

# **The German National Medication Plan – A Tool to Improve Medication Safety**

**Prof. Martin Schulz, PhD, FFIP, FESCP**

Bonn, 29 March 2017



**Patient Safety**  
Global Ministerial Summit 2017

# Rationale for Medication Management

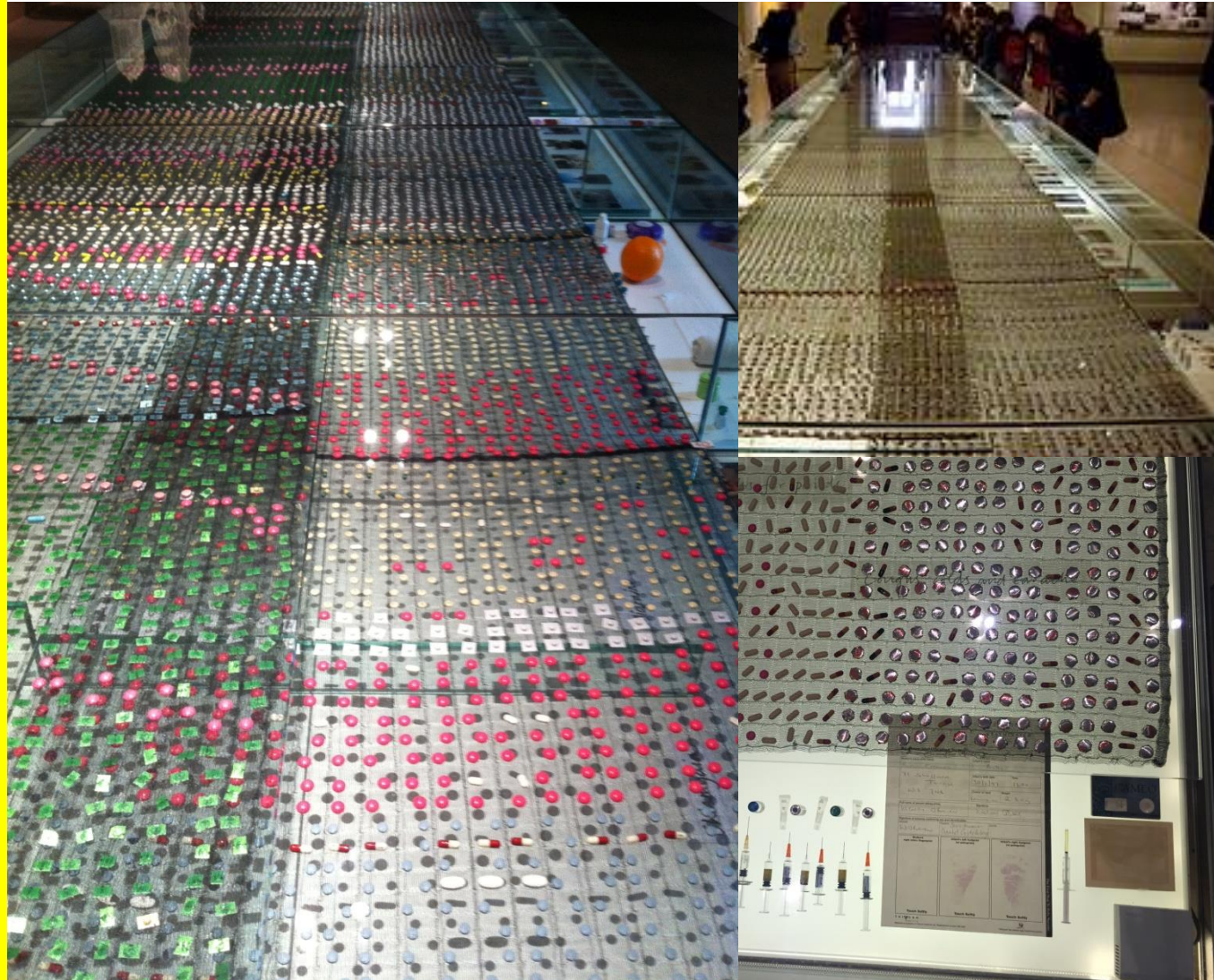
(Cradle to Grave Pharmacopoeia, British Museum)

**N = 14,000**

**Estimated number  
of prescribed doses  
to every person in  
Britain over their  
lifetime.**

**Interpretation:  
Appr. 7.7 years  
polypharmacy  
(defined as  $\geq 5$   
medicines per day)**

**+ OTC !**



# Challenges Medication Safety (Data 2015)

Results:

- 5% hospitalisations by ADE/ADR
  - at least 25% avoidable
- In Germany:
- 250,000 hospitalizations by avoidable medication errors (ME)
  - Costs: >1bn €

**879M Rx**

8M prescribing errors (1%)

(Self-) **Diagnosis**

- 44.6bn € drug turnover pharmacies
- **Potential savings:**
  - > 1bn € avoidable ADR/ME
  - > 10bn € non-adherence

**Dispensing**

Patient:


- Adherence 50%
- 72% w/o yearly med safety check
- >37% OTC

**Non-adherence**  
50% of chronic Rx

**+ OTC =  
526M  
packs**

- 14M dispensing/counselling errors (1%)
- In 94% of med safety checks need for modifications

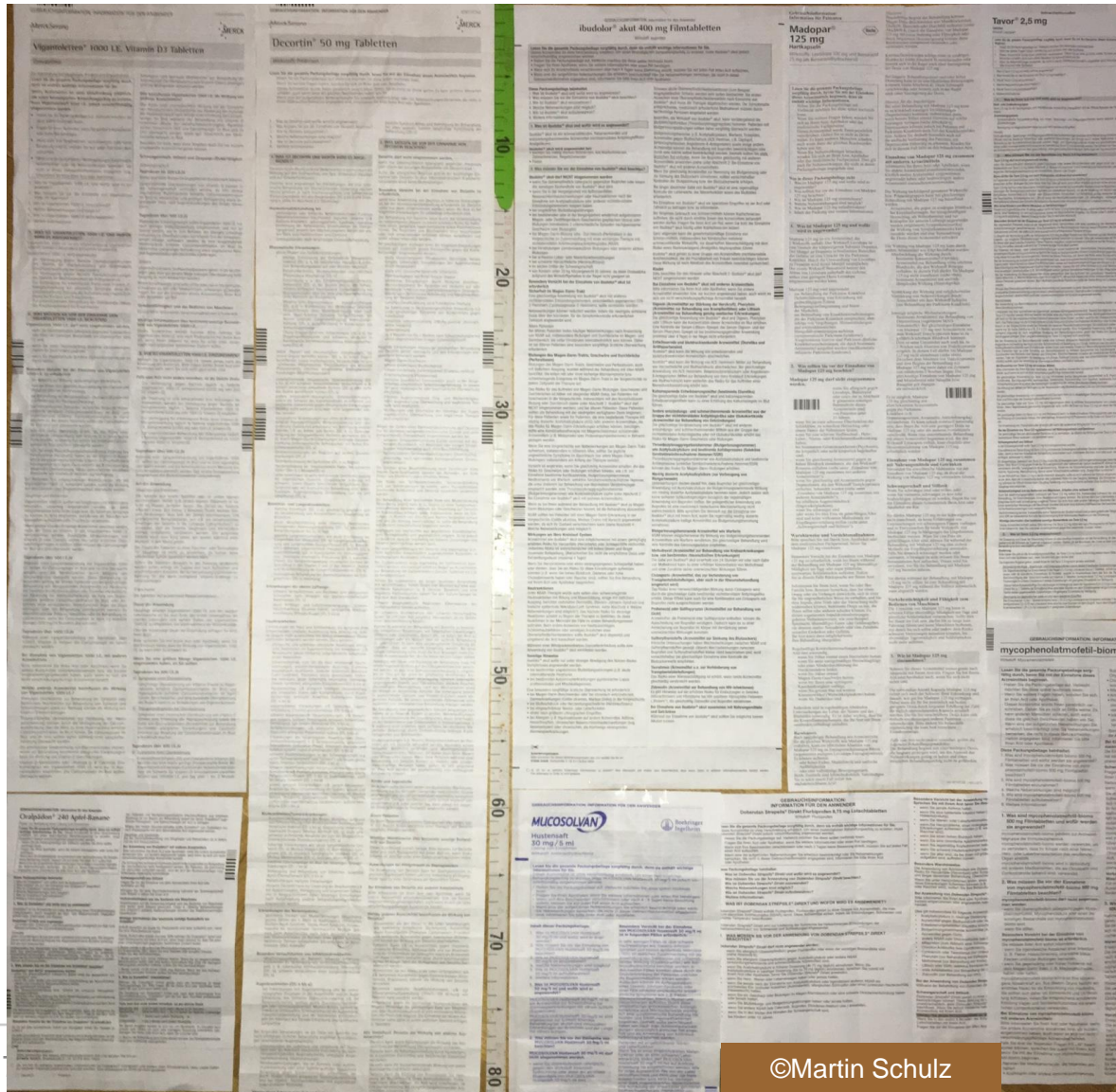
## AOK Northeast, 1–6/2015 in %



	5 – 9	10+ medicines
Berlin	61,1	18,0
Brandenburg	64,3	18,9
Mecklenburg-Vorpommern	68,0	22,6



# At first: let's read the package inserts of my 12 medicines ...



GEB.

	MEDIKAMENTIERUNG	MO.	MF.	AB
1.	ASPIRIN-PROTECT-100 mg	—	1	—
2.	SIMVABETA-40 mg	—	—	1
3.	RAMIPRIL-1A PHARMA-2.5 mg	1	—	—
4.	MAGNETRANS FORTC-150 mg	1	1	—
5.	OMEPRAZOL-KSK-40 mg-KAPSELN	1	—	—
6.	FUROSEMID-RATIOPHARM-40 mg	1	—	—
7.	NOVAMINSULFON-500 mg-30/40 Tabletten	9 <sup>00</sup>	15 <sup>00</sup>	2 P
8.	SALOFALK GRANU-STIX-500 mg	BEI BEDARF		
9.	VITAMIN-D	bis Ende März		

Simvastatin 1A Pharma 40mg	Col.	1
Alacard PROTECT 32mg	Bl. Dr. 0.5	1/2-1/2 0.5
Marcumar nach INR	Phenoprogramm 3 mg	
Hct Gamma 25		1
Carvedilol beta 12.5mg	50mg Bet. Bl. 1	(2) 1/2-1/2 1 (2)
Ducloplavin 75mg/100mg Pta		1
Clopidogrel TAD 75mg		1
Amlodipin 5mg		1

... or develop my medication schedule ...

WFGELISTET-20.07.2012

STARKE ALLERGISCHE REAKTIONEN

AUF BICALUTAMID-DIOMO

(HERZRYTHMUSSTÖRUNGEN-HAUTERKRANKUNGEN)

bitte nehmen Sie folgende Medikamente wie angegeben ein:

Kalsarkan/Plavix

Medikament		morgens	nittags	abends	nachts
CORDINATE 160MG FILMTABL	98STFTA	0	1	0	0
JODID 100	100STTAB	1	0	0	
OMEBETA 20	50STKMR	1	0	0	
SIMVABETA 20MG FILMTABL	100STFTA	0	0	1	
CLOPIDOGREL - CT 75MG	28STFTA	1	0	0	Plavix
DURATENOL COMP	100STFTA	1	0	0	
COMBIGAN AUGENTROPFEN	3X5MLATR	1	0	1	glaukoma
ATENOLOL AAA 50MG TABL	100STTAB	0	0	1/2	
METFORMIN ATID 850MG	120STFTA	1/2	0	0	

morgen mittags abends

Bitte halten Sie die Termine ein. Vielen Dank.

Ihr Praxisteam Colzim Brause 1 Tag 1 Pkt

Debrinol 20.000 I.E. in 1 X

Knochenstärker Calcium 600 + 93

15 DN 840mg 20 mg (Dawel 20 mg)

1/2 jänstlich proline 60 mg Inj.

Hydrogel

Freigofas J et al.

e-Health 2014 – Special edition  
medication plan/-safety



- » A medication list has been identified as a relevant patient safety indicator.<sup>1</sup>
- » The **Medication Plan (MP)** may be seen as a combination of a medication list and the information on a personalized prescription drug label.
  - › Highly relevant for patient safety,
  - › and one out of 14 identified significant patient safety indicators for Germany.<sup>2</sup>

→ Measures of the Action Plans for Medication Safety of the Federal Ministry of Health 2008-2009 – 2016-2019.

- » [1] Wenger, Young. J Am Geriatr Soc. 2007; 55 (Suppl. 2): S285.
- » [2] Kuske S et al. Gesundheitswesen. 2012; 74 (2): 79–86.

„The MP is a printable document for the patient. It specifies the complete medication (Rx, self medication) [...] The MP facilitates the correct administration of the medication after patient counseling in the pharmacy.“

- › Overview of the complete medication.
- › Specifies the active ingredient, form, dosage and unit of each drug.
- › Includes administering information and the medical indication.
- › The Medication Plan (MP) may be seen as a combination of a medication list and the information on a personalized prescription drug label.



## „Action Plans for Medication Safety“ Issued by the Federal Ministry of Health

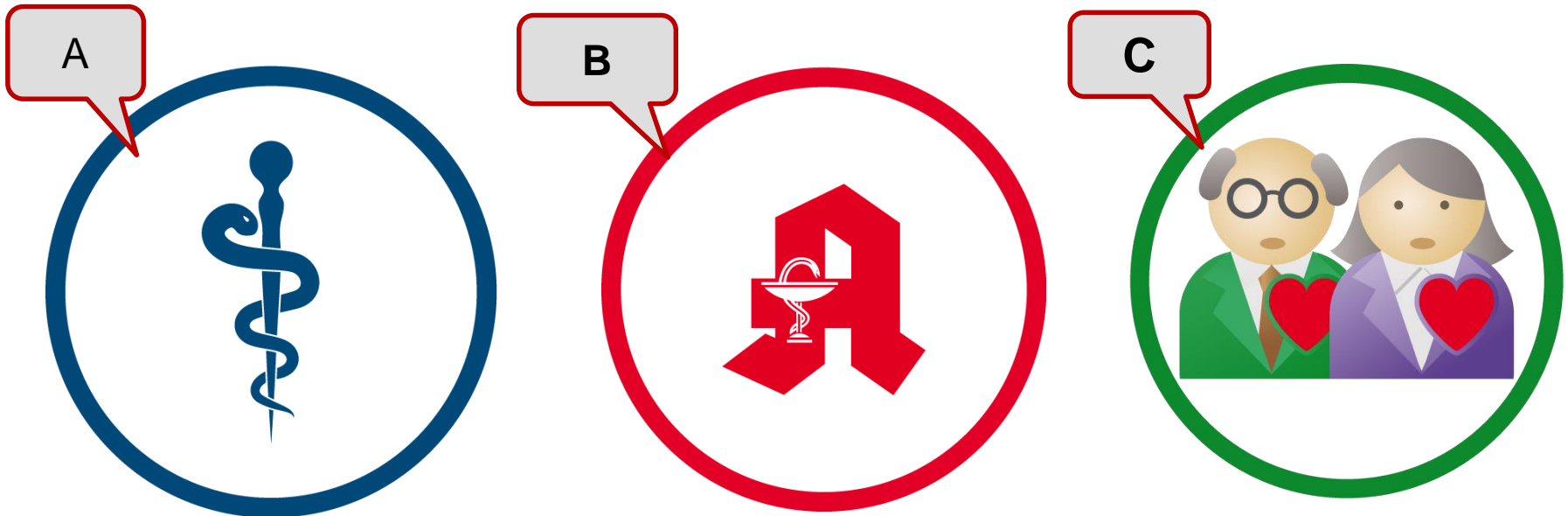
### » 2008/2009

- › Identification of patient safety indicators suitable for Germany  
→ medication list 1 of 14 relevant safety measures

### » 2010-2012

- › Development of a template for a standardized medication plan (form).
- › Workshops with representatives from all parts of the health care system.
- › Development of a specification for an (electronic) medication plan.

# Completeness of data ?



**$A \neq B \neq C \neq \text{true medication}$**

- [1] Bedell SE et al. Arch Intern Med. 2000;160:2129-34. [2] Lee KP et al. Ann Pharmacother. 2014;48:168-77.  
[3] Azzi M et al. IJQHC 2014;26:397-03. [4] Schmiemann G et al. Int J Clin Pharmacol Ther. 2012;50:614-7.  
[5] Tamblyn R et al. J Am Med Inform Assoc. 2014;21:391-8. [6] Ekedahl A et al. PDS 2011;20:1177-83.  
[7] Bikowski RM et al. J Am Geriatr Soc. 2001;49:1353-7.

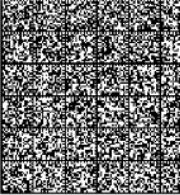

» Discrepancies between different information sources (physician, pharmacy, patient) are rather the rule than the exception:<sup>1-11</sup>

- In 7 – 24% only **no discrepancies**.
- Most frequent deviation: **Patient takes an additional unknown/not documented product**.
- Predictors are **age, number of medicines and prescribers**.
- Main reasons at GP: **organization, documentation, self-medication/OTC-use, Rx by specialists**.

» [1] Bedell SE et al. Arch Intern Med. 2000;160(14):2129–34. [2] Lee KP et al. Ann Pharmacother. 2014;48(2):168–77.  
[3] Azzi M et al. IJQHC 2014;26(4):397–403. [4] Schmiemann G et al. Int J Clin Pharmacol Ther. 2012;50(8):614–7.  
[5] Tamblyn R et al. J Am Med Inform Assoc. 2014;21(3):391–8. [6] Ekedahl A et al. PDS 2011;20:1177–83.  
[7] Bikowski et al. J Am Geriatr Soc. 2001;49(10):1353–7. [8] Tulner LR et al. Am J Geriatr Pharmacother. 2009;7(2):93–104.  
[9] Carow F et al. EJCP 2012;68:1191–9. [10] Waltering I et al. J Eval Clin Pract. 2015;21(5):886–92.  
[11] Köberlein-Neu J et al. Dtsch Arztebl Int. 2016;113:741–8.



- » Defined form and content → standardization
- » Nationwide implementation
- » In pharmacies' and physicians' software
- » 2D Barcode

<b>medication plan</b>		for: <b>Michaela Mustermann</b>		born: <b>13.12.1936</b>			
page 1 von 1		issues by:		<b>Dr. Helga Herz</b> Hauptstraße 55, 01234 Am Ort Tel.: 04562-12345 E-Mail: h.herz@mein-netz.de			
		issue date: <b>24.09.2015</b>					

Active ingredient	Brand name	Strength	Form	morning	noon	evening	at bedtime	Unit	Instructions	Indication
Magnesium oxide	Magnesium-Diasporal® 150	250mg	Caps	0	0	1		Pcs		Cramps
Metoprolol succinate	Metoprololsuccinat - 1A Pharma®	95mg	Tabl	½	0	0		Pcs		Heart failure
Omeprazole	Antra MUPS® 20mg	20mg	Tabl	1	0	1		Pcs		Heart burn
Methotrexate	MTX HEXAL® 10mg	10mg	Tabl	once a week Monday				Pcs	At night with a glass of water	Joint inflammation
Metamizole (dipyrone)	Novaminsulfon 500 mg Lichtenstein	500mg/ml	Drops	30	30	0	30	Drops		Pain
Combination product	Baldriparan® zur Beruhigung		Tabl	1	1	1	1	Pcs		Restlessness

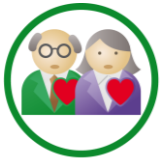
- » Medication plan enacted into law
- » (new) § 31a SGB V – Social Law

<b>Medikationsplan</b> Seite 1 von 1		für: <b>Michaela Mustermann</b> ausgedruckt von: Dr. Manfred Überall Hauptstraße 55, 01234 Am Ort Tel: 04562-12345 E-Mail: m.ueberall@mein-netz.de		geb. am: <b>13.12.1936</b> ausgedruckt am: <b>15.12.2014</b>						
Wirkstoff	Handelsname	Stärke	Form	mon- tag	mit- woch	sonn- tag	Einheit	Hinweise	Grund	
Ramipril	RAMIPRIL STADA 5MG	5 mg	Tabl	1	0	0	Stück	während der Mahlzeiten	Bluthochdruck	
Hydrochlorothiazid	HGT 1A PHARMA 25MG TABL	25 mg	Tabl	1	0	0	Stück	während der Mahlzeiten	Bluthochdruck	
Clopidogrel	PLAVIX	75 mg	Tabl	0	0	1	Stück	während der Mahlzeiten	art. Verschluss	
Simvastatin	SIMVALIP 20MG	20 mg	Tabl	0	0	1	Stück	nach der Mahlzeit	erhöhte Blutfette	
<b>Anwendung unter die Haut</b>										
Insulin-Isophan	PROTAPHANE PENFILL ZAM	300 I.E.	Amp	20	0	10	0	IE	sub cutan	Diabetes
<b>Bedarfsmedikation</b>										
Glyceritrinitrat (Nitroglycerin)	NITRANGIN PUMPSPRAY	0,4 mg	Spray	max. 3			Hub	akut	Herzschmerzen	
Diphenhydramin	VIVINOX SLEEP SCHLAFTAB ST	50 mg	Tabl	0	0	0	1	Stück	bei Bedarf	Schlaflosigkeit
<b>Wichtige Angaben</b>										
Bitte messen Sie Ihren Blutdruck täglich!										

Für Vollständigkeit und Aktualität des Medikationsplans wird keine Gewähr übernommen. \*Medikationsplan-Factory\* ihr EDV-Partner  
de-DE Version 2.2

Insured persons who simultaneously use at least 3 prescribed medicines (for at least 28 days), are entitled to receive a medication plan (in paper, later-on electronically) by their general practitioners as of 1 October 2016.

- » Aim: overview of the complete medication
- » Benefit:



Patient: minimizing confusion and misunderstandings, promoting medication adherence [1].



Health care professionals: identifying and avoiding drug-related problems [2]. Reduction of medication regimen complexity.

 **Medication safety** 

**Requirements: up-to-date, complete and comprehensible !**



# But, do patients understand the standardized MP?

- » Studies: evaluating patients' comprehensibility
  - › N=40 general internal medicine patients (GIM)
  - › N=50 patients with chronic heart failure (CHF)
  - › N=50 patients with diabetes mellitus type 2 (DMT2)
- » Structured face-to-face interviews
- » Mock-up medication plan (6 medicines)
- » Practical approach
  - › Filling of pill-boxes according to the given dosing regimen
  - › Photo documentation
- » Quantified by ET-MP score (0–100%; cutoff: >90%)

# Mock-up medication plan

## medication plan

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for: Michaela Mustermann

born: 13.12.1936

issues by:

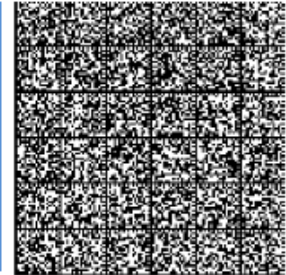
Dr. Helga Herz

Hauptstraße 55, 01234 Am Ort

Tel.: 04562-12345

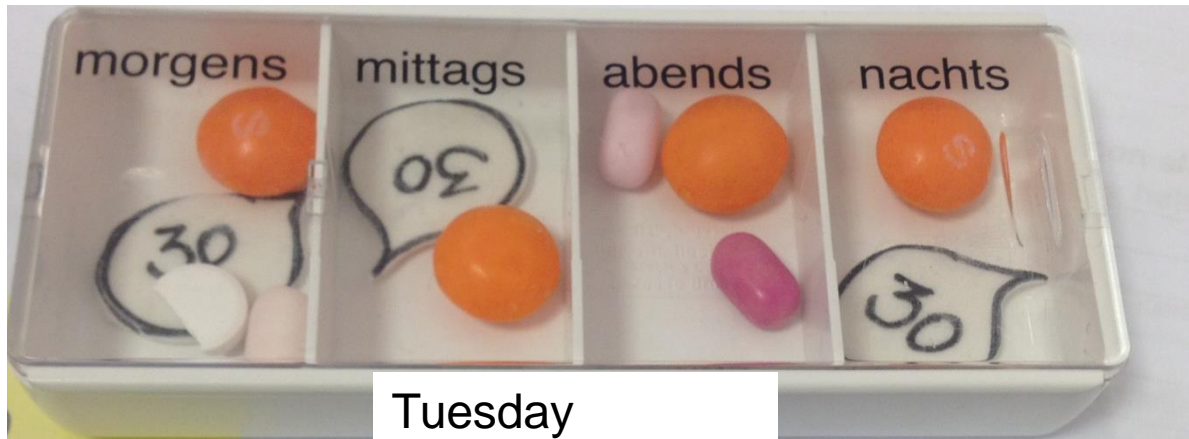
E-Mail: h.herz@mein-netz.de

issue date: 24.09.2015

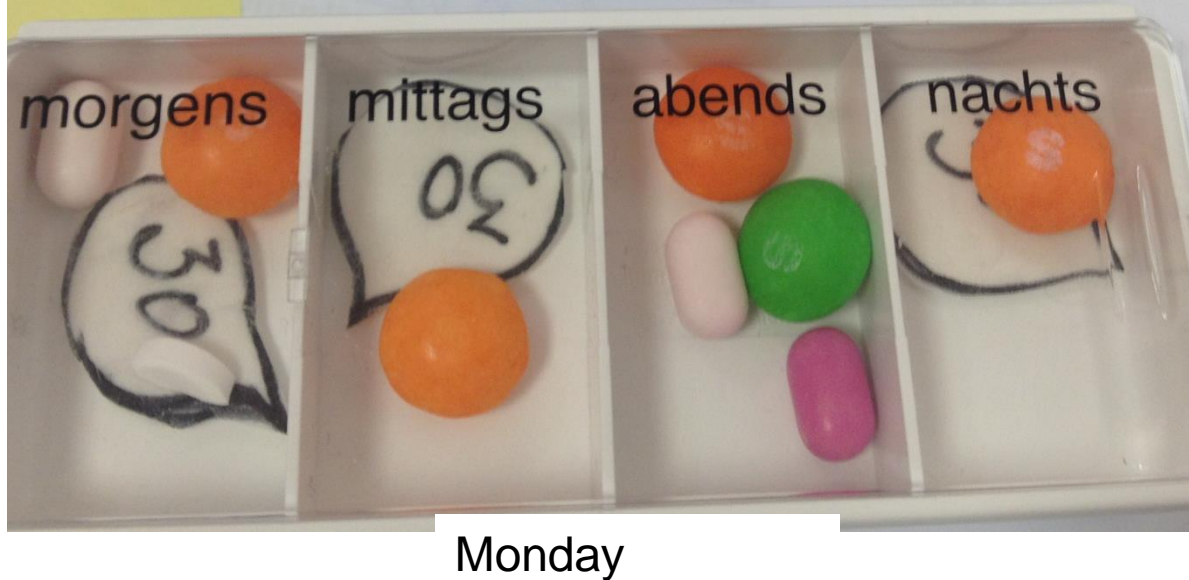


Active ingredient	Brand name	Strength	Form	morning noon evening at bedtime				Unit	Instructions	Indication
Magnesium oxide	Magnesium-Diasporal® 150	250mg	Caps	0	0	1		Pcs		Cramps
Metoprolol succinate	Metoprololsuccinat - 1A Pharma®	95mg	Tabl	½	0	0		Pcs		Heart failure
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Combination product	Baldriparan® zur Beruhigung		Tabl	1	1	1	1	Pcs		Restlessness

**Rating: correct**



**ET-MP Score:  
100%**



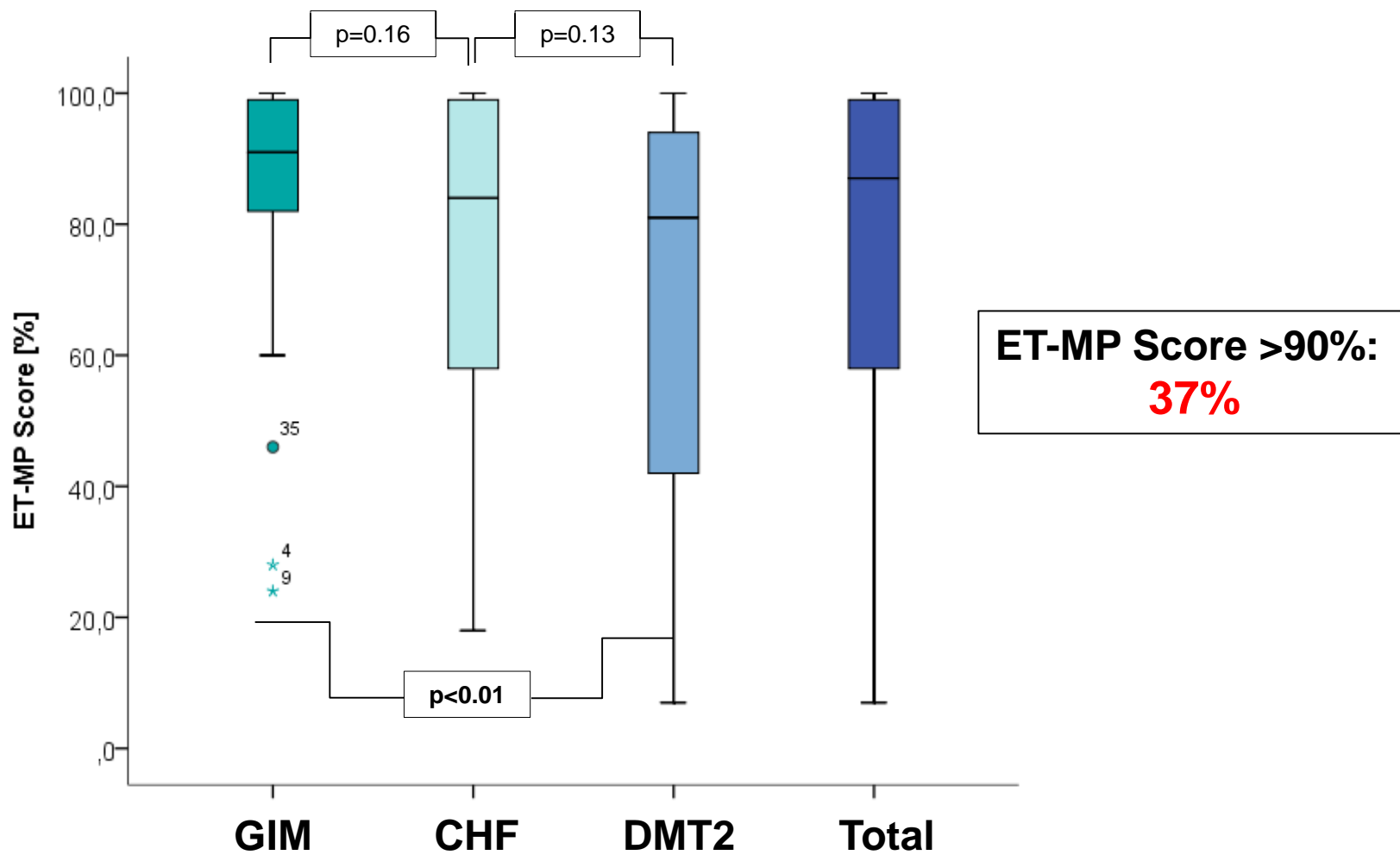


**Rating: incorrect**



**ET-MP**  
**Score: 32%**

# Do patients (N=140) understand the standardized MP?



GIM = general internal med (n=40); CHF = chronic heart failure (n=50); DMT2 = Diabetes mellitus Type 2 (n=50)

## Medication management

- Initial medication review followed by long-term monitoring
- Avoiding ADE and promoting medication adherence

### Medication catalogue

- Facilitating drug selection process for common indications
- Based on guidelines
- 3 drug categories: „standard“ (first line), „reserve“ and „subordinate“

### Preferred generic prescribing

- Prescribing of active ingredients (INN) instead of brand products



- » First contract based on the „ABDA-KBV/Concept“
- » Signed in 2014 for an initial period of 5 years.
- » **ARzneiMittelINitiative Sachsen-Thueringen**  
Partners:
  - › Associations of pharmacists and physicians in Saxony and Thuringia.
  - › AOK PLUS (a large statutory health insurance company; coverage approximately 50% of the population).



# Participating pharmacies and GPs in ARMIN (01/17): 1,527 HCPs

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## » Pharmacies: 984

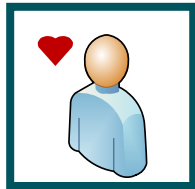
- › Saxony: 509
- › Thuringia: 475



## » Physicians: 543

- › Saxony: 237
- › Thuringia: 306

# 4 Data sources in ARM<sup>IN</sup>



Patient




Physician

**Medication Plan** for: Michael Mustermann DOB: 13.12.1936

Seite 1 von 1

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Mainstreet 55, 01234 Am Ort  
Tel: 04562-12345  
E-Mail: e.everywhere@my-net.com  
printed on: 25.09.2015

 ARZNEIMITTEL THERAPIESICHERHEIT

active ingredient	brand name	strength	form	dosage	unit	instructions	indication
Clopidogrel	Plaviv® 75 mg N1	75mg	Tab	0 0 1	pcs	During the meal	Art. occlusion
Simvastatin	Simvalip® 20mg N2	20mg	Tab	0 0 1	pcs	After the meal	High blood lipids
Clopidogrel	Plaviv® 75 mg N1	75mg	Tab	0 0 1	pcs	During the meal	Art. occlusion
Simvastatin	Simvalip® 20mg N2	20mg	Tab	0 0 1	pcs	After the meal	High blood lipids
<b>Subcutaneous administration</b>							
Insulin human	Insulin B. Braun Basal		Syringe	20 0 10	IU	Hypodermic	Diabetes
<b>PRN medication</b>							
Glyceroltrinitrat	Corangin® Nitrospray		Spray	max. 3	puff	Acute	Cardiac chest pain
	Vivinox® stark		Tab	0 0 0 1	pcs	If required	Insomnia

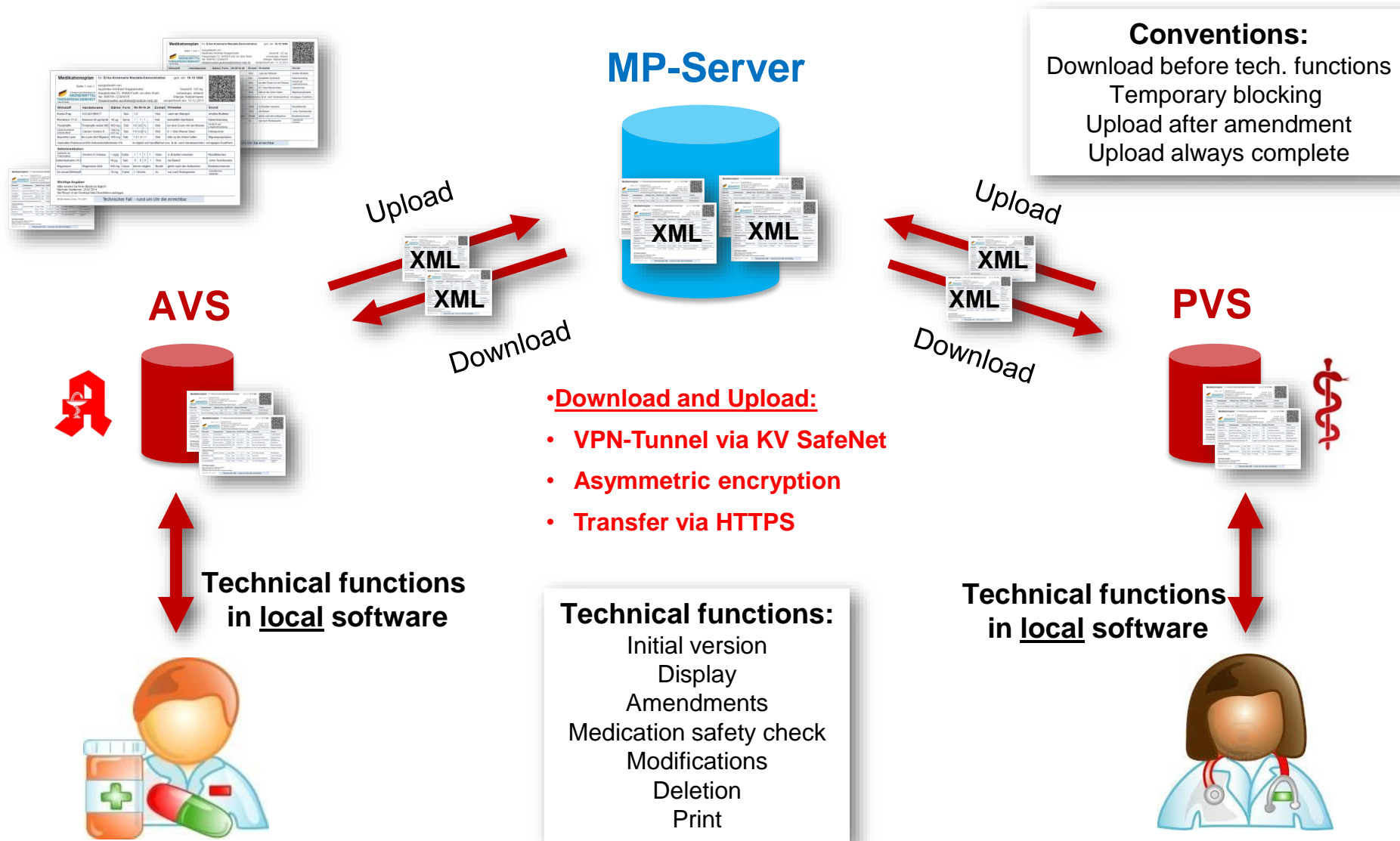


Pharmacy



Health insurance

# Medication Plan Exchange Server in **ARMIN**



## Aim:

- » An up-to-date, comprehensive **Medication Plan**: complete, checked for potential medication safety risks, consolidated between HCPs (and the patient), developed and continuously updated electronically !

<b>Medikationsplan</b>				für: Frau ...				geb. am: xx.xx.1972			
Seite 1 von 1				ausgedruckt von:							
<b>ARMIN</b>				ausgedruckt am: 24.09.2015							

Wirkstoff	Handelsname	Stärke	Form	Morgens	Mittags	Abends	Nachts	Einheit	Hinweise	Grund
Mycophenolat	Mycophenolatmofetil-biomo® 500 mg	500 mg	Tabl	2	0	2		Stück		Myasthenie
Prednisolon	Decortin® H 1mg	1 mg	Tabl	1	0	0		Stück	jeden 2. Tag	Myasthenie
Colecalciferol	Vigantoleiten® 1.000 I.E.	1000 I.E.	Tabl	1	0	1		Stück		Vitamin D-Mangel
Pramipexol	Pramipexol Stada® 0,18mg	0,18 mg	Tabl	0	0	0	1	Stück	auf der Bettkante	bei unruhigen Beinen
Gabapentin	Gabapentin abz® 300mg	300 mg	kaps	1	0	0	1	Stück		geg. stechenden Schmerz
Gabapentin	Gabapentin Pfizer® 100mg	100 mg	Kaps	0	1	0		Stück		geg. stechenden Schmerz


**Selbstmedikation**

Kombi-Präp.	Hair Energizer®		Kaps	1	0	0		Stück	Aminosäuren, Vitamine, Mineralstoffe	Haarausfall
-------------	-----------------	--	------	---	---	---	--	-------	--------------------------------------	-------------

**Bei Bedarf**

Metamizol	Novaminsulfon 500 mg Lichtenstein®	500 mg	Tabl	0	0	0	2	Stück		Körper-Schmerzen
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A photograph of two sparrows perched on a tree stump. The bird on the left is facing right, while the bird on the right is facing left, with its wings spread. A red thought bubble is positioned above the bird on the right, containing the text "... I'm already shut !". The background is a soft, out-of-focus green.

... I'm  
already  
shut !

- » Discrepancies – rather the rule than the exception –
  - › between physicians' and pharmacists' documentation and the medication the patient is actually taking
  - › Only in 7-24% of the cases **no discrepancies**
- » Patient knowledge
  - › Patient tend to forget or
  - › misunderstand given information
  - › Written instructions can help (→ if easy to understand/easy language)
- » Threat for medication safety
  - › Ignorance of the complete medication can cause drug-related problems
    - i.e. double medications or
    - Interactions or
    - medication non-adherence

# Data exchange in ARMIN

