

The New Wave in Real World Evidence – Integrated Datasets

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Agenda

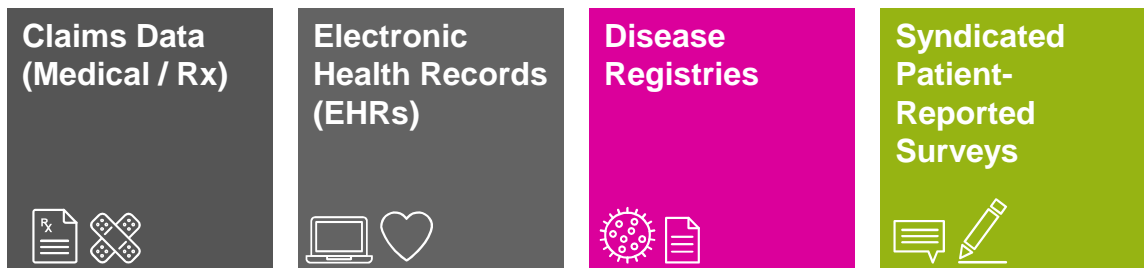
Methods for Linking RWD Global Perspective	Healthcare Databases in Japan Diabetes Research Results	Privacy and Regulatory Restrictions in Japan	Integrated Claims / Survey Analysis Side by Side	Questions and Discussions
10 mins	10 mins	10 mins	15 mins	15 mins

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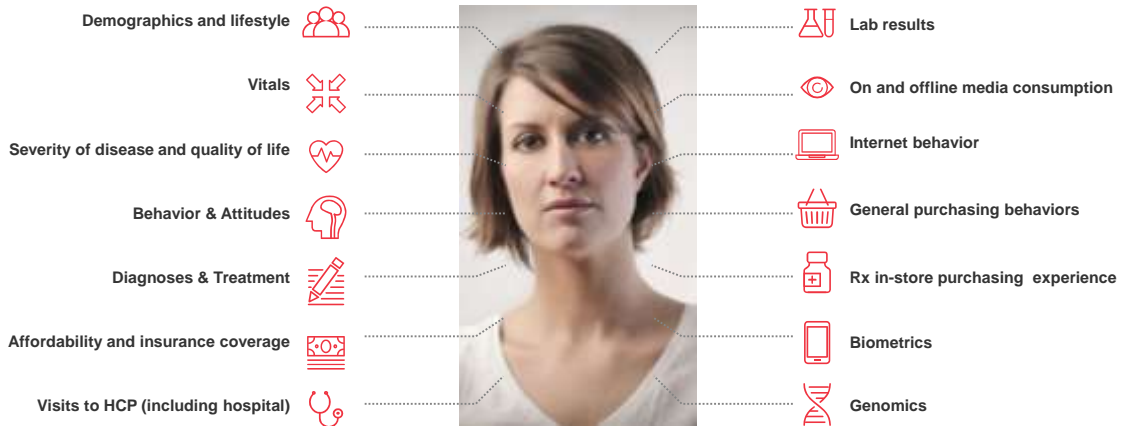
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Why Integrate Real-World Data

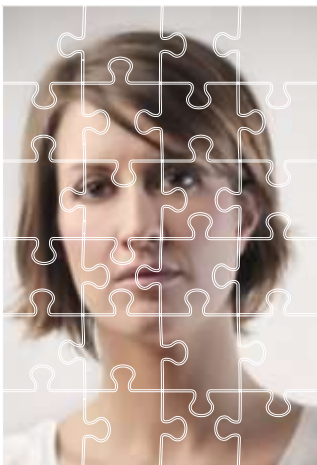
Real-World Data is generally only available in silos



Real-World Data (RWD) and Outcomes Research – Understanding the Patient as a Person



RWD Integration – Answering studies where objectives cross datasets



How does the patient **Quality of Life** compare among those with **controlled vs. uncontrolled Type 2 Diabetes**?

How do **treatment patterns** differ for those with **severe, moderate, or mild RA**?

How does **adherence to <drug x>** differ by **<certain clinical values>**?

Claims
Surveys
EHR

RWD Integration Approaches

Patient-level Matching



Propensity Matching / Fused Data



Side by Side Analysis



RWD Integration Approaches – Patient-level Matching



How is it performed?

- Based on knowing common PII / PHI attributes for both datasets
- Typically first/last name, address, date of birth, gender

Is it presently available?

- Quite common in the US for EHR and claims data
- Also available – matching clinical data and survey data

What are the limitations?

- Is there enough overlap for a good-sized cohort?
- Is patient privacy maintained?

RWD Integration Approaches – Propensity Matching



How is it performed?

- Build propensity-matched model based on common attributes (Claims and Survey)
- Impute survey results into claims based on look-alikes

Is it presently available?

- Kantar Health research with Harvard Medical School
- In final stages of Machine Learning approach based on patient matched “seeds”

What are the limitations?

- Need to have patient matched seed as a starting point
- Need to have a large enough seed to produce strong enough imputation model

RWD Integration Approaches – Side by Side Analysis



How is it performed?

- Based on 2 or more datasets with common attributes
- Provide analysis based on same criteria, but different end points

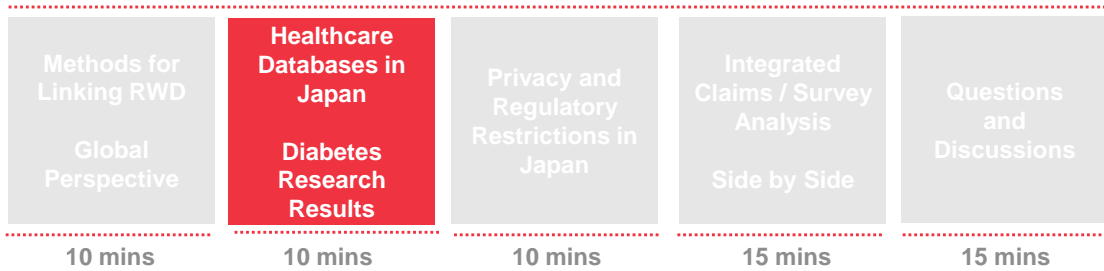
Is it presently available?

- To be discussed in this workshop

What are the limitations?

- Cannot perform cross-dataset analysis
- Can't make any assumptions around casuation

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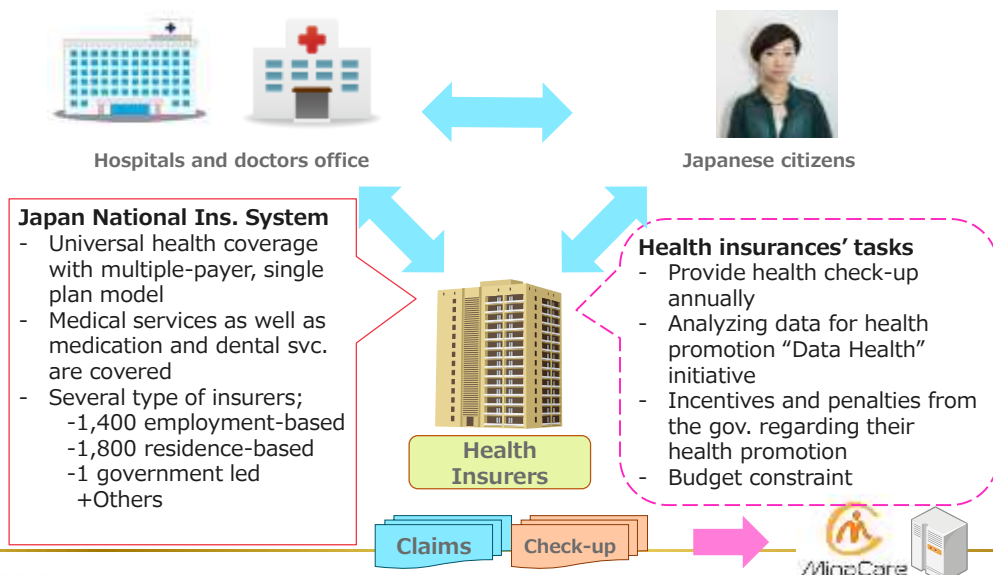
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Health care system and its data generation in Japan



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Data fields in the claims database (excerpt)

Claims data

1	Subject ID
2	Age
3	Gender
4	Insurance type
5	Claim type
6	In-/Out- patient
7	Date of care
8	Total amount billed
9	Length of stay
10	Medical center ID
11	Diagnosis code
12	ICD-10 code
13	Disease grope
14	Flag for main diagnosis
15	Flag for differential diagnosis
16	Diagnosis
17	Date of diagnosis

18	Pharmacy ID
19	Drug name
20	Drug code
21	Drug price
22	Flag for generic drug
23	Dosage
24	Prescription days
25	Date of prescription
26	Date of dispense
27	Procedure code
28	Procedure name
29	Date of procedure
30	# of procedure

Check-up data

1	Subject ID
2	Age
3	Gender
4	Date of check-up
5	Body height
6	Body weight
7	BMI
8	Waist circumference
9	Blood pressure(S/D)
10	Fasting blood sugar
11	HbA1c
12	Total cholesterol
13	HDL
14	LDL
15	Triglyceride
16	AST
17	ALT
18	Gamma GTP
19	Urinary sugar
20	Urinary protein
21	Smoking habit



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Data extraction method

The MinaCare database is a subject-level database that protects the identity of individuals. MinaCare is allowed to use such anonymized data for public health purposes under the data transfer contract with its client health insurers.

Subjects' data are extracted with the following conditions;

- Patients with diabetes are identified using the ICD-10 code of diabetes in at least one claim record month each fiscal year
- Smoking status, obesity, HbA1c, and FBG are extracted from those who meets the condition above and who have check-up data
- Prescription for diabetes are identified using the drug code for anti-diabetes
- There are no exclusion criteria for this study.



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Data extraction result

		2010	2011	2012	2013	2014	2015	2016	
Number of diabetes patients		75,140	118,525	138,068	112,511	117,467	107,269	96,741	
Age	mean	57.6	56.4	56	54.8	54.7	54.4	54.2	
	SD	11.8	12.1	12.3	12.1	12	12	12	
Sex	Male	n	49,414	74,037	84,879	69,116	71,571	64,290	56,312
		%	65.8	62.5	61.5	61.4	60.9	59.9	58.2
	Female	n	25,726	44,488	53,189	43,395	45,896	42,979	40,429
		%	34.2	37.5	38.5	38.6	39.1	40.1	41.8
Smoking status	%	25.2	24.1	23.9	24.2	23.6	23.4	23.6	
Obesity (BMI ≥ 25)	%	44.5	43.8	44.1	47.2	47.7	48.2	49.7	
Diagnosed Hypertension	%	56.1	55	55	54.1	53.9	53.8	53.3	
HbA1c	mean	6.49	6.38	6.38	6.44	6.43	6.43	6.44	
	SD	1.26	1.57	1.52	1.32	1.35	1.31	1.21	
Fasting blood glucose	mean	125.64	122.89	122.05	119.81	119.52	119.11	118.84	
	SD	41.2	40.11	39.89	38.9	36.62	36.57	36.1	
Rx use for T2D	%	41.2	41.3	41.5	42.1	42.2	42.6	42.5	



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Movements from Legal (and practical) restriction

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Personal information (個人情報) and Special care-required PI (要配慮個人情報)

Definition under the Act on the Protection of Personal Information (PPI)

Personal Information (PI)	Information about a living individual which can identify the specific individual by name, date of birth or other description contained in such information
Special care-required PI	PI comprising a principal's race, creed, social status, medical history , etc. ... as those of which the handling requires special care so as not to cause unfair discrimination, prejudice or other disadvantages to the principal.



<http://www.japaneselawtranslation.go.jp/law/detail/?vm=04&re=01&id=2781&lvm=02>

Special care-required PI (要配慮個人情報) also includes..

Definition under the Cabinet order to Enforce the act on PPI

Disorders	Having physical/intellectual/mental disabilities
Medical checkup	Results of medical check-ups, done for prevention/early detection of a disease
Recommendation based on medical checkup/diagnoses	Guidance for the improvement or medical care / prescription, based on the result of medical check-ups etc.



<http://www.japaneselawtranslation.go.jp/law/detail/?vm=04&re=01&id=2885>

Difference between PI and special-care required PI

How can data be provided to third parties?

Base case (OPT-IN)	Need to obtain in advance a principal's consent
Exceptional (OPT-OUT)	Do not OBTAIN the consent but INFORM it (can be denied)
"Exceptional (OPT-OUT)" procedure CANNOT be adopted for the Special-care required PIs	

Then, how can claim data / health data can be obtained???

Another way for providing health data via opt-out method – Anonymously processed Information

Anonymously Processed Information (匿名加工情報) is..

- | | |
|-----|--|
| 1 | Info. produced from processing personal information so as NEITHER to be able to identify a specific individual |
| and | |
| 2 | NOR to be able to restore the personal information |

API can be provided to the third party via OPT-OUT method



How to secure Anonymously Processed Information (API) ??



https://www.mdv.co.jp/privacy_policy.html



Personal information law (PIL) and Next Generation Medical Foundation Law (次世代医療基盤法)

Next Generation Medical Foundation Law aims to...

1	Constructing the foundation of health data (not simply claim data) which help to realize “State-of-the-art health, medical, caregiving system.
2	Healthcare facilities can provide “CLINICAL INFORMATION (医療情報)” unless principals denied to be done so
3	Health care facilities do not need to anonymize (匿名化) their information, without any outsourcing contract
4	Patients CAN DENY the provision of their clinical information

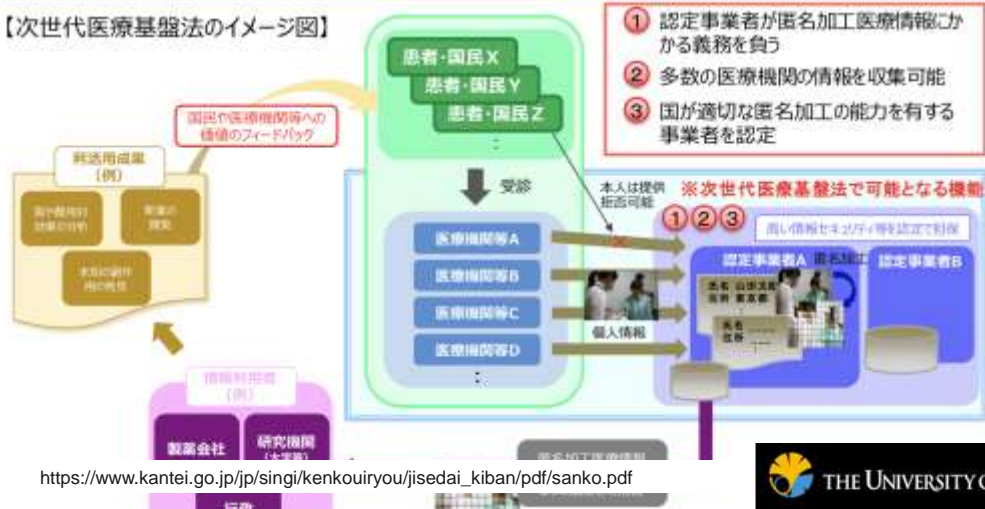
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次世代医療基盤法の全体像(匿名加工医療情報の円滑かつ公正な利活用の仕組みの整備)

個人の権利利益の保護に配慮しつつ、匿名加工された医療情報を安心して円滑に利用することが可能な仕組みを整備。

- ① 高い情報セキュリティを確保し、十分な匿名加工技術を有するなどの一定の基準を満たし、医療情報の管理や利活用のための匿名化を適正かつ確実に行うことができる者を認定する仕組み(=認定匿名加工医療情報作成事業者)を設ける。
- ② 医療機関等は、本人が提供を拒否しない場合、認定事業者に対し、医療情報を提供できることとする。認定事業者は、収集情報を匿名加工し、医療分野の研究開発の用に供する。

【次世代医療基盤法のイメージ図】

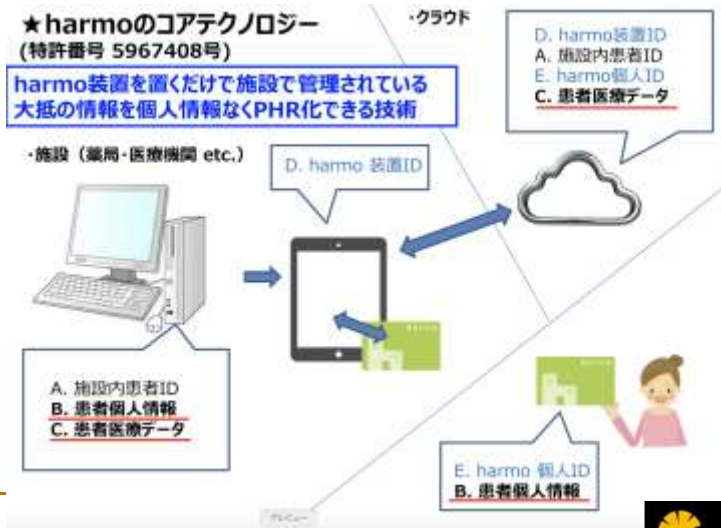


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https://www.kantei.go.jp/jp/singi/kenkouiryou/jisedai_kiban/pdf/sanko.pdf

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Another example to construct database WITHOUT any personal information..harmo system



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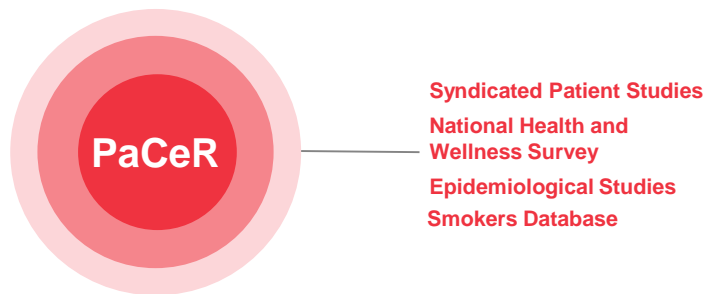
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Kantar Health Patient-Centered Research (PaCeR) Program

- Kantar Health's National Health and Wellness Survey (NHWS), part of Patient-Centered Research (PaCeR)
 - + Annual cross-sectional Internet-based survey of adults (18 years and older)
 - + Includes epidemiological data, treatment information, **health behaviors, and health outcomes**
 - + Recruited through Internet panels using a stratified random sampling framework to ensure demographic representativeness



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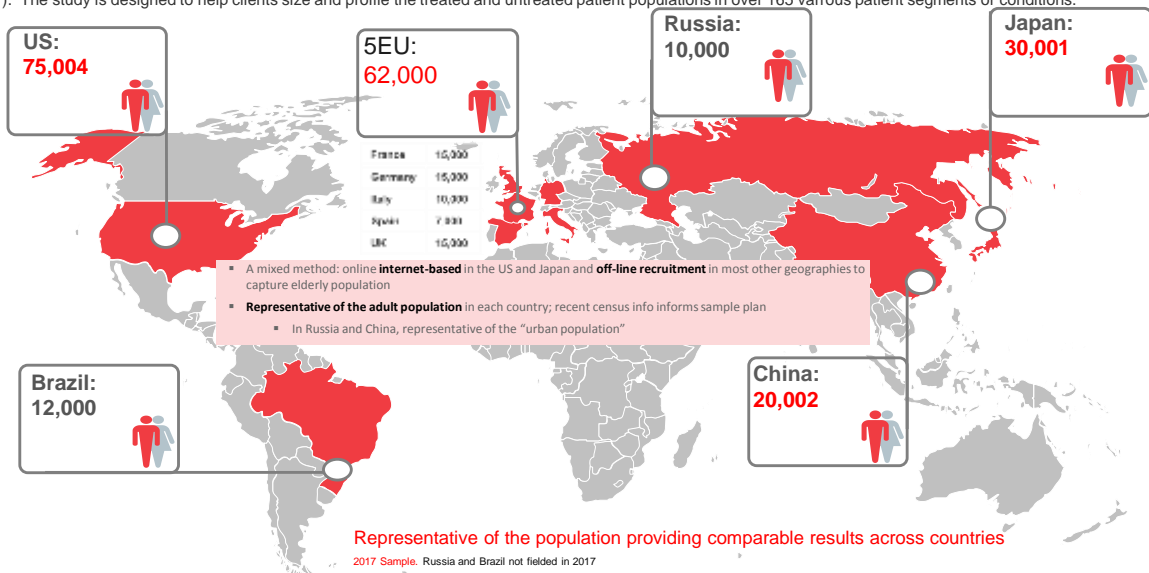
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PaCeR (Patient Center Research) Sample Sizes

The Kantar Health survey provides a unique look into the healthcare market from the viewpoint of the consumer. Data has been collected annually (sometimes every other year). The study is designed to help clients size and profile the treated and untreated patient populations in over 165 various patient segments or conditions.



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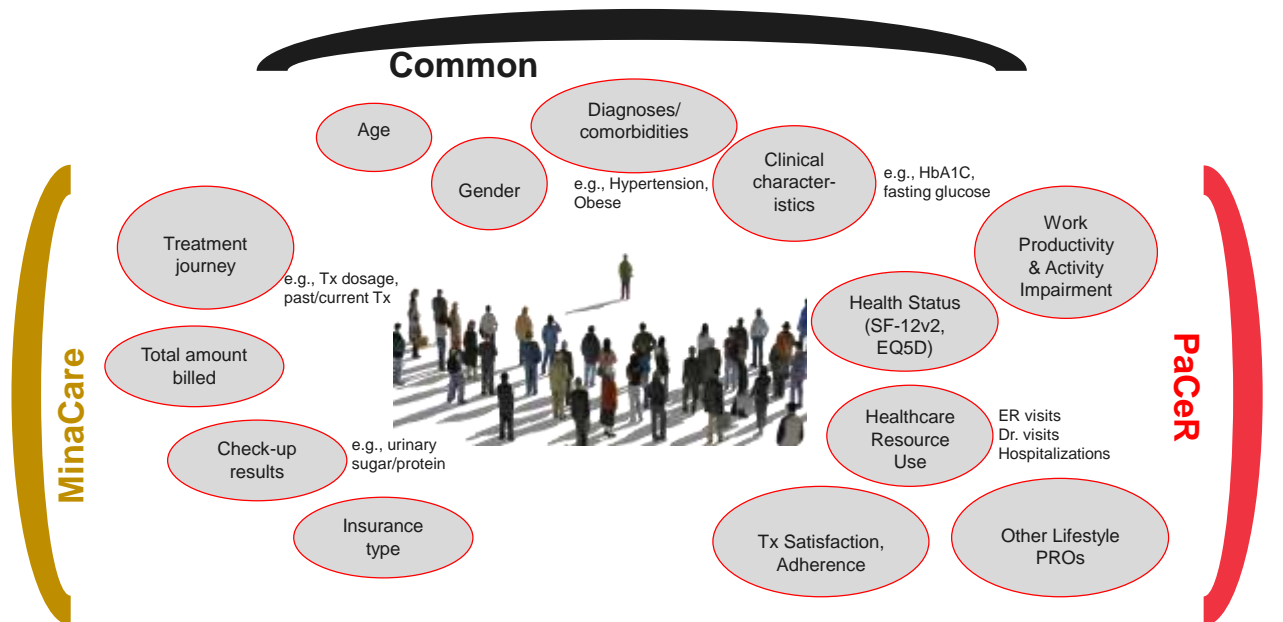
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What if we want to evaluate **humanistic burden** AND **treatment patterns**?

INTEGRATION of **PRO data** and **healthcare claims and health check-up data**.



Full insights from using **BOTH** datasets, to leverage on their strengths.



Insights from the Kantar Health patient-reported outcomes data (PaCeR data)

Disease of interest	
Self-reported diagnosis of T2D	
Obesity Based on BMI (BMI \geq 25) that was converted from self-reported height and weight	
Health outcomes	Demographics and Health History
Health-related quality of life (HRQoL) SF-12v2 <ul style="list-style-type: none"> • Mental component summary score • Physical component summary score • EQ5D Index Healthcare resource utilization <ul style="list-style-type: none"> • No. of physician visits • No. of emergency room (ER) visits • No. of hospitalizations Work Productivity and Activity Impairment <ul style="list-style-type: none"> • Absenteesim • Presenteesim • Overall work productivity loss • Overall activity impairment 	Age Gender Education level Smoking status Alcohol use Exercise behavior Patient Activation Measure Charlson comorbidity index <small>Based on self-reported physician diagnoses</small>

Patient-reported Outcomes – What PaCeR data can do...

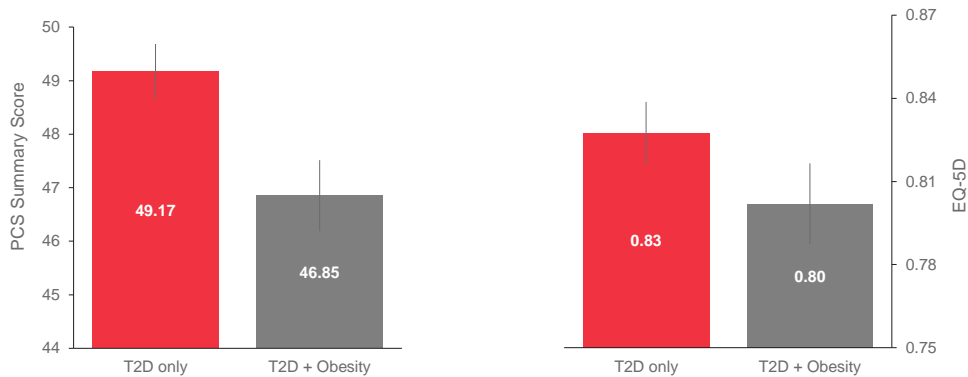
- To quantify humanistic burden and treatment adherence and satisfaction associated with obesity among T2D patients
 - HRQoL
 - Healthcare resource utilisation
 - Work productivity and activity impairment
 - Treatment satisfaction
 - Treatment adherence
 - Etc...



MULTIVARIABLE RESULTS – Burden

T2D patients with obesity scored significantly lower on the mean PCS score and EQ-5D index, compared to T2D patients without obesity.

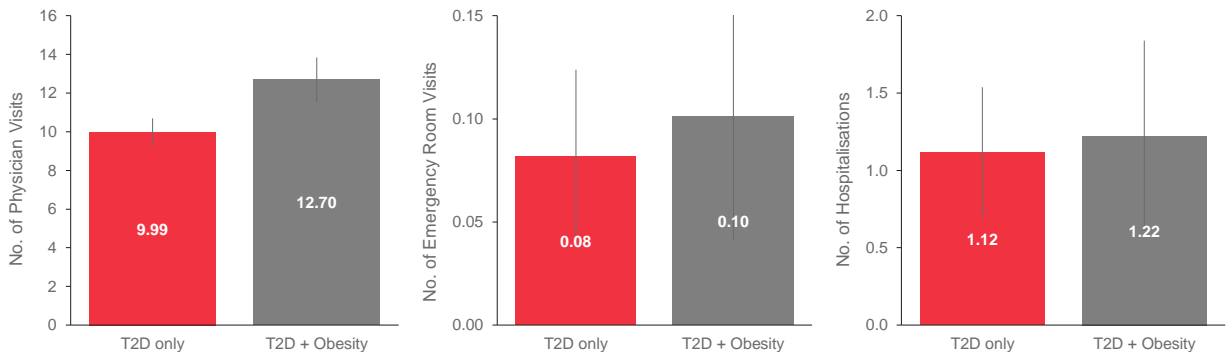
Adjusted HRQoL Scores for Obese Patients among Patients with T2D



MULTIVARIABLE RESULTS – Burden

Significantly more average physician visits, emergency room visits, and hospitalisations during the prior 6 months were observed among T2D patients with obesity, as compared to T2D patients without.

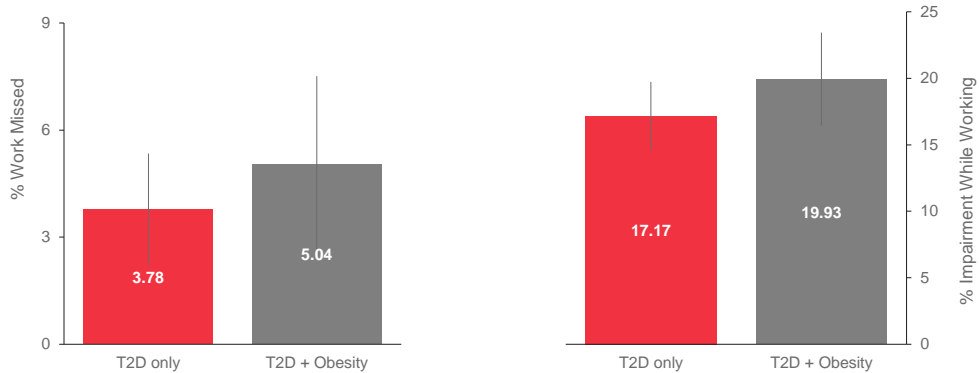
Adjusted Healthcare Resource Utilisation for Obese Patients among Patients with T2D



MULTIVARIABLE RESULTS – Burden

Patients with T2D only have significantly less WPAI, compared to patients with T2D and obesity.

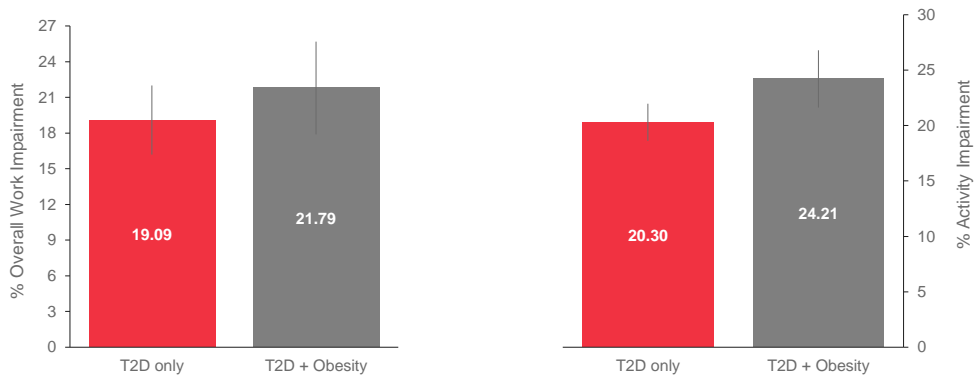
Adjusted WPAI Scores for Obese Patients among Patients with T2D



MULTIVARIABLE RESULTS – Burden

- Patients with T2D only have significantly less WPAI, compared to patients with T2D and obesity.

Adjusted WPAI Scores for Obese Patients among Patients with T2D



Diagnosed T2D Patients Characteristics from PaCeR

			2010	2011	2012	2013	2014	2016
Number of diabetes patients			957	1057	1067	1053	1067	1480
Age	mean		62.0	61.26	61.93	60.87	60.23	63.5
	SD		11.1	11.38	10.75	11.09	10.46	6.92
Sex	Male	n	766	782	836	820	902	1207
		%	80.0	74.0	78.4	77.9	84.5	81.6
	Female	n	191	275	231	233	165	273
		%	20.0	26.0	21.6	22.1	15.5	18.4
Smoking status		%	24.6	23.7	24.0	25.8	28.6	24.3
Obesity (BMI ≥ 25)		%	38.3	38.4	38.7	40.7	40.5	38.0
Diagnosed Hypertension		%	36.9	41.5	43.9	42.1	38.6	41.4
HbA1c	mean		6.64	6.68	6.74	6.85	6.89	6.92
	SD		1.11	1.20	1.17	1.08	1.14	1.16
Fasting blood glucose	mean		119.11	116.79	115.54	115.40	114.77	117.77
	SD		29.37	27.54	26.09	26.92	22.78	30.19
Rx use for T2D		%	79.5	79.2	83.6	81.8	81.3	85.6



Why is Minicare and NHWS different in this study?

- Different sociodemographic status
- Different recruitment procedure
- Different insurance status
- Etc...



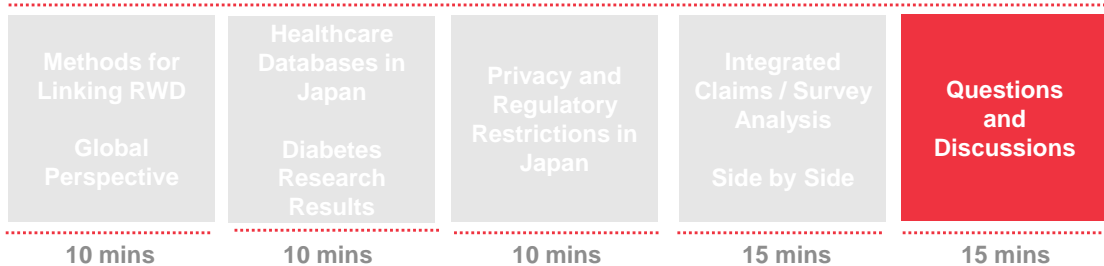
What can we do?

- One-to-one matching is ideal
- Propensity score matching may be useful when there are regulatory restrictions
- Respect the different datasets in what they are telling us for the respective patient cohorts...presenting holistic view of the market

Conclusions

1. Differences may exist between datasets. This calls for data integration methods, such as a propensity score matching method
2. The challenge remains to find the optimal approach to integrate the database to get the holistic view of a patient journey
3. This idea of data integration may be applied to other disease conditions and to other types of disparate datasets (e.g., patient surveys and electronic health record)
4. 'Integrate' datasets when you can but if you can not then ...
...use different data sources/ sets to generate integral parts of the patient ecosystem for a more holistic view of those living with a disease.

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Thank You!

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