



Use of routinely collected electronic healthcare data: Lessons Learned

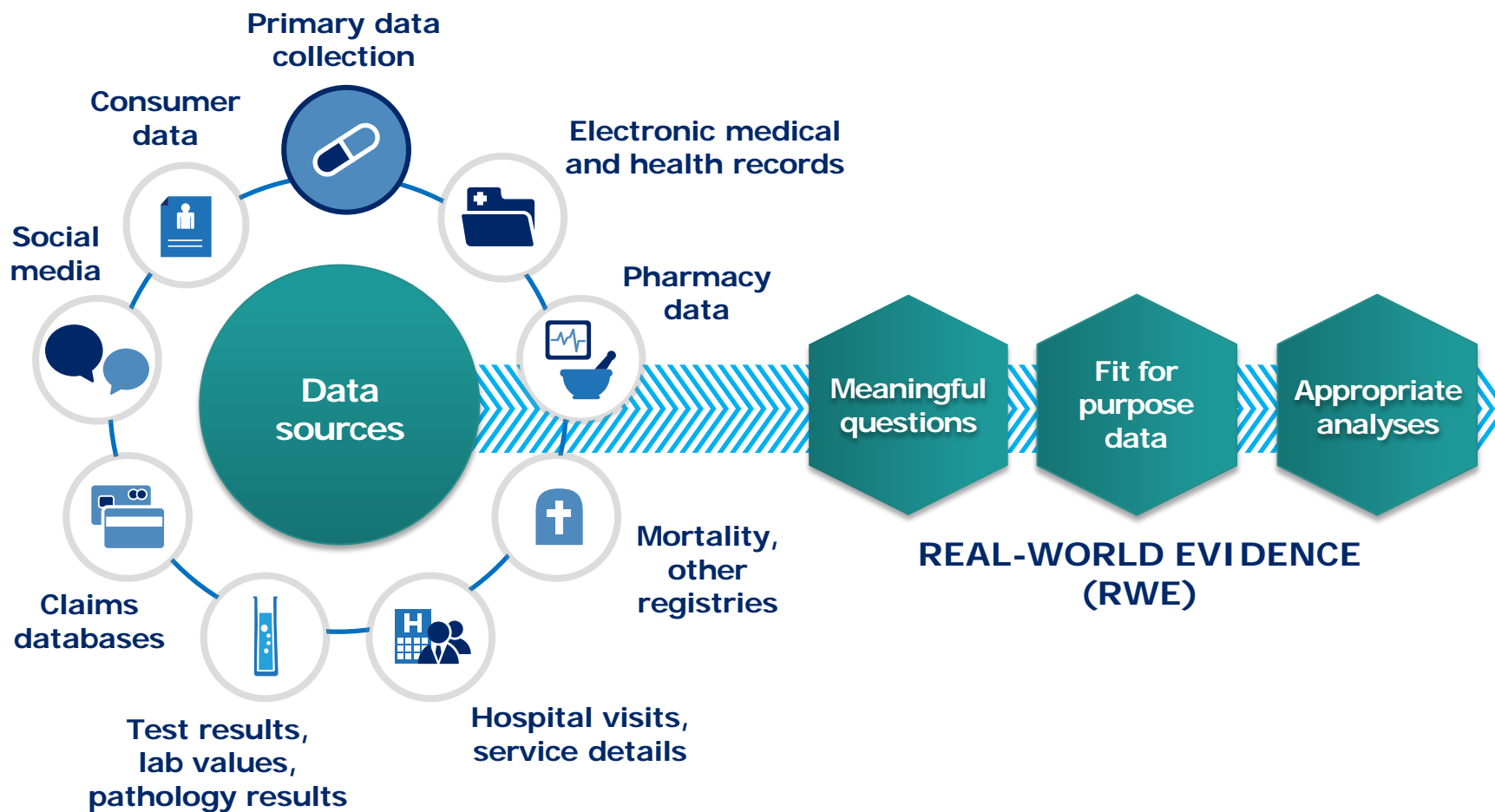
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ENCePP Plenary
25 November 2014
European Medicines Agency



Generating evidence from real world data



Routinely collected healthcare databases?



Healthcare data collected in routine practice

- Minimum intervention in the workflow of care giver as compared to primary data collection
- Data collection continuous, rather than study based
- Close to the real-life “reporting” practice



Examples

- Electronic medical records
- Claims
- Pharmacy dispensing data
- Survey panels
- Lab values
- Connected devices
- Patient-reported outcomes



Scope of this presentation

- Focus on healthcare data collected by a panel of healthcare professionals:
 - EMR
 - LRx
 - RxDx
- For each database
 - Brief explanation
 - Lessons learned
 - Frequently asked question (FAQ)

Key considerations in panel design



Representativeness

- A panel is generally designed to be representative
 - Not always proportionally
- The representativeness criteria is defined based on the function which is expected from the panel
 - Physicians: age, gender, specialty, in/outpatient, years of experience, geography
 - Pharmacies: volume of sales, settings (small, large ...), place (city centre, shopping mall, hospital, ...)



Turn-over

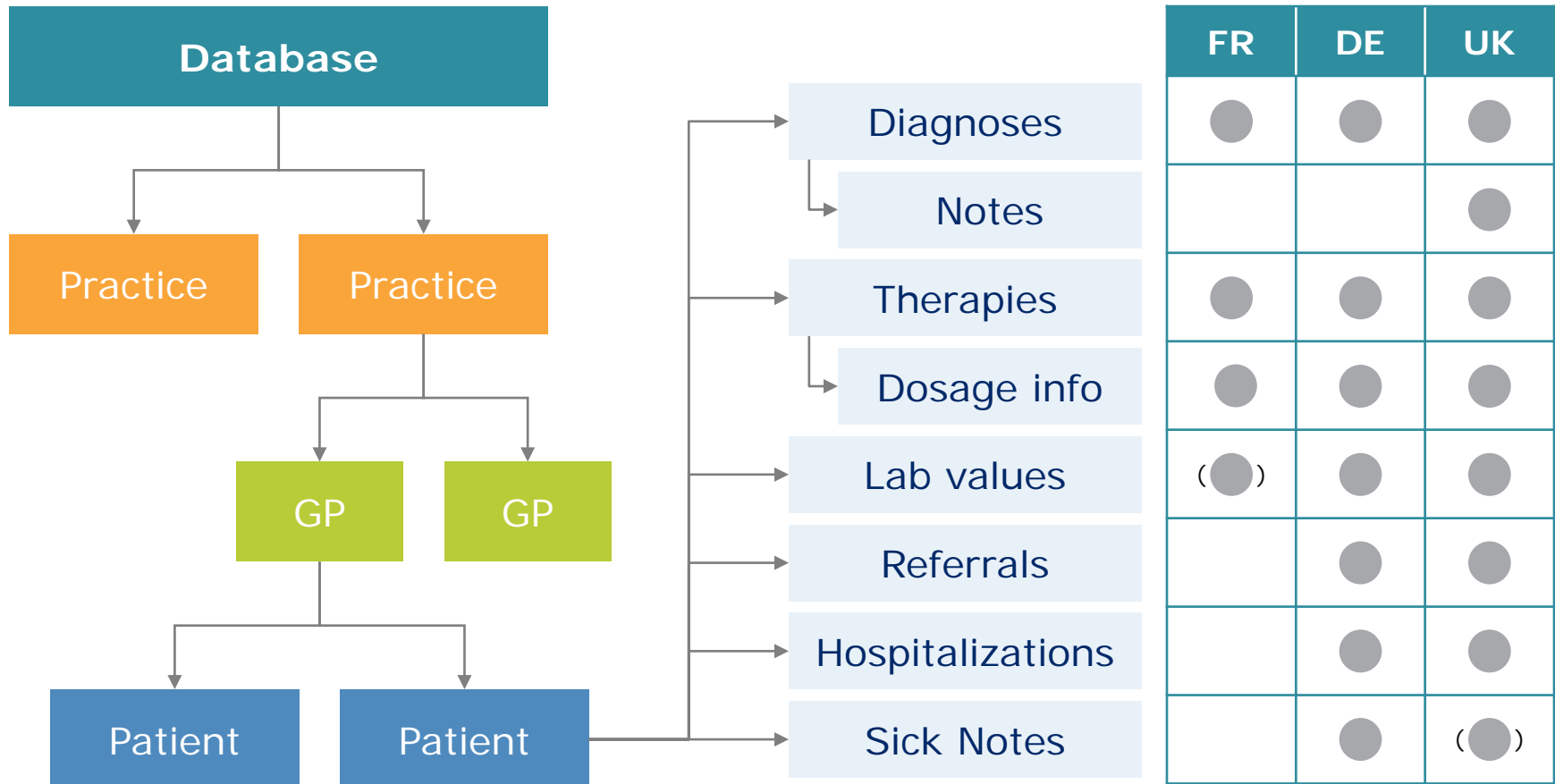
- Inevitable, to compensate loss of numbers:
 - Healthcare professionals move, retire, ...
 - Non compliance in data submission
- Necessary, to compensate loss of relevance:
 - Practice of panel members may change over time
 - Panel members get older and move to the upper age category
- Generally, a regular turn-over is induced.



Anonymity and secrecy

- A panel shall generally be anonymous
 - to avoid other stakeholders (companies, advocacy groups, etc.) influence its members
- This anonymity also offers a second layer of patient data protection:
 - Key-coding at practice level
 - Key-coding at patient level

Electronic medical records (EMR)



Working with EMR data: lessons learned



Advantages

- Often wide geographic coverage
- Demographic, clinical and lab data often available for most important pathologies



Limitations and points to consider

- Full medical history not always available
- Mostly focused on primary care
- Physicians record data which is clinically important
 - Availability of a variables \neq availability of values
 - Missing data is not missing by random, unless it is automatically collected (e.g. lab values)
- Physicians may not enter coded data
 - Errors may occur at coding level



Best fit for

- Cohort studies with both exposure and outcome occurring in the settings of the database
- Study of exposure and outcome occurring in different settings through
 - Linkage to other database
 - Linkage to primary data (eCRF, ePRO, device ...)

FAQ: What about representativeness?

Comparison of diabetes patients in 2005 by age group

Patient age	GEK patients (%)	Disease Analyzer patients (n = 12,533)	
		%	95% CI
≤39	11.4	12.1	(10.7-13.4)
40-49	14.3	15.9	(14.4-17.4)
50-59	23.3	24.1	(22.3-25.9)
60-69	27.0	27.0	(25.2-28.9)
70-79	17.8	16.5	(15.0-18.1)
>80	6.3	4.4	(3.5-5.2)

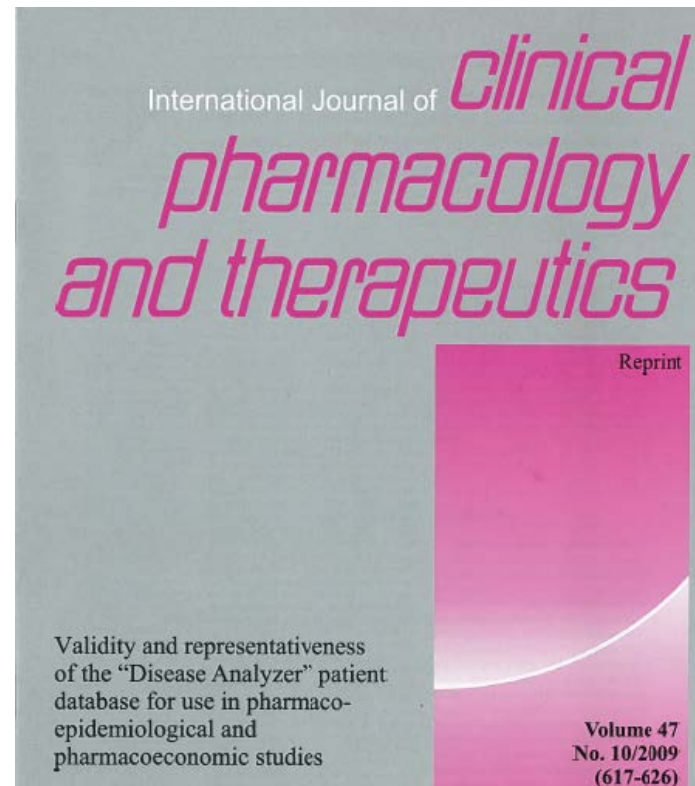
Comparison of antihypertensive patients treated in 2005 by gender

ATC class	GEK male patients (%)	Disease Analyzer patients (n = 2,156)	
		%	95% CI
C03A diuretics	54.6%	53.0%	(50.2-55.8)
C07 β-blockers	57.5%	56.4%	(54.7-58.2)
C08 calcium-antagonists	61.3%	58.7%	(56.0-61.4)
C09AB ACE-inhibitors	63.8%	63.8%	(62.0-65.7)
C09CD sartans	58.6%	57.4%	(54.6-60.2)

CI = Confidence interval

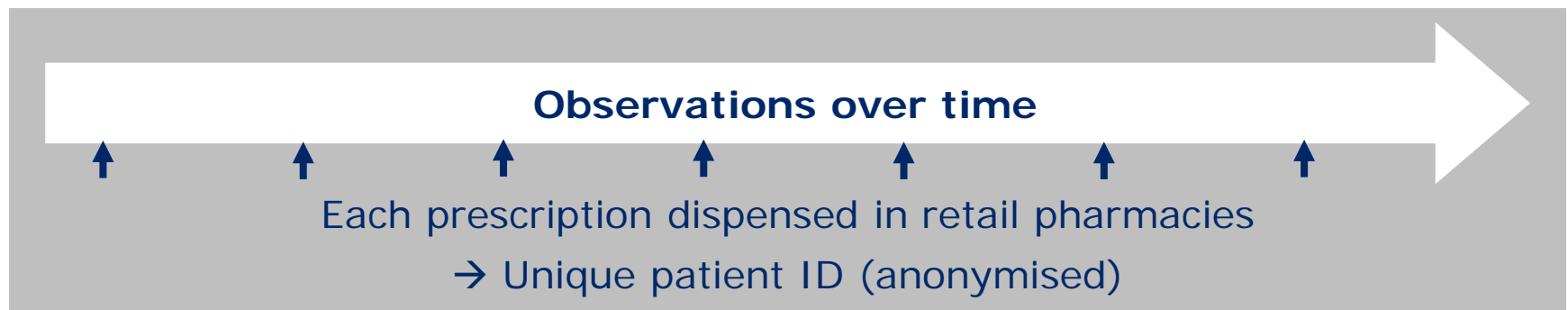
Source: [Glaeske and Janhsen 2007]

- Important to know if the database is representative, but the importance of representativeness shall be considered in the context of the research question.
 - Comparison of panel participants and non participants is not always useful/possible.



Longitudinal dispensing databases

- A representative panel of pharmacies contributes dispensing data of patients to a database
- Patients can be tracked
 - Over time
 - Across pharmacies of the panel
- Submitted information
 - Dispensing information (drugs dispensed, volumes, date, specialty of the prescriber, settings of the prescription)
 - Patient's characteristics (age, gender)



Working with LRx data: lessons learned



Advantages

- Widely available
- Large coverage (often 20-90% of prescriptions)
- Less affected by operator's selection of data
- Frequent updates
 - Thus very useful in observing dynamics of drug use



Limitations and points to consider

- Patients are less loyal to their pharmacies than to their physicians
 - Thus the longitudinal picture would not be complete.
- Not fit when clinical data is needed
 - Sometimes algorithms can be defined for identification of patient profiles (e.g diabetes)
- Picture on OTC drugs is often incomplete or misleading.



Best fit for

- Simple, longitudinal drug utilization studies (prescriber behavior)
 - Especially when various specialties prescribe the drug and EMR data are not available
- Study of drug use dynamics
 - Treatment pathways
 - Switch / add-on use
 - Persistence

FAQ: What about patient loyalty to pharmacies?

- Patients are less loyal to their pharmacies than to their doctors
 - Better to be checked per study
- More likely to be loyal
 - Older patients
 - Those with chronic disease
 - Those living in rural area
- Points to consider
 - Sub selection of loyal patients may cause a selection bias
 - Make sure the characteristics of loyal and non-loyal patients are similar
- Loyalty question, not specific to pharmacies
 - This question shall be asked for EMRs, Claims, etc based on the context of the health system

Number of pharmacies of the panel visited in 2013 in France	Number of patients (all categories)	% of patients
1	12 352 447	71.5%
2	3 924 534	22.7%
3	787 904	4.6%
4	170 027	1.0%
5	38 417	0.2%
6	9 678	0.1%
7	2 710	0.0%
8	830	0.0%
9	307	0.0%
10	150	0.0%
11	77	0.0%
12	40	0.0%
13	23	0.0%
14	17	0.0%
15	18	0.0%
16	4	0.0%
17	8	0.0%
18	2	0.0%
19	4	0.0%
20	2	0.0%
21	3	0.0%
22	1	0.0%
23	1	0.0%
24	3	0.0%
25	1	0.0%
31	1	0.0%
32	1	0.0%
33	1	0.0%
40	1	0.0%

Prescription-diagnosis data (RxDx)

- Systematic, cross-sectional collection of prescriptions along with diagnoses related to each prescribed drug



- One of the oldest and most widely available forms of routinely collected healthcare data
 - Under-used in pharmacoepidemiology

Physician panel stratified by region and speciality									
	Specialty	1	2	3	4	5	6	7	Total
001	General Practice	34	30	63	12	51	46	64	300
	001 General Practice	21	15	32	7	26	23	36	160
	054 Family Practice	13	15	31	5	25	23	28	140
002	Internal Medicine	4	4	12	3	8	6	8	45
003	Pediatrics	6	6	14	3	13	11	12	65
006	Rheumatology	3	2	8	1	7	4	5	30
007	Gastroenterology	4	4	10	3	9	6	9	45
008	Cardiology	4	5	10	3	9	6	8	45
009	Surgery	3	3	8	1	6	4	5	30
010	Dermatology	3	3	7	1	7	4	5	30
011	Endocrinology	3	3	8	1	6	4	5	30
012	Ophthalmology	3	3	9	3	7	5	5	35
013	Gynecology	4	4	9	3	10	7	8	45
015	Odontology	4	5	9	3	8	7	9	45
016	Otorhinolaryngology	3	3	7	1	6	5	5	30
017	Traumatology	3	4	7	3	8	5	5	35
018	Urology	3	3	7	1	6	5	5	30
020	Pulmology	3	3	8	1	6	4	5	30
021	Neurology	3	3	8	1	7	4	4	30
022	Psychiatry	3	4	8	1	10	4	5	35
	Total	93	92	212	45	184	137	172	935

DATE DE CONSULTATION	LIEU DE CONSULTATION	PATIENT	CATEGORIE SOCIO-PROFESSIONNELLE
29/10/12 JJ MM AA	<input checked="" type="checkbox"/> Cabinet <input type="checkbox"/> Clinique <input type="checkbox"/> Domicile	Age 56 ans Sexe <input checked="" type="checkbox"/> M <input type="checkbox"/> F Bébé [] mois Poids [] kg (à 24 mois)	<input type="checkbox"/> Agriculteur <input type="checkbox"/> Artisan, Commerçant <input type="checkbox"/> Cadre supérieur <input type="checkbox"/> Profesion libérale <input type="checkbox"/> Profession intermédiaire <input type="checkbox"/> Employé <input type="checkbox"/> Ouvrier <input type="checkbox"/> Retraité <input type="checkbox"/> Chômeur <input checked="" type="checkbox"/> Autre <input type="checkbox"/> Sans activité professionnelle <input type="checkbox"/> Etudiant <input type="checkbox"/> Invalidité

1^{er} DIAGNOSTIC ou à défaut MOTIF de CONSULTATION: Arthrite

ACTES: Traitements ou examens pratiqués AU COURS de cette consultation

PRESCRIPTION(S) DE PRODUIT(S), avec ou sans AMM, ESSENTIELS MÉDICAUX

→ NON (Veuillez passer à la question suivante "AUTRES PRESCRIPTIONS", si nécessaire)
 → OUI (Merci de préciser ci-dessous)

Vous pouvez préciser l'indication du produit, le volume du lot et le statut sur l'automatisme sans permettre de ne pas recevoir les prescriptions, cependant il est impératif de compléter les informations concernant l'indication et le mécanisme d'action du produit.

PRODUIT	POSOLOGIE	Forme posologique	Autres (présent)	En cours de traitement	En traitement lors de cette consultation	En attente de traitement	En attente de traitement	Autres (présent)
<u>Kardégic 75mg</u>	<u>1 comprimé</u>	<u>comprimé</u>	<u>Non</u>	<u>Non</u>	<u>OUI</u>	<u>Non</u>	<u>Non</u>	<u>Non</u>
<u>Blavix ch</u>	<u>1 comprimé</u>	<u>comprimé</u>	<u>Non</u>	<u>Non</u>	<u>OUI</u>	<u>Non</u>	<u>Non</u>	<u>Non</u>
<u>Lyrica 100mg gélule</u>	<u>1 gélule</u>	<u>gélule</u>	<u>Non</u>	<u>Non</u>	<u>OUI</u>	<u>Non</u>	<u>Non</u>	<u>Non</u>
<u>Lyrica 50mg</u>	<u>1 gélule</u>	<u>gélule</u>	<u>Non</u>	<u>Non</u>	<u>OUI</u>	<u>Non</u>	<u>Non</u>	<u>Non</u>

AUTRES PRESCRIPTIONS: Courrier biologique Certificat Arrêt de travail Verres correcteurs / Lentilles Exploration (Radio, Echo, Scopie) Rééducation fonctionnelle Autres (préciser):

2^{ème} DIAGNOSTIC ou à défaut MOTIF de CONSULTATION: HTA

ACTES: Traitements ou examens pratiqués AU COURS de cette consultation

PRESCRIPTION(S) DE PRODUIT(S), avec ou sans AMM, ESSENTIELS MÉDICAUX

→ NON (Veuillez passer à la question suivante "AUTRES PRESCRIPTIONS", si nécessaire)
 → OUI (Merci de préciser ci-dessous)

Vous pouvez préciser l'indication du produit, le volume du lot et le statut sur l'automatisme sans permettre de ne pas recevoir les prescriptions, cependant il est impératif de compléter les informations concernant l'indication et le mécanisme d'action du produit.

PRODUIT	POSOLOGIE	Forme posologique	Autres (présent)	En cours de traitement	En traitement lors de cette consultation	En attente de traitement	En attente de traitement	Autres (présent)
<u>Atenolol 50mg</u>	<u>1 comprimé</u>	<u>comprimé</u>	<u>Non</u>	<u>Non</u>	<u>OUI</u>	<u>Non</u>	<u>Non</u>	<u>Non</u>
<u>Ramipril 50mg ch</u>	<u>1 comprimé</u>	<u>comprimé</u>	<u>Non</u>	<u>Non</u>	<u>OUI</u>	<u>Non</u>	<u>Non</u>	<u>Non</u>

AUTRES PRESCRIPTIONS: Courrier biologique Certificat Arrêt de travail Verres correcteurs / Lentilles Exploration (Radio, Echo, Scopie) Rééducation fonctionnelle Autres (préciser):

Working with RxDx data: lessons learned



Advantages

- A well established process
 - Panel representativeness
 - Data collection, coding and extrapolation
- Large geographic availability
 - In some countries the only available healthcare data
- Simple data structure which is consistent across countries
- Availability of most specialties



Limitations and points to consider

- Disproportional sample
 - Non-weighted data shall be used with care
- Not fit for drugs with small prescription volumes
 - Panel size: generally 1 to 2% of each specialty
 - Data collection, often during 7 consecutive days per quarter/semester (4-8% of days in a year)
- Not fit when patient follow up is needed



Best fit for

- Simple multi-country drug utilization studies for the assessment of off-label use
 - Both extrapolated and non extrapolated data
- Case population studies
 - Extrapolated data
- The extent of prescriptions to be assessed in advance

FAQ: Are these reports reliable?

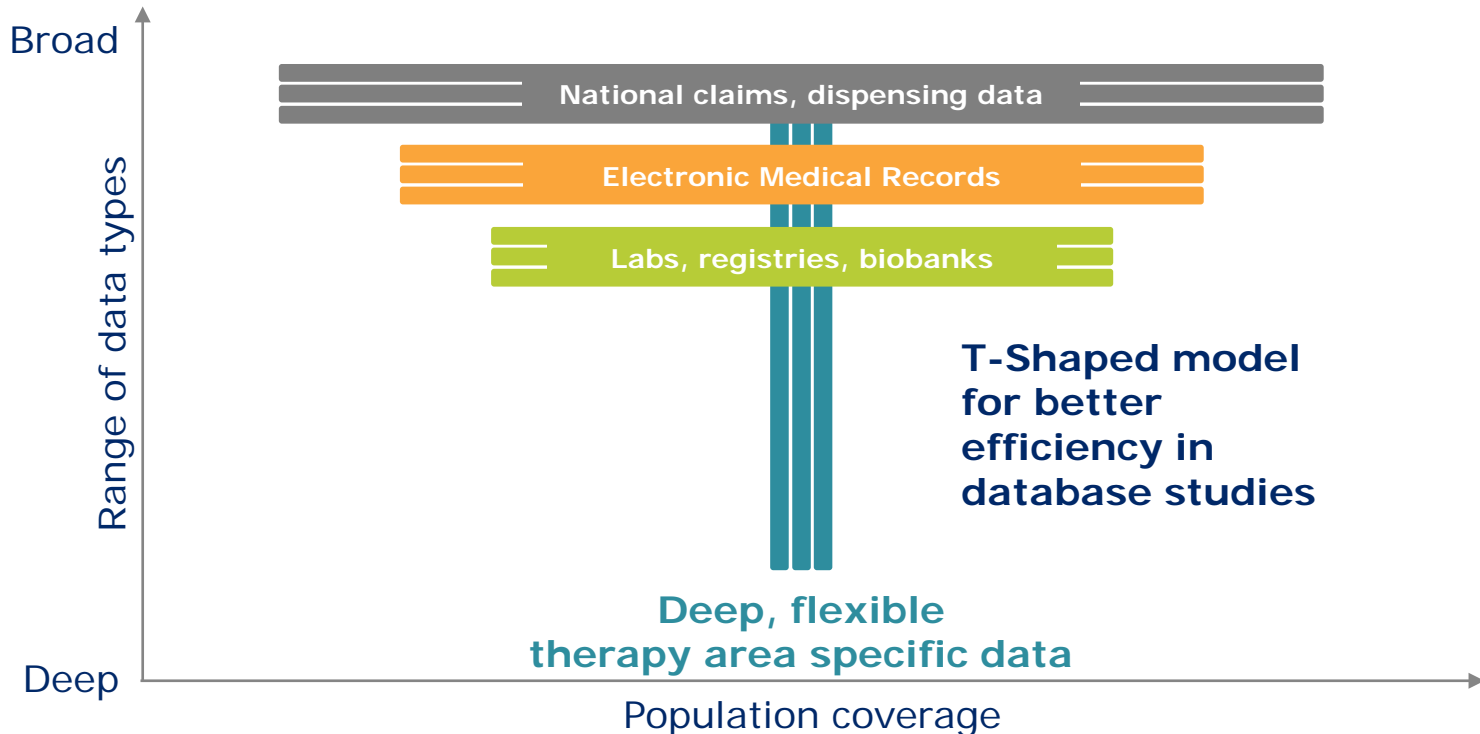
- Important to identify between:
 - Deviation from practice
 - Deviation from reporting rules
- Reporting problems often occur when
 - an important clinical condition or drug overshadows a less important one
 - a general practitioner renews the drugs prescribed by a specialist
- Points to consider
 - A small proportion of aberrant values reported as the reason for the prescription of a given drug: to be treated as outliers.
 - Large quantity of aberrant values: to check whether this drug is widely misused or the reporting is affected by one of the above conditions.

DATE DE CONSULTATION	LIEU DE CONSULTATION	PATIENT	CATÉGORIE SOCIO-PROFESSIONNELLE			
19/04/13 JJ MM AA	<input checked="" type="checkbox"/> Cabinet <input type="checkbox"/> Clinique <input type="checkbox"/> Domicile	Age 64 ans Sexe <input checked="" type="checkbox"/> M <input type="checkbox"/> F Bébé [] mois Poids [] kg (r. de 24 mois)	<input type="checkbox"/> Agriculteur <input type="checkbox"/> Artisan, Commerçant <input type="checkbox"/> Cadre supérieur <input type="checkbox"/> Profession libérale <input type="checkbox"/> Profession intermédiaire (administrative et commerciale)	<input type="checkbox"/> Employé <input type="checkbox"/> Ouvrier <input checked="" type="checkbox"/> Retraité <input type="checkbox"/> Chômeur	<input type="checkbox"/> Autre <input type="checkbox"/> Sans activité professionnelle, Etudiant	
1 ^{er} DIAGNOSTIC ou à défaut MOTIF DE CONSULTATION			renouvellement ttt AVC			
ACTES : Traitements ou examens pratiqués AU COURS de cette consultation						
PRESCRIPTION(S) DE PRODUIT(S), avec ou sans AMM, DISPOSITIFS MÉDICAUX → NON (veuillez passer à la question suivante "AUTRES PRESCRIPTIONS", si nécessaire) → OUI (veuillez préciser ci-dessous) Vous pouvez joindre l'ordonnance du patient, le report de n° du produit sur l'ordonnance vous permettant de ne pas recopier les prescriptions, cependant il est impératif de compléter les informations concernant l'indication et le renouvellement du produit.			Patient renouvant pour le 1 ^{er} 30j ou produit (produits)			
<input checked="" type="checkbox"/> PRODUIT à reporter sur l'ordonnance	<input checked="" type="checkbox"/> PROSOLOGIE	Vautavaul LP 35 Précisez la forme sup, orales... 1 → 3	<input type="checkbox"/> En violation d'un nouveau traitement	<input type="checkbox"/> En remplace- ment d'un autre produit	<input type="checkbox"/> En additi- on au traitement existant	<input checked="" type="checkbox"/> Produit renou- vé au cours de cette consultation
<input checked="" type="checkbox"/> PRODUIT à reporter sur l'ordonnance	<input checked="" type="checkbox"/> PROSOLOGIE	Kardozic 60 1 → 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/> PRODUIT à reporter sur l'ordonnance	<input type="checkbox"/> PROSOLOGIE		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> PRODUIT à reporter sur l'ordonnance	<input type="checkbox"/> PROSOLOGIE		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
AUTRES PRESCRIPTIONS			<input type="checkbox"/> Courrier <input type="checkbox"/> Certificat <input type="checkbox"/> Arrêt de travail <input type="checkbox"/> Verres correcteurs / Lentilles <input type="checkbox"/> Exploration (Radio, Echo, Scopie...) <input type="checkbox"/> Biologie <input type="checkbox"/> Rééducation fonctionnelle <input type="checkbox"/> Autres (précisez) :			
2 ^{ème} DIAGNOSTIC ou à défaut MOTIF DE CONSULTATION			douleur artérielle			
ACTES : Traitements ou examens pratiqués AU COURS de cette consultation						
PRESCRIPTION(S) DE PRODUIT(S), avec ou sans AMM, DISPOSITIFS MÉDICAUX → NON (veuillez passer à la question suivante "AUTRES PRESCRIPTIONS", si nécessaire) → OUI (veuillez préciser ci-dessous) Vous pouvez joindre l'ordonnance du patient, le report de n° du produit sur l'ordonnance vous permettant de ne pas recopier les prescriptions, cependant il est impératif de compléter les informations concernant l'indication et le renouvellement du produit.			Patient renouvant pour le 1 ^{er} 30j ou produit (produits)			
<input checked="" type="checkbox"/> PRODUIT à reporter sur l'ordonnance	<input checked="" type="checkbox"/> PROSOLOGIE	bolipran 1000 1 → 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
<input type="checkbox"/> PRODUIT à reporter sur l'ordonnance	<input type="checkbox"/> PROSOLOGIE		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> PRODUIT à reporter sur l'ordonnance	<input type="checkbox"/> PROSOLOGIE		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<input type="checkbox"/> PRODUIT à reporter sur l'ordonnance	<input type="checkbox"/> PROSOLOGIE		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
AUTRES PRESCRIPTIONS			<input type="checkbox"/> Courrier <input type="checkbox"/> Certificat <input type="checkbox"/> Arrêt de travail <input type="checkbox"/> Verres correcteurs / Lentilles <input type="checkbox"/> Exploration (Radio, Echo, Scopie...) <input type="checkbox"/> Biologie <input type="checkbox"/> Rééducation fonctionnelle <input type="checkbox"/> Autres (précisez) :			

Trimetazidine and aspirin are both associated to a treatment renewal for cerebrovascular accident. The general practitioner probably lacks details on the context in which the original prescription was made by the specialist. However, this information is recorded as-is in the database, and often interpreted as misuse.

Conclusion

- The best database is the one which is most fit-for-purpose.
 - ask how the database is made (it's story), not just what it contains.
 - run a feasibility if you are not sure about the quality and content of a database.
 - have in mind that a combination of different data sources may be the best solution



Thank you!

Questions?

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