



Bundesärztekammer
Arbeitsgemeinschaft der deutschen Ärztekammern

Review of the German OST guidelines

- Legal framework, contents, and perspectives -

TAIEX Workshop on drug substitution treatment programmes
– 26./27. Sept. 2012 in Zagreb(Croatia) –



- 1. Statistical data to the current situation of OST in Germany**
- 2. How did OST start in Germany?**
- 3. Legal framework of OST in Germany**
- 4. Guidelines of the German Medical Association (BÄK):
what is / not covered / what is new?**
- 5. Further developments / what is needed?**



Extent of problem drug use in Germany

Illegal drugs	Estimates on problematic drug use
Heroin	@ 150-180.000
Cocaine	
Amphetamine	@ 50-70.000
other synthetic drugs	
Cannabis	@ 600.000
Σ	@ 800.000 1 / 100



Onset of Opiate Substitution Treatment (OST) in Germany

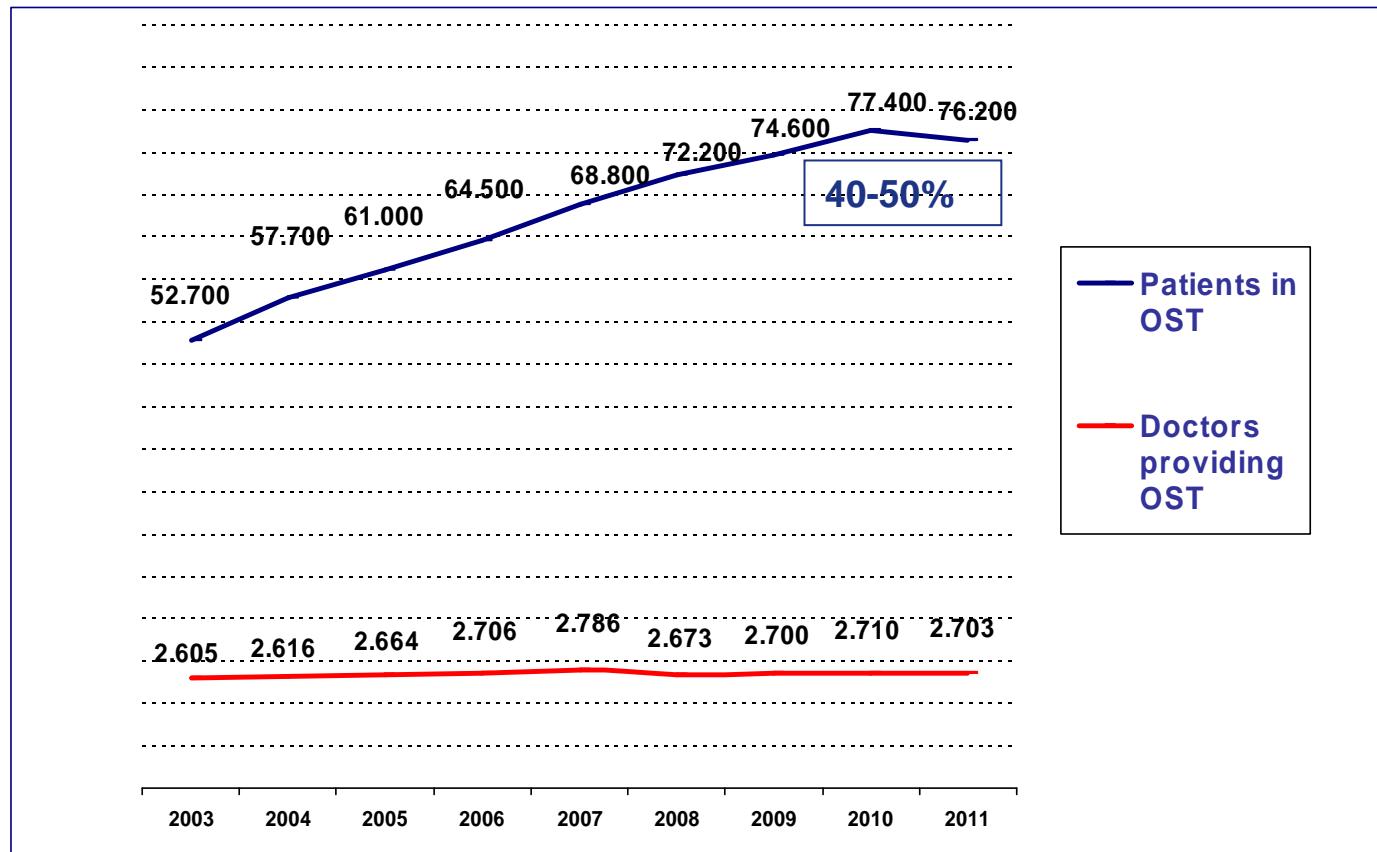


Germany:
81.8 Mio. inhabitants
357.000 qm₂
87% covered by
statutory health insurance

Croatia:
4.5 Mio.
56.540 qm₂

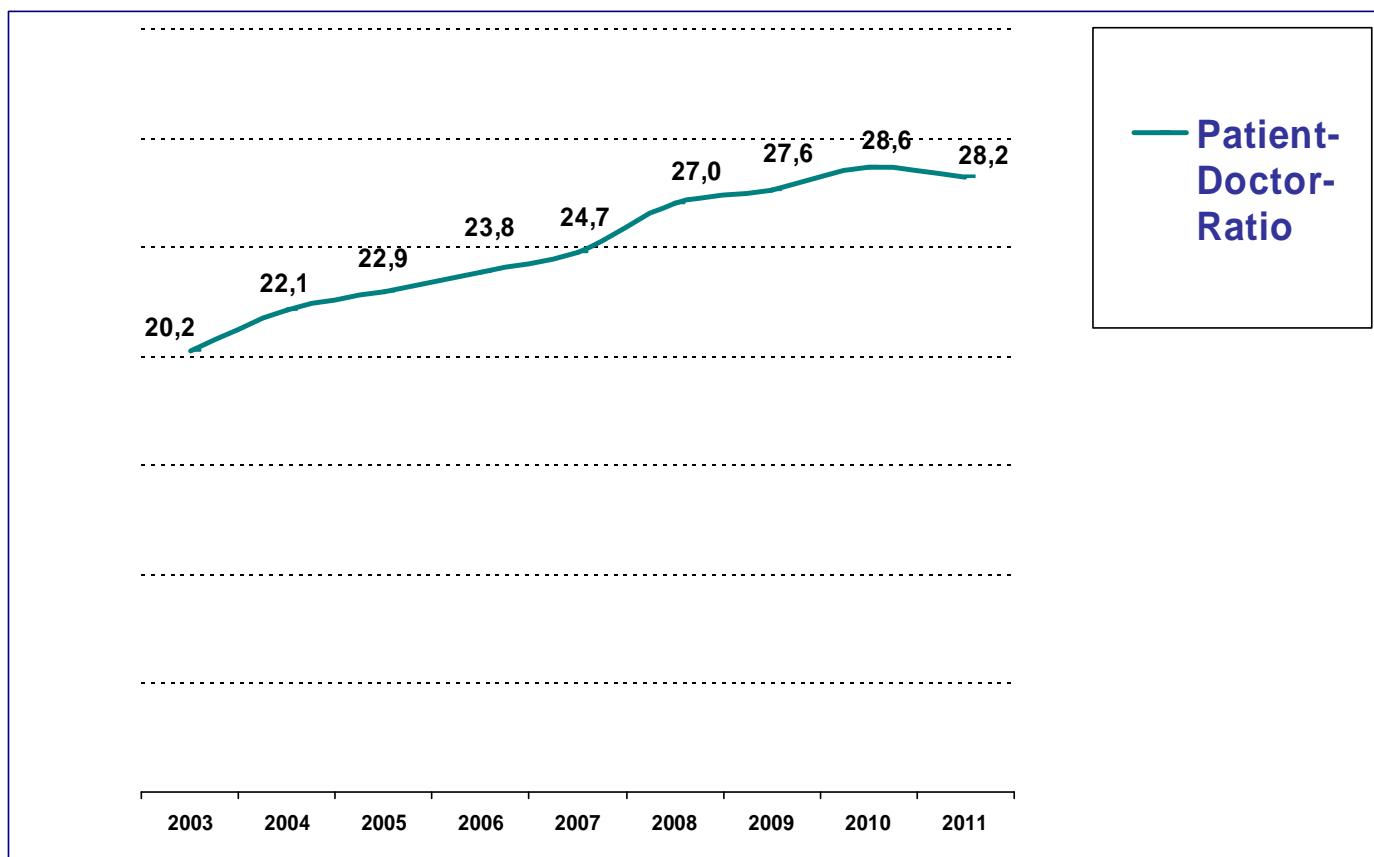


Data on Opiate Substitution Treatment in Germany



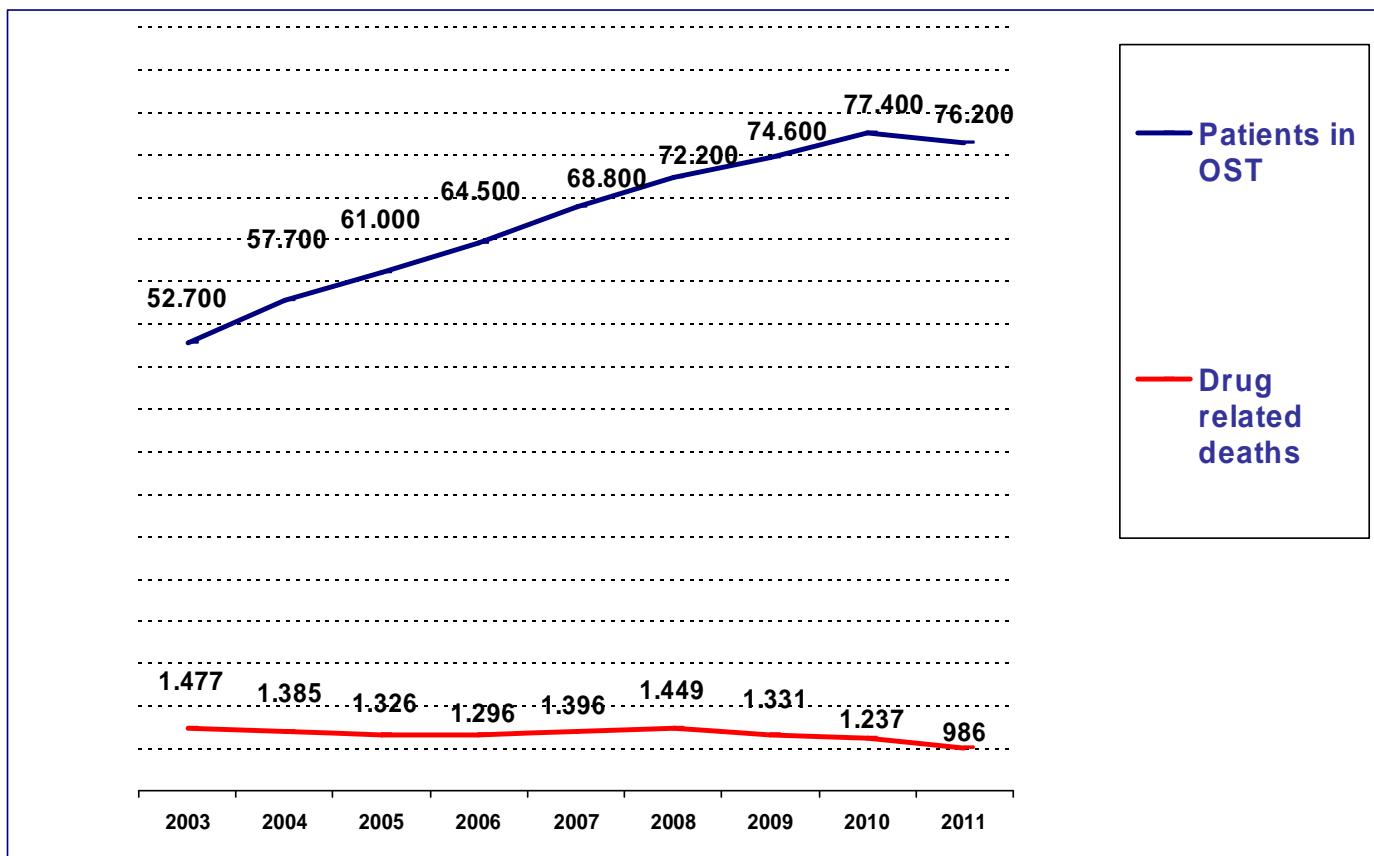


Patient-Doctor-Ratio in OST





Drug related deaths in Germany





Legal Framework of OST in Germany

Narcotic Drugs Law (BtMG)

(3 classifications of narcotic drugs)

Narcotic Drugs Prescription Code (BtMVV)

Guidelines of the German Medical Association (BÄK-RL)

Guidelines for treatment under Statutory Health Insurances (MvV-RL)



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Narcotic Drugs Law (BtMG)

(3 classifications of narcotic drugs)

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Narcotic Drugs Prescription Code (BtMVV)

Purpose of OST:

1. Treatment of opiate addiction in order to achieve abstinence
2. Treatment of a serious disease accompanying opiate addiction
3. Reduction of risks of opiate addiction during a pregnancy or after birth



Narcotic Drugs Prescription Code (BtMVV)

Prerequisites for patients and doctors to participate in OST

1. Patient has been registered with the Federal Opiate Register
2. The physician is the sole source for OST
3. Doctor provides proof of his qualification for OST
4. OST is not contraindicated by another medical condition
5. OST includes needed psychiatric or psychotherapeutic treatment and psychosocial counselling
6. Patient complies with required treatment-elements as listed under 5.)
7. Patient does not consume other substances jeopardizing OST
8. Patient does not misuse prescribed opiates
9. Patient complies with required medical appointments, usually 1x/week



Narcotic Drugs Prescription Code

Approved OST-medication:

- Levomethadon
- Methadone
- Buprenorphine
- other approved medication for OST
- Codein / Dihydrocodein as a 2nd-line medication
- Diamorphine
 - for a subpopulation of heavily opiate dependant patients



Narcotic Drugs Prescription Code (BtMVV)

Mandate of the GMA for regulation

- to define certain aspects of OST
- to reflect the current state of medical science

(BtMVV §5 (11))



Narcotic Drugs Law (BtMG)

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NDPC-mandate for GMA guidelines

Determination of

- medical conditions contraindicating OST BtMVV §5 (2) 1.
- concomitant drug use jeopardizing OST BtMVV §5 (2) 4.c
- appropriate OST-medication BtMVV §5 (4)
- needed psychiatric or psychotherapeutic treatment and psychosocial counselling BtMVV §5 (2) 2.

Assessment of treatment process
regarding take-home prescription

BtMVV§5 (8)

Establishment of standards for treatment-documentation

BtMVV §5 (10)

To set a minimum-standard for physicians` OST-qualification

BtMVV §5 (2) 6.



Revised GMA-Guidelines 2010: General Considerations

- Evaluation of regulations according to current state of medical science
- Consideration of the legal framework
set by the German BtMG, BtMVV and AMG
- Balance quality vs. quantity of care
- Balance doctor's freedom of treatment choices
vs. society's interest in drug control
- Discrimination between general guidelines according to NDPC
and elaborated treatment-guidelines



Treatment Goal

Revised GMA-Guidelines – 2010

Treatment goals and levels are

- ensuring patient's survival
- reducing consumption of other substances
- stabilization of patient's health and treatment of accompanying diseases
- social and professional participation
- abstinence

Former GMA-Guidelines – 2002

Primary goal of OST is abstinence to be accomplished by:

- *ensuring patient's survival*
- *stabilize patient's health and social well-being*
- *professional rehab and social reintegration*



Requirements for participation of patients in OST - contraindicating conditions and concomitant drug use

Revised GMA-Guidelines – 2010

- Diagnosed opiate addiction according to **ICD F11.2**
- Symptoms have been present for at least **a year**
- Concomitant drug use has to be considered and treated **regarding its extent**
- When comorbid substance-disorders exist, **no additional hazards** should be caused by OST

Former GMA-Guidelines – 2002

- *Diagnosed opiate addiction according to international convention*
- *Symptoms have been present for **at least two years***
- *Concomitant drug use has to be considered and treated before initiation of OST*
- *If other substance-disorders are prevalent, **OST cannot be initiated***



Requirements for participation of doctors in OST

Revised GMA-Guidelines – 2010

- 50-h curriculum on substance abuse
- Additional 6-h curriculum to qualify for OST with diamorphine

Former GMA-Guidelines – 2002

- *50-h curriculum on substance abuse*



Needed psychosocial counselling (PSC)

Revised GMA-Guidelines – 2010

- PSC according to **standards** of counselling agencies
- Mode and extent of counselling regarding patient's individual situation and course of disease,
- **OST also possible without PSC** to bridge treatment gap or avert health hazards,

5. Oktober 2012

Former GMA-Guidelines – 2002

- *Extent of counselling* regarding patient's individual situation and course of disease,
- *PSC has been proven to be useful and therefore is necessary*



Take-home-Prescription

Revised GMA-Guidelines – 2010

- **Deletion of all deadlines,**
- **Preconditions for Take-home:**
 - stable OS-dosis
 - stabilized health condition
 - minimized risks for personal healths and health of others
 - concomitant use of substances has been stabilized and does not jeopardize OST
 - progressed psychosocial reintegration
 - weekly doctor consultation and urine drug screening are recommended

Former GMA-Guidelines – 2002

- *in OST for at least 6 months,*
- *for at least 3 months without dangerous concomitant use of other substances,*
- *weekly doctor consultation and urine drug screening are recommended*



Screening of concomitant drug use

Revised GMA-Guidelines – 2010

- Urine drug screening before initiation of OST
- Obligation for random unannounced urine drug screening **cancelled**

In case of positive drug testing:

- **Adjust dosis** according to concomitant drug use
or omit OST,
- **Analyze and treat reasons for** comorbid consumption of drugs

Former GMA-Guidelines – 2002

- *Urine drug screening before initiation of OST*
- *Obligation for random unannounced urine drug screening,*
- *no OST if concomitant drug use is hazardous*



Treatment cessation

Revised GMA-Guidelines – 2010

- **Normal cessation** based on mutual agreement of doctor and patient
- Cessation as a result of **failed treatment**
 - OST proved inappropriate
 - Continuing hazardous concomitant drug use
- Lack of cooperation
 - threat of violence against doctor or patients
 - trading with substances
 - missing doctor's or PSC-appointments
 - refuses controls
- Cessation as a **last means**

Former GMA-Guidelines – 2002

- *Criteria for cessation are:*
 - *Continuing hazardous concomitant drug use*
 - *lack of cooperation*
 - *trading with substances*
- *Cessation only if other interventions of doctor or PSC failed*
- *Patient has to be informed about consequences*
- *Transferral to other doctor or detox clinic should be considered*



OST with Diamorphine

OST with Diamorphine was legalized in 2009

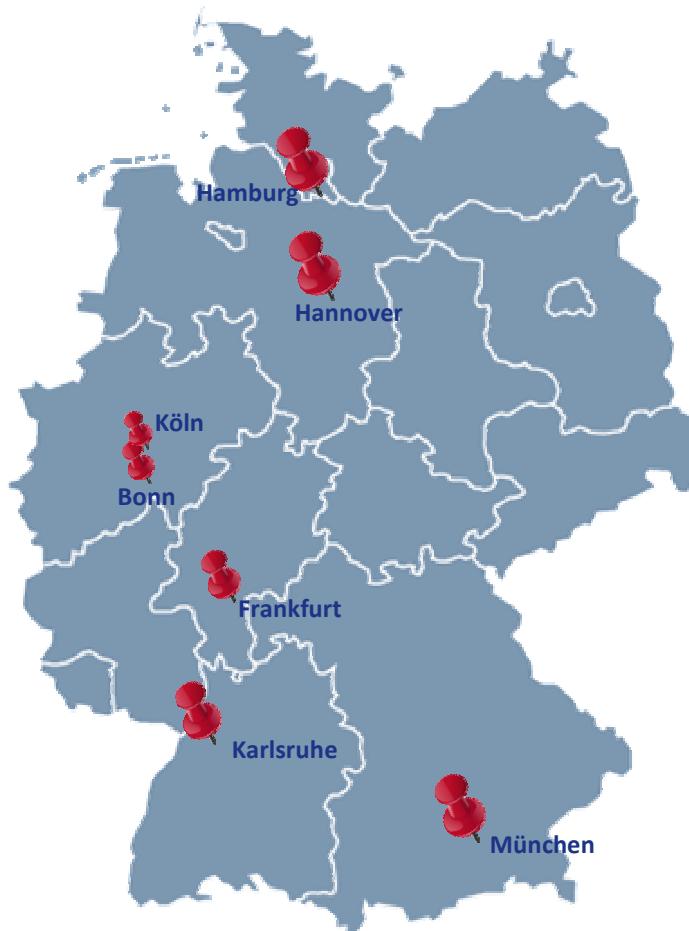
Criteria for OST with Diamorphine

- according to NDPC - BtMVV(§5, Abs. 9a-d) :
 - minimum age of 23 years
 - opiate addiction exists for more than 5 years
 - serious somatic or mental disorders accompanying opiate addiction
 - proof of at least 2 unsuccessful treatment attempts of opiate addiction
 - one with another OS-medication for at least 6 months
 - including psychosocial counselling
 - treatment only in licensed centers
 - i.v. application of diamorphine
 - Psychosocial counselling for at least 6 months
 - Review of treatment every 2nd year



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Centers für OST with Diamorphine (331 Patients - Stand: 31.12.2009)





Documentation and Quality Assurance

Revised GMA-Guidelines – 2010

Internal Quality Assurance:

- secure diagnosis
- set up an individual therapy plan
(define and quantify goals, ongoing control of results , define needed PSC, set urine drug controls, criteria for treatment cessation)
- Recommendation for ASTO-
Handbook for internal Quality management

External Quality Assurance:

- State Chambers of Physicians have to establish Drug-Commissions
- Cooperation with QA-controls of Statutory Health Insurance System

Former GMA-Guidelines – 2002

Internal Quality Assurance:

- secure diagnosis
- set up an individual therapy plan
(define and quantify goals, ongoing control of results , define needed PSC, set urine drug controls, criteria for treatment cessation)

• Recommendation for ASTO- Handbook for internal Quality management

External Quality Assurance:

- *State Chambers of Physicians can establish Drug-Commissions*
- *Cooperation with QA-controls of Statutory Health Insurance System*



Open topics

- Abstinence-paradigm in OST
- Quantity of OST-doctors and availability of OST
- Dispensing of narcotic drugs
- Punishment for violations
- Take home medication for parents with children
- Standards for PSC
- ageing population
- OST in prisons



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Thank you for your attention !



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Narcotic Drugs Prescription Code

OST with Diamorphine:

- Patient >23 years old
- opiate addiction for more than 5 years
- serious accompanying somatic or mental disorders
- proof of at least 2 unsuccessful treatment attempts of opiate addiction
 - one with another OS-medication for at least 6 months
 - including psychosocial counselling
- treatment only in licensed centers
- i.v. application of diamorphine
- Psychosocial counselling for at least 6 months
- Review of treatment every 2nd year



Narcotic Drugs Prescription Code

Practical application of OS-medication to patients conducting of treatment in a doctor`s office

- Medication can only be dispensed by doctor, his substitute or instructed medical personnel for immediate consumption



Narcotic Drugs Prescription Code

Prerequisites of a „Take-home-prescription“:

- Maximum period of 7 days,
- Patient`s condition is stabilized:
 - no concomitant consumption of other substances jeopardizing OST
 - stable daily dosis
 - no misuse of other substances



Narcotic Drugs Prescription Code

OST in Prison:

Extent of intramural OST:

- 3 – 10% of opiate addicted inmates (estimations)

GMA-Guidelines

- low dosis after incarceration according to tolerance-level
- when switching to a different treatment setting, continuity of treatment has to be guaranteed
- Drug-commissions of State Medical Chambers set and control quality standards