to 127 in 2016), in particular in the age group of 30 to 39 year-olds.

The figures presented below stem from the reported data on new hepatitis C diagnoses, as well as acute hepatitis B cases reported to the RKI in the year 2017 (RKI, 2018a; RKI, 2018b).

Hepatitis B reporting data

The case definitions were changed in 2015, in such a way that now not only cases where both the clinical picture and the laboratory diagnosis are present are deemed to fulfil the definition, but also infections proven through laboratory diagnostics for which the clinical picture is not fulfilled or is unknown. The criteria for laboratory detection are now only met by the direct detection of the hepatitis B virus; the old laboratory diagnosis criteria no longer apply. The changes are described in greater detail in section 5.2.2. The changes not only enable an alignment with the European case definitions but also aim to investigate active, i.e. infectious and therefore transmissible, hepatitis B infections, regardless of the severity of the symptoms. With the introduction of new case definitions, the number of published hepatitis B virus infections increased, as expected.

For 2017, 12 cases according to the old case definition and 3,570 cases according to the new case definition were recorded and reported. In the previous year, 629 cases were reported based on the old definition; thus the change to the case definitions can be considered complete this year. The proportion of cases confirmed by clinical laboratory diagnosis among all reported cases remained broadly unchanged from the previous year at

20 %; for the remaining cases, the clinical picture was unknown or not completely fulfilled, the infection was however proven through laboratory diagnosis.

In 2017 a total of 3,622 hepatitis B infections were reported (2016: 3,466, 2015: 3,873). Of the reported cases, 3,582 (99 %) met the reference definition, thus 551 more than in the previous year. The following evaluations are based on cases which meet the reference definition.

The incidence of hepatitis-B in Germany was 4.4 cases per 100,000 population (2016: 3.7). The incidence for hepatitis B among boys and men, at 5.7 infections per 100,000 population, was twice as high as among girls and women (2.9). Among women, the age group of 25 to 29-year-olds was the most affected (7.6). In contrast, the highest level among men was in the age group of 15 to 19-year-olds (11.9). The incidence rates vary significantly between *Laender* and for 2017 amounted to between 0.6 infections per 1,000 population in Thuringia and 7.9 in Bavaria.

In just 163 (4.6 %) of the reported cases was sufficient information provided on the probable mode of transmission for the evaluation. In the evaluation, in cases where several modes of transmission were given, these were reduced to the most probable. Sexual transmission was recorded most frequently (62 cases, 38 %), of which 22 were cases of homosexual contact among men. Shared accommodation with a hepatitis B carrier was the second highest mode of transmission, at 49 cases (30 %), followed by injecting drug use (37 cases, 23 %).

Between 2001 and 2009 a decline was observed in reported acute hepatitis B infections, which is probably due primarily to an improved level of immunisation through the introduction of general vaccination recommendations for nursing infants in 1995. This trend stagnated, with minor fluctuations, between 2009 and 2014. Since 2015, (change in the case definition), a sharp increase in the numbers of cases can be seen, as shown in Figure 6.

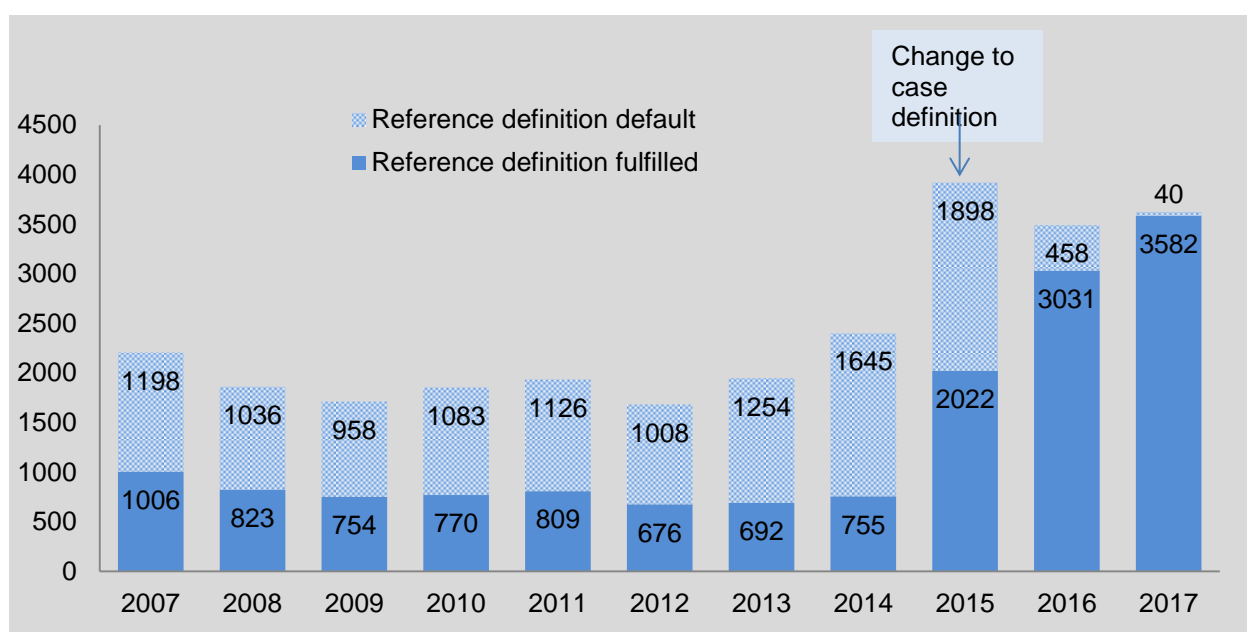


Figure 6 Trend of HBV diagnoses

This increase can be explained in part by the expansion of the reference definition to cases with no, with unclear and with unknown symptoms, however other influencing factors should also be considered. The increase in cases falling in case definition category E might be an indication of increased testing. Specifically in *Laender* with especially high incidence rates or sharp increases such as Bavaria and Saxony, increased testing of asylum seekers who migrate from regions with a high prevalence of hepatitis B must be taken into account. The peak frequency among 15 to 19-year-old male adolescents could be a further indication that a part of the increase in hepatitis B cases can be attributed to the increased testing of asylum seekers. One cannot precisely quantify to what extent the increase can be attributed to the change in the case definition, to the increased testing of, for example, asylum seekers, or to an actual increase. This would require further analysis. A further factor is possible double reporting as the absence of a fixed residence for asylum seekers could make the attribution of test results more difficult. No assessment can be made as to whether cases are only acute cases, as the laboratory diagnostics do not always allow such a differentiation to be made. Thus, the situation might be that the recording of chronic cases increased the figures obtained, also in view of the amended IfSG in July 2017 as well as the limited research possibilities. As time passes over the next few years, the ability to interpret the reported data will increase, as comparability will be restored through uniform criteria in case and reference definitions.

The incidence rates among men were significantly higher than women as in previous years, with peaks in the rates at younger adult ages. Since 2015, the age distribution for men has shifted to younger adults and adolescents. In contrast, the age distribution among women remained similar. The peak of incidence and stated expositions indicate that, as in the previous year, sexual transmission represented the most significant mode of transmission.

Information on country of birth is only recorded in cases of asylum seekers and has been able to be reported from the end of 2015. This group presumably represents a considerable proportion of the people affected in Germany, hence there is a need here for improvement in detection, prevention and treatment of cases. It is strongly recommended that all nurslings, children and adolescents as well as further, defined at-risk groups are consistently vaccinated, in particular in the case of sexual behaviour with a high risk of infection or in the case of injecting drug use (RKI, 2018a).

Hepatitis C reporting data

As it is barely possible, either in laboratory diagnostics or clinically, to distinguish between acute and chronic HCV infections and the majority of new infections of hepatitis C (approx. 75 %) are asymptomatic, all newly diagnosed infections are recorded. Thus, the overall number of cases presumably contains a considerable percentage of already chronic hepatitis C cases (in the sense of a viral replication of more than 6 months). In 2015, the case definition was changed, and since then only cases with a direct pathogen detection fulfil the criteria for a laboratory diagnostic confirmation, therefore only active hepatitis C infections are factored in. This enables a better approximation of the true incidence rate. Due to the

change in case definition, current case numbers are only comparable to a certain degree to the numbers of cases from previous years, so trend evaluations are only possible to a limited extent. A decrease in the reported numbers of cases occurred as expected due to the change in case definitions. For more information on the methodology see 5.2.2.

For 2017, a total of 4,798 cases of newly diagnosed hepatitis C were reported (RKI, 2018b). This represented a national incidence of 5.8 new diagnoses per 100,000 population (2016: 5.4; 2015: 6.0).

Since 2005, there has been a downward trend in the incidence level and in the absolute numbers of newly diagnosed hepatitis C cases, a trend which then slowed after 2009. From 2011 onwards, the incidence has remained relatively stable with slight fluctuations. After an increase in newly diagnosed cases in 2014, the incidence dropped again in 2015 – following the changes to the case definitions – to the level of the five previous years and fell further in 2016. The incidence rate increased slightly in 2017, mainly through an increase in the number of cases in the second half of 2017. In this time period, more direct anti-viral acting drugs have been approved on the German market, and this may have led to increased testing and case detection. Also, various, in part regional campaigns and projects on increasing awareness of viral hepatitis and case detection were carried out. Finally in July 2017 the amendment to the IfSG came into force, under which all laboratory diagnostic evidence of hepatitis C must be reported, meaning that all active (acute or chronic) infections are captured.

In 2017, as in previous years, the incidence of newly diagnosed cases of hepatitis C in the male population (8.2/100,000 population) was more than twice as high as that in the female population (3.5). The peak frequency of incidence for both genders also remained stable over time for the 30 - 39 age group. The incidence rate among women in this age group was 5.9, however this was only one third as high as that of men (19.7).

Evaluable information as to the probable mode of transmission was provided in 1,129 (24 %) of the newly diagnosed cases (see Figure 7). Where several modes of transmission were mentioned, these were reduced to the most probable.

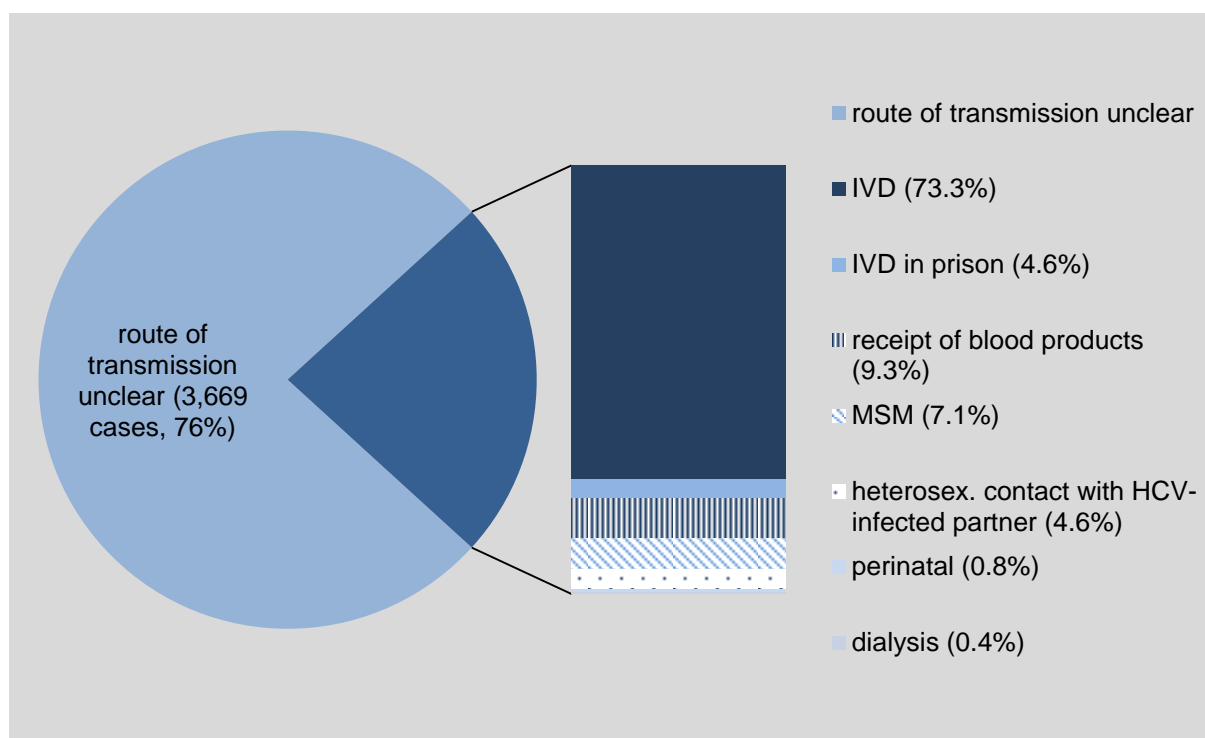


Figure 7 Modes of transmission for HCV diagnoses 2017

Injecting drug use, which has a high probability of being causally related to the hepatitis C discovered, was reported for 879 newly diagnosed cases (78 % of those with information as to the mode of transmission). This mode of transmission accounted for 82 % of the entries for men ($n=711/872$) and 65 % of those for women ($n=165/253$). The more detailed specification of "injecting drug use in prison" was recorded for 47 of the males (5.4 %) and 5 of the females (2.0 %) for whom "injecting drug use" was recorded. This value has been around 80 % since 2012, with some fluctuations. The numbers of cases and the proportion of all diagnoses accounted for by the mode of transmission injecting drug use over the last ten years is shown separately for men and women in Figure 8 (the numbers of cases fluctuate in line with the development of total numbers in the HCV reporting data; the proportion is however interpretable irrespective of the absolute number of cases).

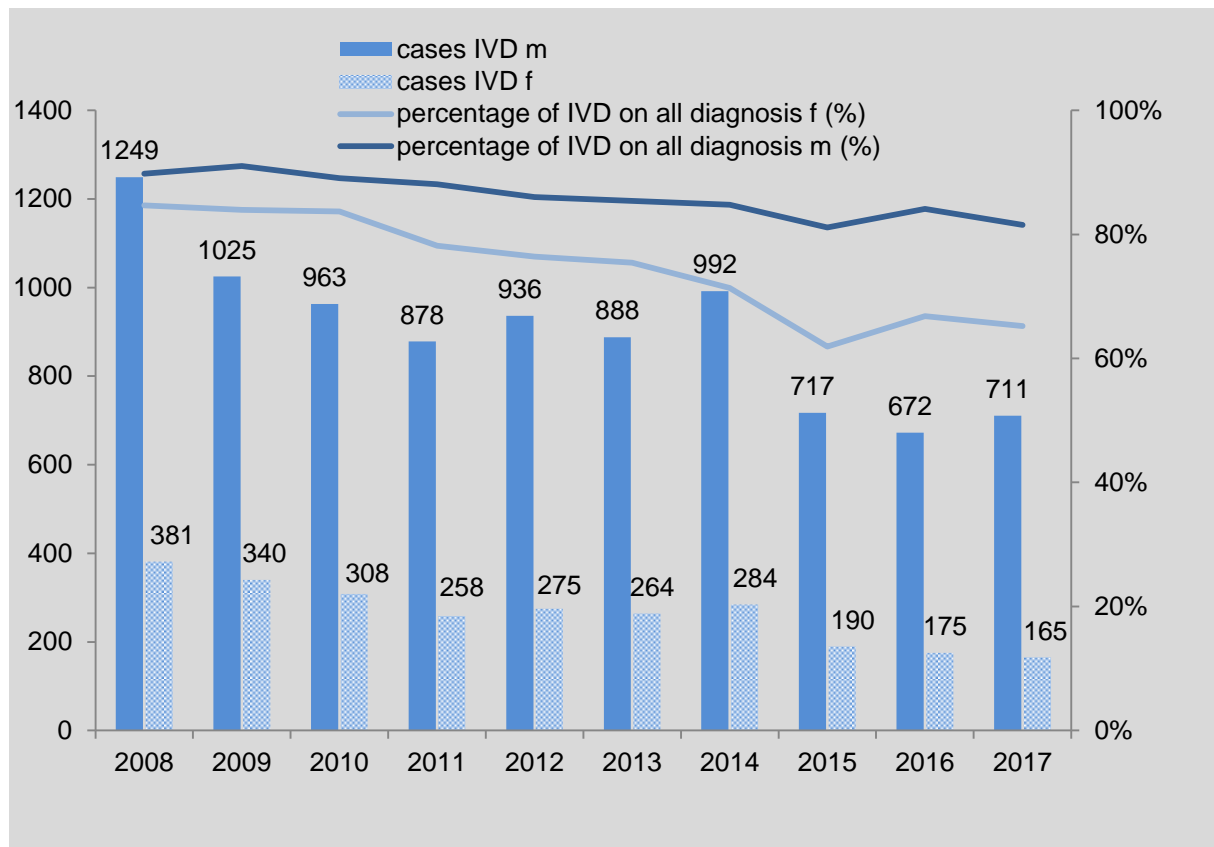


Figure 8 Trend in HCV diagnoses with mode of transmission injecting drug use for men and women

The overall incidence rate of reported hepatitis C cases increased slightly compared to the previous year, after being significantly lower in both of the previous years than in the years prior to 2015. This was presumably mainly due to the restriction in case definition, according to which only active infections with pathogen detection now meet the laboratory diagnostic criteria. The slight increase in the reporting year was mainly caused by increased numbers of cases in the second half of the year. In this time period, additional direct, anti-viral acting drugs have been approved for the German market, and this may have led to increased testing and case detection. Also, various, in part regional campaigns and projects on increasing awareness of viral hepatitis and case detection were carried out. Finally, in July 2017, the amendment to the IfSG came into force, under which all laboratory diagnostic evidence of hepatitis C must be reported, meaning that all active (acute or chronic) infections are captured.

As in previous years, the incidence was markedly higher among men than women. The fact that men more frequently use drugs than women and that this is the most commonly reported mode of transmission, explains, amongst other things, the considerably higher incidence of new diagnoses of hepatitis C among men. Since 2003, Berlin has been the *Land* with the highest incidence rate of newly diagnosed cases; the numbers have, however, significantly reduced compared to the median of previous years. A possible cause is the above average

proportion of people in metropolitan urban centres who belong to at-risk groups such as injecting drug users and MSM (men who have sex with men).

The number of reported newly diagnosed cases for which injecting drug use was recorded has decreased in comparison to the previous three years. One reason for this could be that according to the old case definition infections that had already been cured were often reported as well whereas they do not meet the new case definition. It is also possible that drug users were indeed regularly screened for HCV antibodies, however potentially a secondary diagnosis was not always carried out in addition. The highest priority should continue to be afforded to prevention of hepatitis C amongst drug users, as well as to case detection, diagnosis and treatment in this group.

Before the introduction of diagnostic testing, the number of newly diagnosed cases with blood products as the probable mode of transmission increased from the previous year; since the introduction of testing of blood products, the new diagnoses are not new transmissions but long-time infections that are only now being diagnosed. The number of reported newly diagnosed cases contracted as a result of sexual contact between men has increased slightly compared to the previous year. Information on co-infections within the scope of the IfSG is not collected, however one can assume that there is a sexual transmission of hepatitis C in particular where there is an underlying HIV infection.

Indeed, information on the probable country of infection can serve as an approximation for the estimate of new hepatitis C diagnoses among persons from countries with a higher hepatitis C prevalence, however there is a considerable limitation in the interpretation of reported hepatitis C cases, in that information on the migration status or country of origin could only be reported for all hepatitis C recordings since the amendment to the IfSG in July 2017. The recording of data is currently being switched over to SurvNet@RKI, therefore there is as yet no information to be evaluated for this reporting year. The proportion of newly diagnosed hepatitis C cases in persons from high prevalence regions is therefore unknown, apart from for asylum seekers for whom this information has been collected since 2015. It can be assumed that persons from high prevalence countries represent a higher proportion of people afflicted with hepatitis C in Germany. Germany has committed to the WHO goal of eliminating viral hepatitis by 2030. In order to achieve this, there is a need for improvement in case detection, prevention and treatment of the named groups.

1.3.2 Notifications of drug-related infectious diseases

There was a local HIV outbreak with 28 subtype C infections in Bavaria. Most infections were in 2016 (21 confirmed new diagnoses) with some early cases in 2015 and a few diagnoses in 2017; the outbreak can thus be considered over. Of the 28 reported infections, for 22 the most probable mode of transmission was given as "injecting drug use". An analysis by the RKI showed that the individual infections were directly connected to each other (phylogenetic analysis showed a 98 - 100 % match within the subtype C cluster). In addition, filter dried residual serum of the original samples was present in 19 cases, in 8 of which synthetic

cathinones were detected, hence the RKI assumes a connection between the use of synthetic cathinones and this outbreak (Fiedler et al., 2018).

1.3.3 Prevalence data of drug-related infectious diseases outside the routine monitoring

The DRUCK study, which examined 2,077 injecting drug users in eight major cities in Germany between 2011 and 2014, has produced data on prevalence rates of HIV, HBV and HCV. The findings of the study are detailed in the Harms and Harm Reduction workbook in the REITOX Reports of 2015 and 2016 (Dammer et al., 2016; Pfeiffer-Gerschel et al., 2015) and only referred to here as comparative values.

HIV: Data outside the routine monitoring

In the Hamburg Basic Documentation on outpatient addiction support (Basisdokumentation der ambulanten Suchthilfe, BADO), data is available on the prevalence of HIV among clients from 60 addiction support facilities. In 2016, data for 15,473 clients was documented. Of those, 1,492 were relatives of drug users. 32 % of treated drug users reported a primary opioid problem (n=4,395; similar to the previous year: 33 % and n=4,456), the largest proportion, however, exhibited polytoxic drug use patterns. The somatic and psychological comorbidities are set out in more detail in section 1.4.1.

The HIV infection rate among all drug users in 2016 was, at 2.3 %, around the same level as the previous year (2015: 2.4 %). Among opioid users it was, at 4.0 %, as in the last few years, higher, but stable to slightly decreasing over time (2015: 4.3 %; 2014: 4.6 %). Differentiating by gender once more reveals a slightly higher infection rate among female opioid users in this reporting year (4.7 % versus 3.7 %). 7.0 % of all clients and 4.7 % of opioid dependent clients stated that they had not as yet had an HIV test. Among opioid users, the test rates for men were, as in previous years, significantly higher than for women (non-tested men: 3.5 %, non-tested women: 8.1 %), whereas it was similar for both genders in the overall group (7.0 % men, 6.9 % women; Lindemann et al., 2017).

Data is now also available from the Consumption Room Documentation, which covers four consumption rooms in Frankfurt (Stöver and Förster, 2017), on the HIV status of the 4,705 clients³ treated in 2016. 2,601 persons (55 % of all clients) answered the question of whether they had already had an HIV test. Of these, 91.5 % had already been tested. Women and men had themselves tested approximately equally often. For 1,624 persons there is a note of when their last HIV test was. 37.8 % of those persons stated that their test was in 2016 and therefore up to date. A further 46.4 % were in 2015. The remaining tests (15.8 %) were a longer time ago. 49 % of all consumption room users (2,297 persons) provided their test results. 3.3 % stated they were HIV positive, whereby women, at 7.5 %, were, as in previous

³ The number of clients is calculated from the individually assigned "HIV codes". It is possible that some people possess multiple codes, hence the number of clients actually being treated could be somewhat lower.

years, affected markedly more often than men, at 2.5 %. Looking at the longer term, no clear trend can be ascertained for HIV infections. It has fluctuated since 2009 between 4.4 % and 2.9 %. Furthermore, inaccuracies in the survey system must be assumed (not all clients are surveyed; for some, the testing was further in the past), hence any interpretation should only be undertaken with great caution. For years, HIV infections have been rarer among new users of consumption rooms than among continuing users (2016: 0.9 % of new users, 4.3 % of continuing users); in particular female continuing users have a higher than average HIV infection rate (2016: 10.3 %).

If one summarises the findings from Hamburg, Frankfurt am Main and from the DSHS, the resulting average HIV prevalence rate among opioid users ranges from approximately 1 % to approximately 10 % depending on subgroup. The figure for new users of consumption rooms is somewhat lower overall. Women are more affected than men. The values must be interpreted with caution due to the high number of untested clients. However, the values do correspond quite closely to the values collected in the DRUCK study (RKI, 2016), which established an HIV prevalence between 0 % and 9 % (depending on study city) and also revealed that women were more frequently infected than men (7 % v. 4 %).

Hepatitis B and C: Data outside the routine monitoring

ECHO study

The ECHO study studied 2,467 clients in opioid substitution therapy (OST) for hepatitis C prevalence rated (Schulte et al., 2018). The duration of the substitution therapy amounted to between 0 and 27 years at the time of the survey (mean value 6.4 years). 24 % of clients were in OST for the first time. 58.8 % of the 2,386 persons tested returned positive results for HCV antibodies; 27.3 % of the 2,260 persons tested were positive for HCV RNA and therefore have a potentially contagious hepatitis C infection. Based on 78,500 clients in opioid substitution treatment in Germany, the authors estimate that around 21,500 people in substitution are potentially infected with infectious hepatitis C.

The incidence rate for a new infection in this sample of OST patients amounted to 2.1 to 2.5 cases per 100 person-years. Those who were newly infected during the study showed a high burden of symptoms, a particularly high level of drug use and significant social problems.

Data on treatment outcomes is available for 134 of the 151 patients between baseline and follow-up treated for hepatitis C. For 88.6 % of those patients, the virus was no longer detected in their blood stream long term meaning the infection had therefore been cured. For a further 6.1 %, only short-term data on viral absence is available (there is no long-term data). 3.1 % experienced a relapse, 0.8 % were non-responsive and a further 0.8 % terminated the treatment prematurely.

The authors conclude, on the basis of the good treatment outcomes and the low rate of new infections in the sample with the same high level base prevalence, both that more persons in opioid substitution should be treated and that more persons who are already in opioid

substitution should also be treated for hepatitis C. In addition, robust monitoring data which is continuously followed up is required for this group.

Routine data

According to the BADO, in 2016, 19.9 % of all clients and 46.2 % of opioid clients in Hamburg were infected with hepatitis C. In recent years, the rate of infected opioid users has proven roughly stable at a very high level. 6.8 % of all clients and 4.7 % of opioid users had never had themselves tested for hepatitis C, whereby the proportion of men who had been tested was, as with HIV, markedly better than that of women (non-tested men: 3.4 %, non-tested women: 6.6 %; Lindemann et al., 2017) Data on hepatitis B is not collected in the BADO.

In the Frankfurt Consumption Room Documentation 2016 (Stöver und Förster, 2017), 55 % (n=2,609) of consumption room users provided information as to whether they had already had an HBV and / or HCV test; of these 93.4 % had had a test. Test results are available for 49 % (2,305 persons) of all those treated, of whom 34.9 % tested positive for hepatitis C, 0.8 % for hepatitis B and a further 1.9 % for a comorbid hepatitis B and C. There were hardly any gender-specific differences. Similar to the situation regarding HIV and consistent with the results of recent years, older drug users were more likely to be infected with HCV than younger users. Also, continuing users showed a higher infection rate than new users (HCV: 37.6 % versus 28.5 %; comorbid HCV and HBV: 2.2 % versus 1.2 %). The authors note that the infections rates overall, as well as in the last three years, exhibit a downward trend: in 2004 the proportion of clients affected with one or both hepatitis infections was still up at 66 %. In 2013, 45 % of clients were HCV positive; this figure was 37 % for 2016 (including comorbid HCV and HBV infected persons). However, the authors also refer here to recording-related inaccuracies, as far from all consumption room users provide their infection status.

In relation to HBV, a very low infection rate is seen in Frankfurt. However, this is of very limited meaningfulness due to the extremely high estimated number of unreported cases and the low number of cases reported. If one compares it to the data collected in the DRUCK study, a considerable underestimation must be considered: in that study, a prevalence rate of around 25 % was recorded (between 5 % and 33 % depending on the study city) (RKI, 2016).

If one combines the HCV data from Hamburg and Frankfurt, the resulting estimate of the prevalence of chronic hepatitis C among opioid users is between a third and a half of all those treated. As the data involved is self-reported, one can assume that this is a conservative estimate. In addition, there is a high number of clients who have not been tested; against the background of a high estimated number of unreported cases, these numbers must be interpreted with caution. This is further complicated by the different options for testing for an HCV infection, the differences between which are likely rarely known to the clients. In fact, the methodologically significantly sounder DRUCK study records, overall, a somewhat higher prevalence among injecting drug users: an average HCV prevalence of

66 % (42 % to 75 % depending on study city) and a prevalence of potentially infectious hepatitis C of 44 % (23 % to 54 % depending on study city) (RKI, 2016).

More reliable numbers could also be obtained through routine reporting, by direct testing of clients in the facilities they attend. In the day to day running of low-threshold facilities, there is no funding for this however, therefore such services are not available. A possible continuation of the DRUCK study is currently being planned by the authors.

1.3.4 Drug-related infectious diseases – behavioural data

In the BADO in 2016, 60.7 % of opioid users reported having injected drugs in the past. 30.3 % reported having shared a syringe with someone and 5.4 % reported having done this in the previous 30 days (2015: 63.0 %, 31.9 % and 5.2 % respectively) (Lindemann et al., 2017).

Detailed data is available from the DRUCK study on risk behaviour and knowledge of risks and protection possibilities for injecting drug users, which was presented in detail in the Harms and Harm Reduction workbook in 2015 and 2016.

1.3.5 Other drug-related infectious diseases

There is currently no information available on other drug-related infectious diseases.

1.3.6 Additional information on drug-related infectious diseases

No additional information is currently available on this.

1.4 Other drug-related health harms

1.4.1 Other drug-related health harms

In addition to the suffering caused by the infectious diseases described above, drug users are to a considerable extent affected by a series of other somatic and psychological comorbidities. Comprehensive national or representative studies on this topic are not available. In the DSHS, data is collected on comorbidities, however since data is missing for a large majority of all documented patients, no serious estimate of comorbidity can currently be made on the basis of the few remaining data points.

Comorbid somatic and psychological disorders amongst opioid users in Hamburg

In the BADO 2016, information on both the physical and mental health of clients treated is available (Lindemann et al., 2017) which cannot claim to be representative, however it does offer an insight into this specific, heavily impacted clientele.

The 4,395 opiate clients often exhibited additional substance-related and also non substance-related addictions. On average, 4.3 additional problem areas were documented among opiate clients (including gambling and eating disorders, excluding tobacco). In the number of additional problem areas, there were no relevant differences between the

genders, although there were differences in where the additional problems were focussed. The substances most commonly used in addition to opiates were, as in the previous year, cocaine (68 %), cannabis and alcohol (both 58 %), crack (45 %) and sedatives (43 %). The proportions of males treated were, as in previous years, mostly somewhat higher than those for females, in particular for cannabis (67 % versus 54 %). In contrast, proportionately more women were affected by eating disorders (15 % versus 3 %).

26 % of the people in the group of opioid users were assessed by the counsellors as suffering from considerable or extreme physical health effects. A further 32 % were classified as suffering from a medium health impairment and in the case of 13 % a recognised disability status was documented. Sleep disorders were documented for 50.3 %; 36.2 % were found to have a tooth status requiring treatment and a further 6.3 % had a ruinous tooth condition. Data on HIV and hepatitis status can be found under section 1.3.3.

For years, clients' psychological stress has been consistently classified as high by counsellors: as in the previous year, 38 % of clients were classified as considerably or extremely mentally burdened, whereby women (49 %) were affected far more often than men (34 %). The rate of suicide attempts has also been consistently high for years; 31 % of clients reported at least one suicide attempt in the past (women 42 %, men 29 %), with 15 % reporting more than one attempt (women 21 %, men 13 %). The most commonly reported symptoms are depressive mood (22 %), restlessness (19 %) and anxiety / phobias (16 %). Excessive self-confidence (11 %), lack of impulse / emotional control (8 %) and aggression (6 %) were mentioned somewhat less often. The psychological symptoms are a clear indication that a majority of these clients would have to utilise further psychiatric-psychotherapeutic care in future in addition to the existing addiction-specific treatment in order to stabilise themselves in the longer term. 37 % of clients take psychotropic pharmaceutical drugs prescribed by doctors, (women 40 %, men 36 %), whereby 23 % take anti-depressants, 10 % sedatives and 8 % neuroleptics. It was documented that 13 % of the opioid group never or rarely availed themselves of necessary medical care and 29 % only occasionally did so.

For information on the treatment of psychological disorders in people with simultaneously occurring dependence problems see the Treatment workbook (Bartsch et al., 2018).

CaPRis: Effects of cannabis use

Against the background of continuingly high prevalence rates for recreational cannabis use, of the high proportion of drug treatment accounted for by cannabis related disorders as well as the "Cannabis as Medicine" Act which came into force in 2017, the effects of cannabis use continue to be discussed in the German media, politics and among experts. The major addiction medicine professional organisations have published their positions on this topic (a list of which can be found in the Drug Policy workbook from 2016 (Pfeiffer-Gerschel et al., 2016)).

On behalf of the BMG, Hoch et al. (2017) produced an expert report on cannabis ("Cannabis: potential and risks. A scientific analysis (CaPRis)"). The systematic review summarises,

among other things, results from the last 10 years on the psychological, organic and social consequences of the recreational use of herbal and synthetic cannabis products. The summarised results for different areas are presented below:

Cognition

In the area of cognition, the authors state that regular and frequent use of cannabis leads to global deficits in cognition, in particular memory capacity, whereby the picture of these limitations is not as consistent as the acute effects of cannabis. Impaired intelligence in relation to regular cannabis use could not be consistently established. Deficits in cognitive function caused by chronic cannabis use seem to be temporary. Indications of cognitive impairments which are still present after a greater than one-month abstinence from cannabis (1 month) are only found in individual studies (e.g. among test persons with early use in adolescence). Chronic cannabis use is associated with different activity patterns in the brain during cognitive stress, which affect both the intensity and regional distribution of activation. This altered neural activity could be compensating for impaired neuronal processes. There is a lack of data for assessing gender specific differences; individual studies point to differential effects of cannabis on cognition among women. An influence of age of first use of cannabis on long-term cognition disorders could not be conclusively explained; therefore there is significant need for longitudinal studies and a control for the age effect in these studies.

Psychological disorders

Cannabis use and dependence seem to increase slightly the risk of anxiety disorders (by a factor of 1.3 and 1.7 respectively), however not all individual studies confirm this finding. Starting cannabis use at an early age (younger than 16), long-term, weekly cannabis use and current cannabis dependence significantly increase the risk of anxiety disorders (by a factor of 3.2; results of a longitudinal study). The risk of depression is slightly increased by cannabis use, depending on the intensity of use (factor of 1.3 to 1.6). This finding was also observed in a study of adolescents (12 to 18-year-olds). The risk of suicidal thoughts seems to be marginally increased with cannabis use, but even this finding does not appear in all individual studies. New-onset bipolar (i.e. manic-depressive) symptoms are increased by a factor of 3 with cannabis use. The new-onset of bipolar disorders through cannabis use is increased by a factor of 1.4 (weekly use) and 2.5 (nearly daily use). In cases of a pre-existing bipolar disorder, cannabis use increases the risk of recurrence of manic symptoms or episodes. Age and gender specific effects were seldom investigated overall. Cannabis use can also increase the risk of psychotic disorders. Large meta analyses have shown that in cases of occasional cannabis use, the frequency of occurrence of psychotic disorders is increased by a factor of 1.4 to 2.0, and by a factor of 2.0 to 3.4 for higher user intensity. The age of onset of the illness is shifted 2.7 years forwards compared to non-users. Cannabis use is associated with an unfavourable progression of psychotic disorders (relapse, length of stay, more pronounced positive symptoms).

Psychosocial consequences

A young age of first cannabis use (before 15th birthday) and more frequent cannabis use in early adolescence are associated with low educational attainment, (higher school drop-out rates, lower participation in university education and fewer academic qualifications). Impairments in educational attainment seem to have a negative linear relationship with the age of starting regular use. Inconsistent and insufficient empirical data is available regarding cannabis-linked issues in social behaviour, delinquency and familial, occupational and economic development. Gender specific effects were not investigated.

The authors found that an internationally valid, standardised collection of important cannabis use variables (especially THC and CBD levels in cannabis used, form of administration, plasma concentrations, age of first use, duration of abstinence and strength / duration of use) is urgently needed in order to improve the comparability of the studies and their results.

Synthetic cannabinoids

The review also covers the harms of synthetic cannabinoid use. In contrast to herbal cannabinoids, synthetic cannabinoids have a stronger pharmacological effect on both cannabinoid receptors, hence their effect and strength is sometimes difficult to predict. The most frequent symptoms of an intoxication or overdose from synthetic cannabinoids are accelerated pulse ("heart racing"), restlessness and nausea / vomiting. There is an increased risk of psychosis for vulnerable persons with pre-existing psychiatric conditions. The use is associated with an increased risk of intoxication requiring emergency medical treatment, which is concluded from historical and reporting data from drug authorities, calls to the emergency services regarding drugs and hospital emergency reports. Severe clinical symptoms (e.g. infarction, kidney failure, epileptic grand-mal seizure, psychosis) are rather seldom, but by no means isolated cases. 32 deaths have been registered internationally to date in connection with synthetic cannabinoids. The true number could, however, be significantly higher, as there is no standardised toxicology for synthetic cannabinoids. The data is based as far as possible on medical emergency case reports and case series as well as authorities' reporting data.

There is a paper by Manthey (2017) on possible strategies for harm reduction in relation to cannabis and the state of application of these measures in Germany.

Psychological and physical stress and resilience⁴ of relatives

Relatives of people with problem substance use encounter particular stresses. A questionnaire based study with 221 relatives investigated the stress experienced, life quality and resilience factors (Soellner und Hofheinz, 2017). The relationship of the relatives to the problem users is not precisely defined, however on the basis of the same age (on average almost 44 years old, standard deviation approximately 14 years in both groups) and gender

⁴ "Resilience" means psychological robustness, i.e. the ability to cope with stress and crises without, in the worst case, becoming ill from it.

distribution (relatives over 90 % female, users almost 80 % male) it can be assumed that the majority are partner relationships or at most siblings.

The study revealed that relatives are psychologically and physically more stressed and described their quality of life as lower than a standard sample. The self-efficacy expectation proved itself as the strongest predictor for resilience, while school education and satisfaction with the support from the support system were of no predictive value. Resilience as a positive dimension in the sense of quality of life in spite of any burden was furthermore associated with satisfaction with the emotional support in their private lives. The authors conclude that an exchange of experiences with other persons affected (i.a. in self help groups or group therapy services) can be an important support option for relatives and therefore should continue to be promoted, as observational learning is an essential factor in strengthening the expectation of self-efficacy.

1.5 Harm reduction interventions

1.5.1 Drug policy and main harm reduction objectives

Harm reduction measures represent one of the four levels of the National Strategy on Drug and Addiction Policy (Die Drogenbeauftragte der Bundesregierung, 2012). Various targeted approaches are used in an attempt to prevent deaths caused by drug use:

- Informing and educating on the risks of overdosing,
- Providing effective treatment measures for drug users, among other things, substitution (c.f. Treatment workbook, Bartsch et al., 2018) and improving retention rates,
- Improving transition management after release from prison (c.f. Prison workbook, Schneider et al., 2018)
- Providing drug consumption rooms,
- Improving the reaction of bystanders in the case of drug emergencies (first aid training, naloxone programmes).

More detailed information on the National Strategy can be found in the Drug Policy workbook (Pfeiffer-Gerschel et al., 2018). The information is also available online⁵.

Since the decision of the German Federal Cabinet of 6 April 2016, the BIS 2030 strategy of the Federal Government has also been active which seeks to reduce HIV, HBV, HCV and other sexually transmitted infections substantially by 2030 (BMG and Bundesministerium für wirtschaftliche Zusammenarbeit und Entwicklung, 2016). Injecting drug users are explicitly named as one of the specific target groups of this strategy, for whom needs-orientated services will be created or expanded and integrated services will be developed. Further aims

⁵ http://www.drogenbeauftragte.de/fileadmin/dateien-dba/Drogenbeauftragte/2_Themen/1_Drogenpolitik/Nationale_Strategie_Druckfassung-Dt.pdf [Accessed: 27 Aug. 2018].

of the strategy are to create a social climate of acceptance for different sexualities and lifestyles in order to remove stigmatisation and discrimination as well as to connect cross-sectoral organisations with one another and to further expand the knowledge base. The strategy is available online⁶.

Recommendations for the further development of harm reduction in Germany on the basis of the DRUCK study also indicate ways in which infectious diseases and other drug-related damage to health can be combated. The recommendations concern low-threshold drug support, outpatient addiction support counselling and treatment facilities, substitution treatment, practice based doctors and correctional institutions. The detailed recommendations can be found in the final report of the DRUCK study (RKI, 2016).

1.5.2 Organisation and funding of harm reduction services

Health aspects of drug use are addressed both in the scope of specific services and treatments offered for drug users as well as within the framework of general healthcare. Data on general healthcare does not provide any information which can be specifically attributed to the target group of drug addicts. Therefore, other than a few isolated cases, there is no data available on the number of emergency responses due to overdoses or other life-threatening conditions caused by drug use. Nor is there any data on the treatment of other secondary diseases carried out in general practitioners' surgeries or clinics. The costs are generally borne by the health insurance providers, however this information is not collected or published separately.

Information on the extent and type of specific services for drug users is only available for some of the measures, as these are provided by specialised facilities or as part of special programmes. There is no uniform financing. The costs of most facilities are borne by the municipalities, however there is also some financing from the Federal Government and the *Laender*.

The availability of harm reducing measures varies widely in Germany. Overall, it is better in cities and heavily populated regions than in rural areas. Provision in prisons is particularly poor (see the Prison workbook). Due to Germany's federal structure, the legal situation regarding harm reducing measures is not exactly the same in all *Laender*, which has an impact in particular on the provision of drug consumption rooms, which are currently only available in six *Laender*.

⁶ http://www.bundesgesundheitsministerium.de/fileadmin/Dateien/ Publikationen/Praevention/Broschueren/ Strategie_BIS_2030_HIV_HEP_STI.pdf [Accessed: 27 Aug. 2018].

1.5.3 Provision of harm reduction services

Provision of opportunities for testing for infectious diseases

There is no systematic, Germany-wide screening for infectious diseases. For hepatitis, the introduction of screening for the general population and in particular for at-risk groups has long been called for by the German Liver Foundation⁷.

The testing possibilities within low-threshold facilities vary widely and are often dependent on financial considerations; there is no national data on services, even if it can be assumed that testing is not rare at least for HIV, HBV and HCV. Some low-threshold facilities cooperate with public health authorities for such testing. In the BADO and Frankfurt consumption room documentation, usually around 90 % of respondents state that they have been tested for these infections (see 1.3.3). However, only around one third of respondents in the Frankfurt consumption room documentation state that the HIV test is up to date, hence it cannot be assumed that there is sufficient testing frequency. In the case of inpatient accommodation, there is frequently the possibility to be tested for various infectious diseases. Generally, any person in Germany can be tested anonymously and free of charge through their public health authority. This service does not exist for hepatitis infections, however.

There are indications however, that low-threshold testing services can work well: The offer of a rapid test in the scope of the DRUCK study was taken up by between 30 and 80 % of participants, depending on study city. The authors conclude that the testing and counselling services in drug support facilities, in particular in the form of short, targeted interventions, which are available on site and take a maximum of 10 minutes, are very well received by drug users (RKI, 2015). Detailed recommendations exist from the DRUCK study for an expansion of testing. The older project, "TEST IT" (January to September 2010) of the German Aids Service Organisation (Deutsche AIDS-Hilfe, DAH), which was conducted in cooperation with the Dortmund Drug Support Facility, KICK, and scientifically supported by the Dortmund University of Applied Sciences and Arts (Fachhochschule Dortmund), also proved to be a success in relation to an increase in the rate of testing for HIV and is being continued, for example in Berlin⁸ (DAH, 2010). Approximately 10 % of the HIV infections detected in Berlin were diagnosed in the scope of the rapid test project (aerzteblatt.de, 2013).

The project „HIV? Hepatitis? Das CHECK ich!“ is conducted by the BZgA in cooperation with DAH and RKI and also with support of the “Private Krankenversicherung (PKV) e.V.” at the very moment. It is carried out in four Bundesländer and aims to enhance testing and care. It is a matter of consulting and test service which offers low-threshold access to free and

⁷ c.f. http://www.deutsche-leberstiftung.de/aktuelles/presseportal/pressearchiv/Welt-Hepatitis-Tag-2014_07_17 [Accessed: 27 Aug. 2018].

⁸ www.testit.fixpunkt-berlin.de [Accessed: 27 Aug. 2018].

anonymous HIV and HCV tests for drug using persons⁹. A pilot project on the possibility of testing for HIV and other sexually transmitted diseases at home is presented in section 3.3.1.

Dispensing syringes and other safer use equipment

Prevention of drug-related infectious diseases in low-threshold drug support facilities consists primarily of providing information on infectious diseases and risks of infection as well as issuing safer-use equipment. Provision of syringes and syringe exchange in low-threshold work is explicitly permitted under the German Narcotic Drugs Act (Betäubungsmittelgesetz, BtMG) and is also practised by many facilities.

Data on the issuing of syringes is for the most part only documented in Germany by individual facilities in their respective annual reports. A nationwide compilation of the data available is not undertaken. The DAH provides a website¹⁰ containing an overview of the locations of syringe vending machines it is aware of. Issuing syringes in low-threshold and other facilities is not documented, however. According to the website, syringe vending machines are only available at all in nine *Laender*; seven *Laender* do not even have a single documented syringe vending machine. Of the 172 syringe vending machines listed by the DAH, over 100 are located in North Rhine-Westphalia (NRW) and 17 in Berlin. From this it is clear that the distribution of locations for the whole of Germany still cannot be described as nationwide by any means. Nonetheless, it must be assumed that the documentation of the syringe vending machines in the other *Laender* is incomplete, which could contribute to a distortion of data in favour of NRW and Berlin. Therefore one cannot really speak of an exhaustive record of all syringe vending machines in Germany.

A new study on low-threshold care with sterile consumption apparatus via vending machines in North Rhine-Westphalia found that even in this relatively well served and documented *Land*, in several districts (with a total population of more than 3.8 million people) no syringe vending machines are available (Deimel et al., 2018). The study also reveals that the proportion of syringes dispensed from vending machines only makes up 6.0 to 7.2 % of all syringes nationwide, however there are extreme differences between urban and rural areas: In cities, the proportion is only 1.2 % to 8.3 %, in rural areas in contrast it is 90.3 % to 100 % of all syringes dispensed. The authors conclude that vending machines dispensing sterile consumption apparatus are a complementary service to existing facilities. Precisely in rural areas (or generally in locations without low-threshold facilities), they can represent the only low-threshold access to sterile consumption apparatus, which is why a nationwide expansion of the syringe vending machine programme, in particular in rural regions, on the basis of dedicated needs planning is required. In this respect, the installation of vending machines in specific locations for specific groups of users is mentioned (e.g. in areas near scenes for men who have sex with men). The report's recommendations also include the use of vending

⁹ <https://www.drogenbeauftragte.de/presse/projekte-und-schirmherrschaften/projekte-des-monats/2018/hiv-hepatitis-das-check-ich.html?L=0> [Accessed: 09.Oct. 2018].

¹⁰ <http://www.spritzenautomaten.de/> [Accessed: 28 Aug. 2018].

machines as a medium of communication, to provide drug users with safer use information. This should be done in the form of multilingual insert leaflets in consumption apparatus packs. As the operation of vending machines causes significant additional costs for the institutions, the authors call for part of the staffing costs to be borne by the municipalities in order to fund the expansion and secure the existing stock of vending machines.

NRW is also the only *Land* which is not a city state where a regular survey is conducted on a local level on the distribution of disposable syringes by the AIDS service. The numbers will be reported in section 1.5.4.

According to healthcare experts, safer-use services in prison in Germany are still lagging far behind what is possible. A syringe vending machine is only available in one of the 180 German prisons (Destatis, 2018). In light of this, the DAH started a campaign back in 2013 to improve the situation of drug users in prisons (DAH, 2013). The initiative is supported by the Paritätische Wohlfahrtsverband (Association of Welfare Charities), the German Association of Parents and Relatives for Acceptance-Oriented Drug Work (Bundesverband der Eltern und Angehörigen für akzeptierende Drogenarbeit) and by akzept e.V. In addition, the DAH had a UNODC handbook for the introduction and implementation of syringe exchange programmes in prison translated; the publication is available online¹¹ (DAH, 2015).

Emergency training and naloxone take-home programme

In Germany, there were 1,272 drug-related deaths in the reporting year 2017. Of these, over half were due to monodrug or poly drug opioid overdoses (BKA 2018, data delivery). This proportion has fallen somewhat in recent years, however opioid poisoning remains the most frequent cause of death among drug-related deaths by some margin. The opiate antagonist naloxone, which has been successfully employed in emergency medicine in the case of opioid overdoses for over 40 years, can also be administered by a layperson and save lives. Therefore the WHO, EMCDDA and the Federal Government Commissioner on Narcotic Drugs recommend dispensing naloxone to people who are frequently present when opioids are used (Die Drogenbeauftragte der Bundesregierung, 2014; European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), 2015; World Health Organization (WHO), 2014). This means opioid users themselves, but also friends and family.

Despite these recommendations, the dispensing of naloxone to laypeople is only sporadically practised in Germany. It is made more difficult by the question of financing and is not integrated into regular healthcare. Regardless of the difficult conditions, a few projects offering naloxone training for lay people do exist. Already existing projects are being further developed and in recent years several new projects have been implemented. Moreover, NGOs are making efforts to clarify and improve the legal situation for naloxone programmes in order to break down barriers to appropriate treatment and enable nationwide availability in the future. The longest-running naloxone programme in Germany is run by Fixpunkt e.V. in

¹¹ <https://www.aidshilfe.de/shop/pdf/7376> [Accessed: 20 Aug. 2018].

Berlin. It has existed since 1998. The resources available for the project fluctuate considerably. Other locations are significantly newer: currently there are naloxone projects outside Berlin in several cities in North Rhine-Westphalia, Munich as well as one which started this year in Saarbrücken. A *Land* pilot project on dispensing naloxone in five cities in Bavaria (including Munich) is due to start soon.

A pilot project on the issuing of naloxone before release from prison could not be started as planned due to administrative barriers (DAH, 2018, personal communication). In Frankfurt, a naloxone project was run by the Integrativen Drogenhilfe in 2014/15, which is currently no longer financed and accordingly is no longer being run. The guidelines which emerged from the project on the implementation of naloxone projects is accessible online, as well as one other set of guidelines¹².

All naloxone programmes in Germany consist of drug emergency training, in which, for example, first aid techniques are provided, along with information on the risks and signs of an overdose as well as on naloxone. In addition, specific exercises are carried out on the administration of the medicine. After the training, where participants are willing and provided a prescription has been given by a doctor, the emergency kits are issued. They contain, in addition to the medicinal drugs, the administration utensils and often single-use gloves and resuscitation face shields. More detailed information on the projects was presented in the Harms and Harm Reduction workbook in the REITOX Report 2016 (Dammer et al., 2016). New developments are explained in that workbook in section 3.3.2.

Provision of drug consumption rooms

Due to the continuing very high-risk patterns of use of heroin and other illicit drugs, drug consumption rooms and low-threshold drug support facilities are important places for affected persons to go. In the drug consumption rooms, the drugs are brought by the drug users themselves. Infection prophylaxis is an intrinsic part of the service provided. Paraphernalia which the drug users bring with them to the consumption rooms may not be used. The aim of this service is the survival and stabilisation of the health of its users. This also applies in respect of immediate intervention in the case of overdoses. In addition, cessation orientated support can be offered to people with drug dependence who could not be reached otherwise. On the basis of Sec. 10a BtMG, which defines the minimum statutory requirements for such facilities, the governments of the *Laender* may pass regulations governing the issuing of licences to operate drug consumption rooms.

Currently, there are a total of 22 drug consumption rooms across 15 cities in six German *Laender* (Berlin, Hamburg, Hesse, Lower Saxony, North Rhine-Westphalia and Saarland) as well as two mobile drug consumption stations in Berlin¹³. In North Rhine-Westphalia and

¹² <http://www.akzept.org/uploads2013/NaloxonBroschuere1605.pdf> and <http://www.akzept.org/uploads1516/NaloxonJESnrw17.pdf> [Accessed: 21 Aug. 2018].

¹³ See also <http://www.drogenkonsumraum.net> [Accessed: 21 Aug. 2018].

recently in Saarland, the use of drug consumption rooms is also allowed for substituting clients; a first progress report with an overall positive evaluation is available from the Essen consumption room and was summarised in last year's workbook. Also, the results from a survey of drug consumption rooms carried out by mudra e.V. on services offered, patterns of use and user demographics were presented in detail in last year's workbook (Dammer et al., 2018).

New developments in the provision of drug consumption rooms in one other *Land* will be presented in section 3.3.3.

A regular survey on the utilisation and clientele of consumption rooms is also available for individual facilities which publish their annual reports on the internet. Data from Frankfurt am Main and NRW is reported below:

Frankfurt am Main

In the four Frankfurt consumption rooms, a total of 181,426 incidences of use were documented in 2016 (Stöver und Förster, 2017). 4,705 people used the consumption rooms, 84 % of those were male, 16 % female. The average age was around 39 years old and has therefore increased by six years over the last ten years (2006: 33 years old). The number of users has remained stable in recent years with slight fluctuations, the number of new users (first time consumption room use) amounted to 1,116 people in 2016 and 24 % of all users in that year. The average was 39 incidences of use per person, however the use frequency varies substantially among users and can be categorised roughly into quarters: one consumption room use (27 %), two to four times (24 %), five to twenty times (23 %) or more than 20 times (26 %). This distribution roughly corresponds to that of previous years.

In many incidences of use, more than one substance was consumed. 86 % of the documented incidences of use involved injecting use, 14 % did not. This amounts to an increase in non-injecting use by six per cent year on year; the authors attribute this to the opening of a room for inhalative use in 2016.

As in previous years, the use of heroin and crack predominated among injecting drug users. The most frequently injected was heroin in 2016 (45 %), followed by a mixture of heroin and crack (32 %) and crack on its own (21 %). Other substances used account for less than 2 % of the incidences of use. After the mixed use of heroin and crack markedly increased over several years, and in 2014 even occurred more frequently than heroin on its own, the combination has since become somewhat less frequently used.

The proportion of non-injecting instances of use (primarily smoking / inhaling the substance), which has been on the increase in recent years, rose considerably again to 14 % (2010: 3 %). Heroin and crack also predominated here and to a lesser degree the mixed use of both substances. Heroin on its own was smoked in around 36.2 % of the incidences of use and snorted in a further 21.6 % (nasal use). Crack was smoked in 33.5 % of cases, in 6.2 % of those it was a mixture of crack and heroin. Only 2.5 % of non-injecting incidences of use were accounted for by other substances.

North Rhine-Westphalia

In NRW in 2017, there were drug consumption rooms in ten cities with a total of 96 places (between three and 18, depending on city). 39 of these places are specifically for inhalation; six places a flexible, for inhaled or injecting use. One drug consumption room offers no inhalation places. The opening times vary between 20 and 73.5 hours per week; some consumption rooms are closed at weekends and / or public holidays.

There were a total of 248,208 instances of uses recorded in 2017. This number has increased over the last five years, with slight fluctuations (2013: 191,759 instances). The proportion of female instances of use has remained stable at 11 %. The average age of users has increased overall over the last four years.

Out of the male instances of use, opioid use accounted for 78 % in 2017, cocaine 16 % and 5 % for a mix of both substances. Amphetamine use was documented in 0.4 % of instances. Women use somewhat less often than men, but opioids remains the most frequently consumed (66 %), while cocaine use is somewhat more frequent (22 %) as well as mixed use of both substances (11 %). At 1.6 %, amphetamine use remains at a low level, however it has markedly increased compared to both of the previous two years (0.1 % each).

Inhaled use is today somewhat more frequently documented than injecting use (51 % versus 45.2 %). This year is the first time this has been the case for women while for men this development happened some time ago. As inhaled use is slightly less damaging to health, this development must be seen as positive. Nasal use was only documented for 3.6 % of the instances of use for men and 4.9 % of those for women; oral use was of no relevance.

There were 597 drug-related emergencies, within which first aid was administered in 326 cases. In eight cases, drug death was prevented through immediate resuscitation measures; emergency treatment was required in 146 cases. Moreover, further support services are offered in the drug consumption rooms. Medical support was provided in 24,499 cases (and thus significantly more frequently than in 2015, where it was 15,156 cases). Examples included vaccinations and wound care. Psychosocial interventions were given in 12,870 cases (e.g. counselling, crisis intervention etc.). This is around 1,000 more cases than two years previously (2015: 11,686 cases). Safer use counselling was carried out in 17,577 cases, counselling for obviously substituting patients in 2,640 cases (there is cross over here with "general" safer use counselling).

Referral to further support services took place in 18,414 cases in 2017; this number has significantly increased (2015: 10,099 cases). Of those, outpatient drug therapy outpatient clinics (5,529 referrals) and social support (5,101), were most frequently referred to, as well as drug counselling centres (2,928) and further medical support (2,040). Clients were placed in withdrawal treatment in 1,621 cases, and in 1,155 cases into substitution treatment (Landesstelle Sucht NRW, 2017).

Measures for the preparation of release from prison

A pilot project on the issuing of naloxone before release from prison could not be implemented as planned due to administrative barriers (DAH, 2018, personal communication). Further information on the measures for the reintegration of drug users after their release from prison and prevention of overdoses after release from prison can be found in the Prison workbook (Schneider et al., 2018).

Treatment of hepatitis C among drug users

Several newly authorised medicinal drugs now increase the chances of recovery from an HCV infection significantly and show a considerably improved side effect profile meaning that the infection, which is very widespread among drug users, is now more treatable than a few years ago. These new developments were reported in detail in the respective workbooks of 2015 and 2016. A recent study by Christensen et al. (2018) compared the effectiveness of HCV treatment between patients in opioid substitution treatment and people who were not in substitution treatment; this included people with current and / or previous drug use as well as people with no drug use. They came to the conclusion that the treatment outcomes of all groups with a success rate of at least 85 % are comparably very high.

The high price of the new medicinal drugs, which has been and still is vehemently criticised by many treatment providers and the specialist public, has not led to the expected "explosion" in treatment costs. In 2015 (right after its introduction), the costs were € 1.4bn., with around 22,000 people treated. Since then, the costs have hugely fallen, mainly due to the Law on the Reorganization of the Pharmaceutical Market (Arzneimittelmarktneuordnungsgesetz; AMNOG) which states a price regulation but also due to the dropping number of treated persons. In 2017 the costs amounted to just € 600m. The Central Research Institute for SHI Healthcare (Zentralinstitut für die kassenärztliche Versorgung, ZI) justified the number of people treated falling by saying that "it has been possible to cure increasing numbers of patients" (Ärztezeitung, 2018). With an estimated 300,000 infected people in Germany (BMG and Federal Ministry for Economic Cooperation and Development, 2016), the falling number of people treated is hardly due to a lack of patients, however¹⁴.

In its latest recommendations on therapy for hepatitis C, the bng cites intermittent drug use (as an indicator for increased risk of transmission) as a reason for initiating therapy as early as possible. In addition, it specifically points out that substitution therapy is not a reason for refusing therapy, as the therapy outcomes are also very good for this group of patients and the re-infection rates to date are acceptable, even if concomitant use is present. For this

¹⁴ The German Professional Association of Gastroenterologists in Private Practice (Berufsverband Niedergelassener Gastroenterologen e.V., bng) points out that the number of 300,000 infected people could represent an overestimation (Berufsverband niedergelassener Gastroenterologen e.V., 2017). Even if the number was to be halved (which would represent a very conservative estimate), this would still not mean that all or even nearly all infected persons in Germany were being treated.

group however, it is highly recommended (just as it is for gay men with an HIV co-infection) to carry out annual HCV-RNA follow-up tests, as these groups exhibit an increased risk of re-infection, according to several studies (Berufsverband niedergelassener Gastroenterologen e.V., 2017).

It is unclear, however, how many drug users, who make up the largest group of those with HCV in Germany, have actually received new medicinal drugs and accordingly were able to benefit from the described innovations. Prior to the introduction of the new medication, there were findings showing that this group are much less widely treated than infected persons with a different risk of infection. This is due to, amongst other things, a widespread negative attitude among doctors towards drug users (Gözl, 2014). Whether this attitude has changed with the introduction of the new medicinal drugs is unclear; those representing drug users' interests however report that the treatment of HCV, even among substituting patients, is seldom a matter of focus¹⁵. The ECHO study also recommended further expanding HCV treatment among substituting patients (see section 1.3.3).

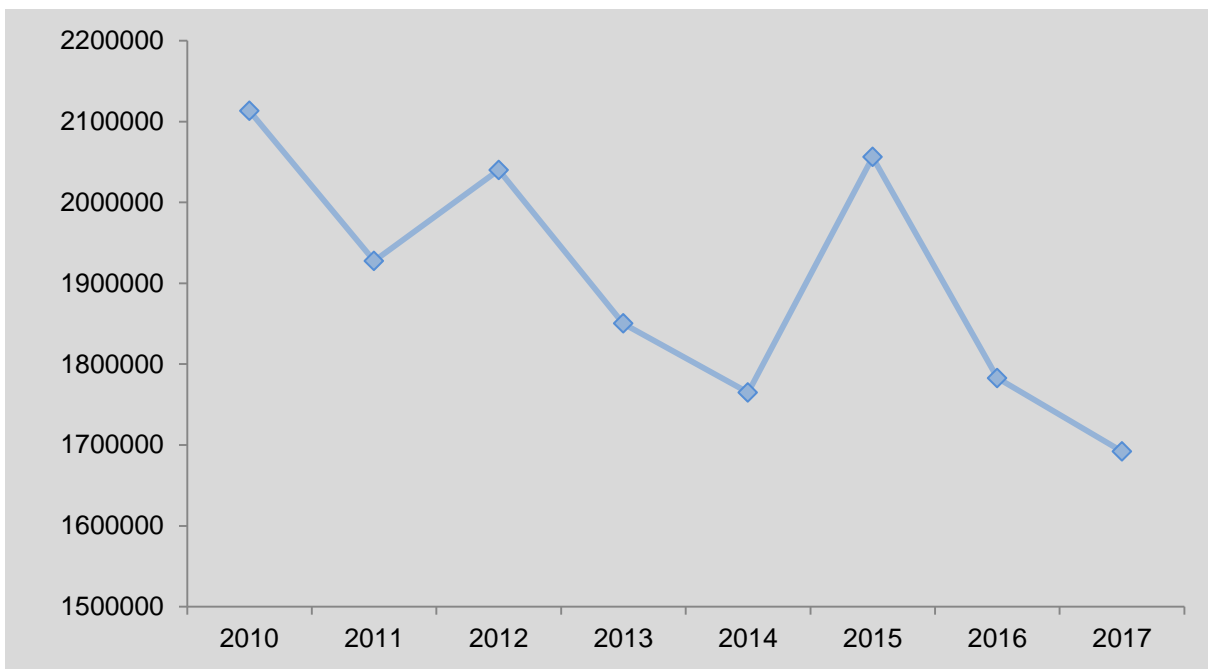
The implementation of both the BIS-2030 strategy and the recommendations from the DRUCK study could significantly further improve the health status of injecting drug users.

The annual World Hepatitis Day on 28 July aims to raise awareness of viral hepatitis. In 2018, the slogan was "Hepatitis: find the missing millions!", as a large proportion of people assumed to be infected are not aware of it. The focus of this year's World Hepatitis Day is therefore to find undiscovered patients in order to treat them early, save them from long-term effects and curb new infections.

1.5.4 Harm reduction services: availability, access and trends

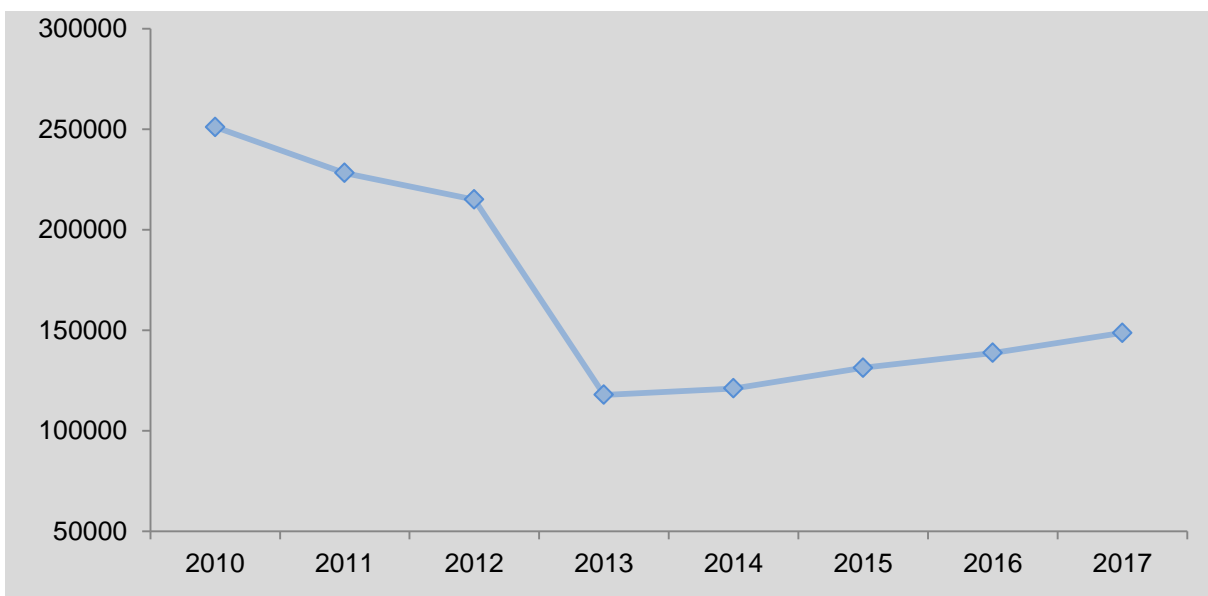
Since there is no nationwide data collected on the number of syringes issued, no national trends can be reported in this area. A regular survey is only carried out in North Rhine-Westphalia (AIDS Hilfe NRW e.V., 2018). Data is also reported from Munich, based on information obtained from three drop-in centres. No conclusions can be deduced for the country as a whole from the regional trends in North Rhine-Westphalia and Munich.

¹⁵ c.f. <https://magazin.hiv/2017/07/25/hepatitis-c-keine-heilung-fuer-alle/> [Accessed: 2 Aug. 2018].



(SAFER USE NRW, 2018)

Figure 9 Trend in syringes issued in projects in NRW, 2010 - 2017



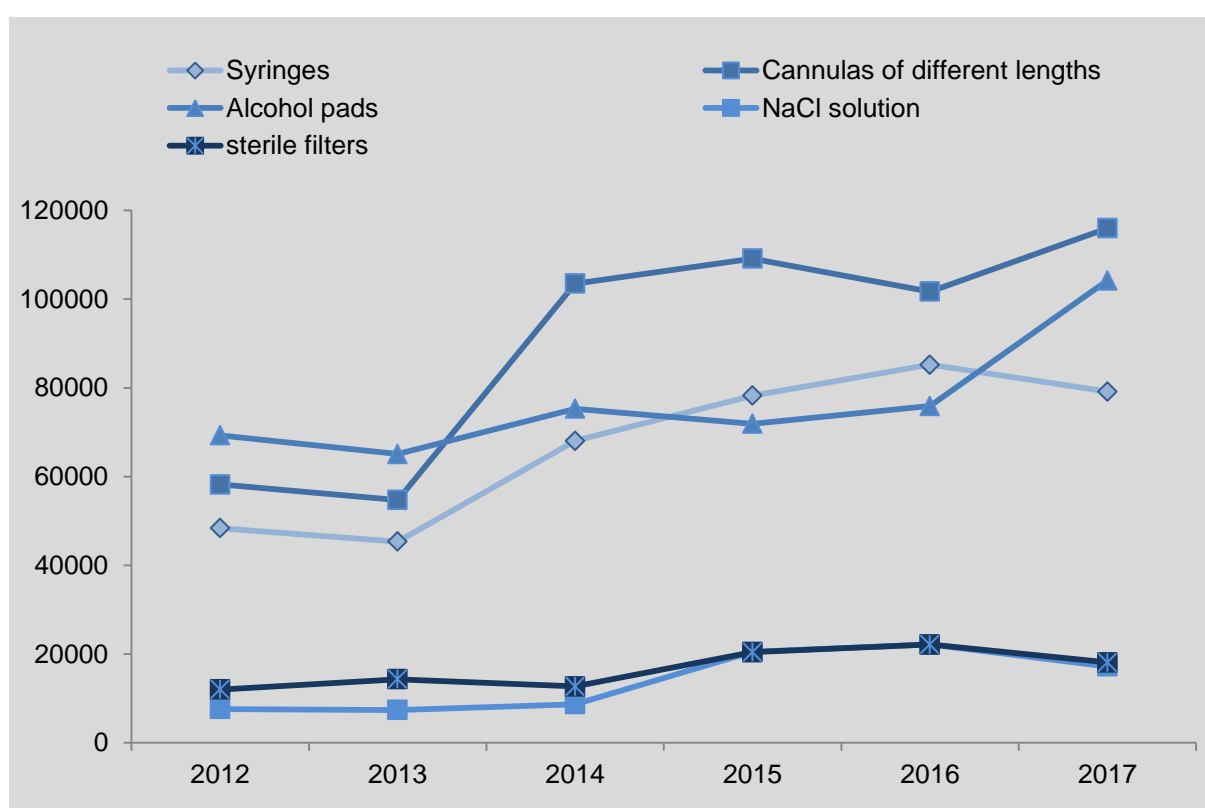
(SAFER USE NRW, 2018)

Figure 10 Trends in syringes issued by vending machines in NRW, 2010 - 2017

The trend in recent years shows a distinct uptick after 2012, both in syringes issued in the course of projects as well as syringes dispensed from vending machines (see Figure 9 and Figure 10). This cannot be explained by a strong reduction in demand, however, rather by the fact that since November 2012 a dispensed pack has contained only one syringe, one hollow needle, one filter and one alcohol pad rather than two disposable syringes and two hollow needles as had previously been the case. Moreover, more Smoke-it-Sets have been

handed out, whilst drug consumption rooms also report increased inhalative use (Aidshilfe NRW e.V. 2015, personal communication). Since this uptick, a slight increase can be seen in syringes dispensed by vending machines. The number of syringes issued in the course of projects fluctuates over time.

For Munich, data is available from three drop-in centres run by Condrobs e.V. Overall, the number of syringes dispensed since 2012 has significantly increased, in the last year however it has slightly decreased again (see Figure 11). The number of hollow needles of various lengths dispensed in 2017 was also significantly higher than 2012, as is the case for alcohol pads. At a lower level, the number of sterile filters and NaCl solution dispensed since 2012 has significantly increased, although the number dropped slightly in the last year.

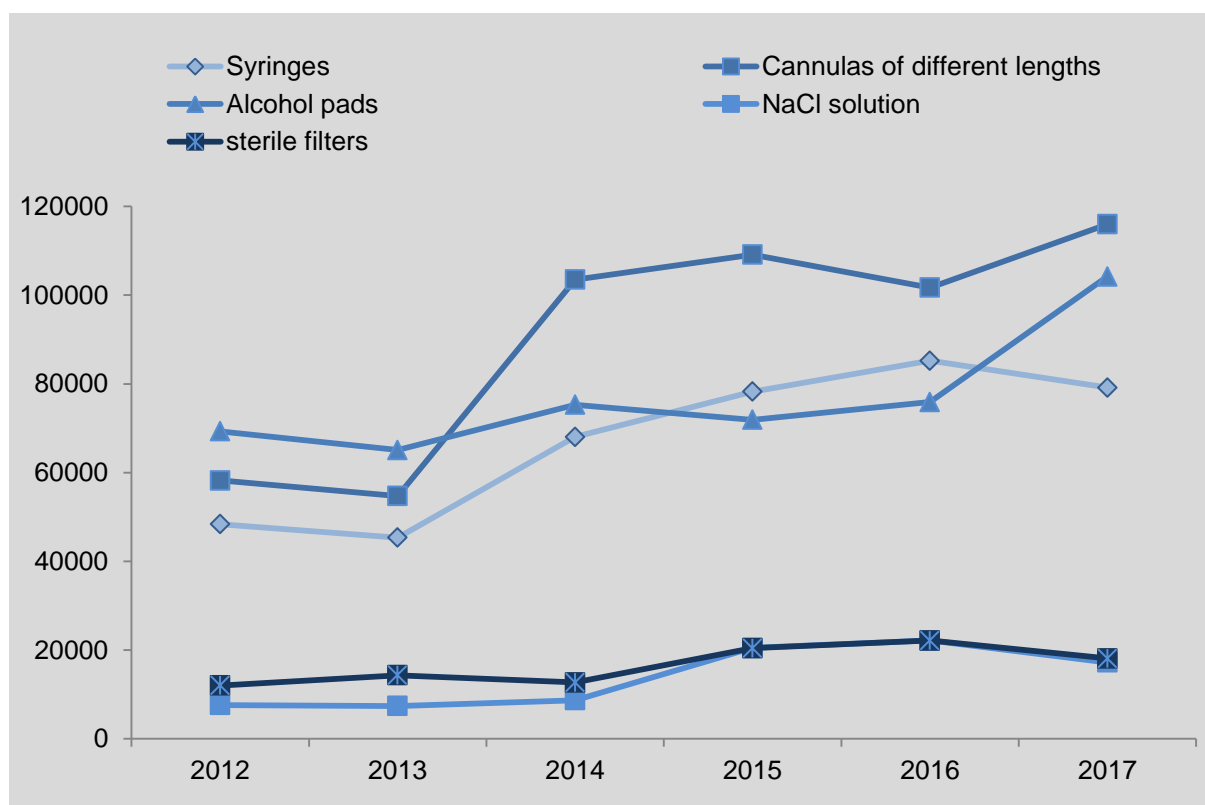


(Condrobs e.V., data delivery)

Figure 11 Trend in the issuing of consumption apparatus in Munich, 2012 - 2017

Looking at the syringes dispensed according to size (1ml, 2ml, 5ml and 10ml), it can be seen that the significant increase in recent years comes from both of the small syringe sizes (see Figure 12). The responsible organisation, Condrobs e.V., explains this massive increase, as well as the increase in the numbers of NaCl solutions and filters dispensed, with the significant rise in the injecting use of NPS, in particular the use of so-called bath salts. The number of 2ml syringes dispensed has slightly decreased in the last year; the reason for this is unclear. The organisation has observed, since around 2013, a change in use behaviour of those "classic" injecting drugs users towards more injecting use of NPS. According to clients'

reports, the period of effectiveness from injected NPS is very short. There are, for example, reports of users who had between 10 and 30 uses per day, which requires a high number of syringes to be used. The organisation attributes the decline in demand for 5ml and 10ml syringes with a lower use of fentanyl patches. According to reports from the scene it has become more difficult to obtain fentanyl patches; several clients report that their doctors have now stopped prescribing fentanyl (Condrobs e.V. 2017, personal communication).



(Condrobs e.V., data delivery)

Figure 12 Trend in the dispensing of different syringe sizes in Munich, 2012 - 2017

No conclusion can be drawn from the data for NRW and Munich regarding national trends in the issuing of consumption apparatus or the use preferences of users.

General information on services for harm reduction are detailed under section 1.5.3, new developments under section 3.3.

1.5.5 Additional information on harm reduction activities

No additional information is available on this.

1.6 Targeted interventions for other drug-related health harms

1.6.1 Targeted interventions for other drug-related health harms

There is currently no available information on this topic.

1.7 Quality assurance of harm reduction services

1.7.1 Quality assurance for harm reduction services

There are currently no binding national guidelines on the quality assurance of harm reduction services. Individual projects are, however, always evaluated. Several projects are presented in the "Best Practice" workbook.

1.7.2 Additional information on any other drug-related harms data

No additional information is currently available on this.

2 TRENDS

No longer in this section, contained in T1.

3 NEW DEVELOPMENTS

3.1 New developments in drug-related deaths and acute emergencies

The current situation and trends in the area of drug-related deaths are presented in section 1.1, the current situation and trends in the area of drug-related acute emergencies can be found in section 1.2. No other new findings are available.

3.2 New developments in drug-related infectious diseases

For the current situation regarding drug-related infectious diseases see section 1.3. With the introduction of new medicinal drugs, the chances of success of hepatitis C treatment have significantly improved also for drug users; the current situation is reported in section 1.5.3. New developments on prophylaxis in the area of infectious diseases is reported in section 3.3.1.

3.3 New developments in harm reduction interventions

3.3.1 HIV prophylaxis: Pilot transmittal-testing project and developments in pre-exposure prophylaxis

Pilot project "S.A.M. – my home test"

The S.A.M pilot project (developed by the Munich Aids Service Organisation and the DAH in collaboration with test providers) is underway in Bavaria¹⁶. The goal of the project is to reach

¹⁶ See <https://www.samtest.de/> [Accessed: 30 Aug. 2018].

more people for the earliest possible testing for sexually transmitted diseases. After online registration and an initial counselling session in person (possible in four locations in Bavaria) participants can order test kits, take the necessary tests themselves at home and then send them to a laboratory for evaluation. The test kits include HIV, syphilis, chlamydia and gonococci (the causative agent of "gonorrhoea"). Each kit costs € 32 and can be ordered every three, six or twelve months. Negative results are sent direct via text message, positive results are communicated by telephone. In the event of a positive result, an additional counselling session with a medical expert is available. The goal of enabling testing at home is to reach people in rural areas as well as people who do not want to go to an existing test centre due to shame or other reservation.

Pre-exposure prophylaxis: study on the distribution and preparation of payment as a reimbursable benefit

Pre-exposure prophylaxis (PrEP) is used as a precaution by people who are not infected with HIV but have an increased risk of infection.

The study "PrEP in Germany" (PRIDE) revealed that since the introduction of much cheaper generic medicines in October 2017, already around 4,500 people in Germany have used the preparation¹⁷. It remains the case however, that it is primarily above averagely educated and better off men who benefit from the medicines, which the study authors attribute above all to the proportionately high costs: generic medicines cost "only" € 50 - 70 per month (previously the price was over € 800), but additional costs of up to € 100 per month arise through regular doctor appointments and laboratory tests, so the less well-off were unable to afford this option.

The German Federal Minister of Health announced that he wanted to introduce PrEP as a service covered under health insurance for insurants with substantive risk for HIV-infection.¹⁸. This health benefit is intended to include medical counselling, the medication and (laboratory) analyses required for its application, so that those eligible for the benefit can use PrEP irrespective of income. The plan is for the umbrella association of statutory health insurance providers (gesetzliche Krankenversicherung, GKV) to negotiate with the National Association of SHI doctors (Kassenärztliche Bundesvereinigung, KBV). The declared objective is also to create a structured treatment service to ensure that the taking of the medication is regulated, and thus that the risk of possible resistance does not increase.

3.3.2 Naloxone take-home programmes

General information on the status of naloxone take home programmes in Germany is detailed in section 1.5.3. More detailed information on the individual projects was presented

¹⁷ <https://idw-online.de/de/news697176> [Accessed: 30 Aug. 2018].

¹⁸ <https://www.aerzteblatt.de/nachrichten/96593/HIV-Präexpositionsprophylaxe-soll-Krankenkassenleistung-werden> [Accessed: 30 Aug. 2018].

in the Harms and Harm Reduction workbook in the REITOX Report 2016 (Dammer et al., 2016).

In December 2017, the drug support centre in Saarbrücken implemented a new project dispensing naloxone, funded by the *Land* initially for two years. The structure and content of the training sessions are strongly based on the already successfully running projects in Munich and Berlin. The plan is to equip up to 50 drug users with naloxone every year. After the project had been running for around six months, 23 people had taken part in the training; during this time, two reports of the successful deployment of naloxone were reported back (Drogenhilfezentrum Saarbrücken, 2018, personal communication).

As it stands, the planned Bavarian pilot project will start in autumn 2018. After the original decision by the Bavarian Landtag (*Land* Parliament) included at least two cities (Nuremberg and Munich), the current planning is for five cities. As well as Nuremberg and Munich, these will include Augsburg, Ingolstadt and Regensburg. The target is that 400 drug users will be reached (Condrobs e.V., 2018).

3.3.3 Improving care with drug consumption rooms

It currently looks likely that Baden-Württemberg will soon pass an ordinance governing the operation of drug consumption rooms, becoming the seventh *Land* to do so, and thus will be able to open consumption rooms there. The adoption of the regulation is expected for the end of 2018 / beginning of 2019 and is intended to be restricted to three years initially. The opening of a drug consumption room will probably only be permitted in cities with more than 300,000 inhabitants. This means that initially three cities in this *Land* will be considered. In Karlsruhe, plans to open a drug consumption room under the ordinance are already well advanced; the city's municipal council has already voted for the opening¹⁹. In Mannheim, the city is currently reviewing the opening of a drug consumption room²⁰.

Saarland has officially opened up its drug consumption room in Saarbrücken to substituting users, the second *Land* to do so after North Rhine-Westphalia. Fechner (2017) has described the initial experiences from North Rhine-Westphalia for a drug consumption room in Essen. The author suspects that substituting patients were already using the consumption room even before it was opened up and drew positive conclusions, as now the risks of substitution and simultaneous drug use could be discussed transparently with the users, now there was legal certainty for the operators and networking between consumption room operators and doctors was possible. In Saarbrücken, the largest intercity provider of supplemental psychosocial care for substitution treatment provides a soup kitchen twice a week at the location of the drug consumption room, thus demonstrating that Fechner's idea of closer networking between the individual providers does seem to be possible.

¹⁹ https://www.rnz.de/politik/suedwest_artikel,-einmuetige-entscheidung-karlsruher-gemeinderat-beschliesst-ersten-drogenkonsumraum-in-baden-wuerttember-arid,354183.html [Accessed: 30 Aug. 2018].

²⁰ https://www.rnz.de/nachrichten/mannheim_artikel,-mannheim-stadt-prueft-drogenkonsumraum-arid,374931.html [Accessed: 30 Aug. 2018].

4 ADDITIONAL INFORMATION

4.1 Additional sources of information

There is currently no data available from additional sources of information.

4.2 Further aspects of drug-related harms and harm reduction

No additional information is currently available on the health effects.

5 SOURCES AND METHODOLOGY

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5.2 Methodology

5.2.1 Recording drug-related deaths

In Germany, there are two general, comprehensive systems for recording cases of drug-related deaths, which differ from one another in various aspects. These are the police data from the "Drugs data file" (Falldatei Rauschgift, FDR) and the "Statistical report on the causes of death" (Todesursachenstatistik) from the German Federal Statistical Office.

Drugs Data File (Falldatei Rauschgift, FDR)

In general, drug-related deaths are recorded by the individual *Land* Offices of Criminal Investigation (Landeskriminalämter), whilst the Federal Criminal Police Office (Bundeskriminalamt, BKA) has access to the base of data, performs data quality control and summarises the figures. Data collection modalities and the basis for the assessment of drug-related deaths differ between the individual *Laender*. The proportion of autopsied drug-related deaths as a measurement for the quality of the classification as "drug-related death" ("Drogentote") varies (in some cases considerably) between the *Laender*. The toxicological examination of body fluids and tissue plays an important role in establishing the cause of death, as only this can provide sufficient information on the drug status at the time of death. Autopsies and toxicological reports are usually produced by different institutions. Since the latter in particular are often only available after a long delay, they are only taken into account in the classification of drug-related deaths to a limited extent.

In order to facilitate the recording of drug-related deaths and reduce errors, the following categories for drug-related fatalities were defined in a leaflet by the BKA (BKA, 1999):

- Deaths caused by unintended overdose,
- Death as a result of damage to health (physical decline, HIV or hepatitis C, organ weakness) caused by long term drug abuse (= "long term harm"),
- Suicide out of despair over one's own living conditions or under the influence of withdrawal symptoms (e.g. delusions, strong physical pain, depressive mood),
- Fatal accidents of persons under the influence of drugs.

General Mortality Register²¹

In Germany, a death certificate is completed for every case of death, containing, alongside the personal details, information on the cause of death. The death certificate is passed on to the health authority and then to the *Land* Statistical Office. Aggregation and evaluation at national level is undertaken by the German Federal Statistical Office ("Statistical report on the causes of death"). Often, this data source also does not take into account the results of delayed toxicological reports when classifying the drug-related deaths.

From the general mortality register, for the purposes of reporting to the EMCDDA, cases are selected which meet the definition of "direct causality". The goal here is to record cases of death, as sensitively as possible, which shortly follow the use of opioids, cocaine, amphetamine (derivatives), hallucinogens and cannabinoids, – i.e. in particular fatal poisonings. The selection is based on the specifications of the EMCDDA (the so-called ICD-10 Code Selection B). As a basis for assignment to the group of drug-related deaths, the assumed underlying disorder (ICD10-codes F11-F19) or the assumed cause of death in the case of accidents and suicides (ICD10-codes X, T, and Y) is used respectively. This means that long-term secondary diseases, accidents not directly caused by poisoning and suicides are not covered by this definition, although individual cases of this type presumably may indeed be included due to erroneous death certificates or coding errors. In 2006 new coding rules of the World Health Organization (WHO) entered into force. The objective of the change was to code, instead of the F1x.x codes, the acute cause of death where possible, namely the substances on which the intoxication was based. In Germany, the new coding has, however, not yet had an effect in respect of the desired increase in specificity, meaning that many F-codes still exist.

5.2.2 Notifications of drug-related infectious diseases

Under the IfSG, which came into force on 1 January 2001, data on infectious diseases, including on HIV and viral hepatitis, are reported to the Robert Koch Institute, RKI. Corresponding data is published at regular intervals²². According to the German Ordinance on Laboratory Reports (Laborberichtsverordnung) and the IfSG, all laboratories in Germany are obliged to report confirmed HIV-antibody tests anonymously and directly to the RKI. These laboratory reports are completed by supplementary anonymous reports from the attending doctors. In this way, HIV reports ideally contain information on age and gender, town / city of residence, route of transmission of the infection as well as information on the stage of the disease and HIV related basic laboratory parameters. In addition, the AIDS-Case-Register collects together epidemiological data on diagnosed AIDS cases in anonymised form, based on voluntarily reports by the attending doctors. Due to changes in

²¹ The use of the term "General Mortality Registry" is based on the terminology of the EMCDDA. The data reported here is from the "Statistical report on the causes of death" of the German Federal Statistical Office (Special series 12, part 4).

²² <http://www.rki.de> [Accessed: 20 Aug. 2016].

the collection of data regarding new HIV-diagnoses, it is now easier to exclude (formerly unrecognised) duplicate entries.

Since the introduction of the IfSG, data on possible modes of transmission of HBV and HCV has also been collected. This is done by the health authorities, which investigate the case persons themselves, or on the basis of data passed on by the reporting laboratories and doctors. The current data is published by the RKI in the "Yearbook – Infection epidemiology of notifiable infectious diseases" (Infektionsepidemiologisches Jahrbuch meldepflichtiger Krankheiten) or respectively in the Epidemiological Bulletin of the RKI.

Since 2007, the DSHS in Germany has included data on the HBV and HCV status of patients in addition to the HIV status. Since the number of facilities which report this data is very small and only patients for whom a test result is available are taken into account, this data requires cautious interpretation. The new core data set was collected for the first time this year, in which the recording of infectious diseases was improved. The first data will be available in 2018.

Changes to the case definition of hepatitis B reports

The case definitions of the RKI were changed in 2015, such that now only the direct detection of the hepatitis B pathogen meets the criteria for a laboratory diagnostic detection. HBe antigen detection has emerged as a confirmation test for HBs antigen detection. The anti-HBc IgM antibody detection, which, according to the case definition up to 2014, was sufficient as an isolated serological marker to fulfil the laboratory diagnostic criteria of the case definition, is no longer used and is only collected as additional information. Among the cases, which were recorded according to the new case definition, now not only cases confirmed through clinical and laboratory diagnostics but also infections established through laboratory diagnostics alone, for which the clinical picture is not fulfilled or not known, meet the reference definition. The described changes not only enable an alignment with the European case definitions but also aim to investigate active, i.e. infectious and therefore transmissible, hepatitis B infections, regardless of the strength of the symptoms. Following the introduction of the new reference definition, the number of published hepatitis B cases is, as expected, higher than previous years.

Changes to the case definition of hepatitis C reports

As it is barely possible from a laboratory diagnostic or a clinical perspective to distinguish between acute and chronic HCV infections, all newly diagnosed infections are included in the statistics of the RKI. Cases for which an earlier HCV laboratory test already exists, are excluded. Thus, the total number of recorded cases contains a considerable percentage of already chronic hepatitis C cases (in the sense of a virus replication of more than 6 months).

The case definition for hepatitis C was changed on 1 January 2015 in respect of the criteria for the laboratory diagnostic proof. In the estimation of the RKI, the previous case definition, according to which (confirmed) antibody detection on its own was sufficient, led to the reporting of infections, in an unknown proportion of cases, which had already been

spontaneously cured or been successfully treated and moreover to an unknown number of multiple reports. Only cases with a direct pathogen detection fulfil the new case definition (nucleic acid detection or HCV core antigen detection). Therefore, the reporting of the RKI, now only analyses HCV infections which are active. This enables a better approximation of the true incidence of new diagnoses. However, it does not capture possible cases that were not supplied to further diagnostics by means of direct pathogen detection after positive antibody screening. As the treatment options in recent years have significantly improved, it can however be assumed that diagnostics in Germany is carried out completely in most cases. Currently, initial diagnoses of hepatitis C transmission - without better data sources on the incidence rate - provide the best possible estimation of the current incidence of infection.

Under the new case definition however, current transmitted case numbers are only comparable to a certain degree to those from previous years, so trend evaluations are only possible to a limited extent. A decrease in the reported numbers of cases occurred as expected due to the change in case definitions. The implementation of the new case definition among public health authorities can be considered to be largely complete; in 2017, only 2.2 % of all cases were still recorded according to the old case definition (2016: 21 %, 2015: 70 %).

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