How to start a registry study

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COI disclosure Information

Presenter: Taiki Kojima

I have two grants to disclose

- Grants-in-Aid for Scientific Research (**Kakenhi# 22K09085**), Ministry of education in Japan

  for **Japan Pediatric Difficult Airway Registry (J-PEDIA) study**

- **Annual Research Grants,** the department of clinical research, Ministry of Health, Labor and Welfare

- The *3rd* largest metropolitan city in Japan

- As of 2015, the population is *10.11* million

Food in Nagoya

Misokatsu
Deep fried pork katsulet
with thick Miso sauce

Tebasaki
Deep fried spicy
chicken wings

Misonikomi Udon
Udon stewed in
a Miso-based broth

Hitsumabushi
Grilled eel on rice
with sweat soy sauce
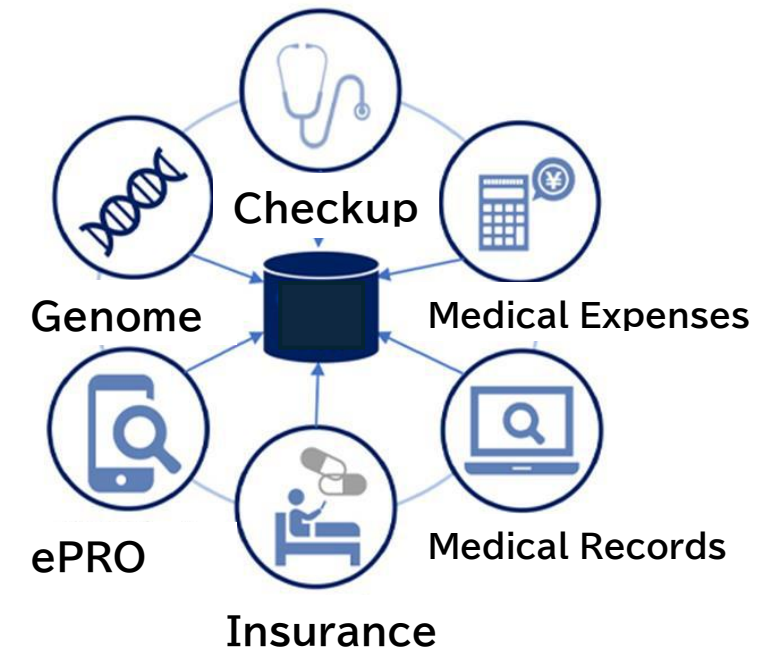

Tenmus
A rice ball with shrimp
tempura on the top

Is RCT ALWAYS BEST ??

Real-world-data（RWD）study

"RWD is data derived from sources that are associated with outcomes in a **HETEROGENEOUS** patient population in **REAL-WORLD SETTINGS**"

- **Registry dataset**
- Health insurance claims
- Electronic health records
- Patient surveys

	Registry study	RCT
Patient background	**VARIOUS**	Very **LIMITED**
What can be assessed	Benefits in **actual practice**	Benefits of intervention itself
Characteristics of results	Can apply to **WIDE RANGE** of patients	Minimized biases
Biases	**MUST** adjust confounders	**LESS NEED** for adjusting confounders
Cost	**Low**	High
Feasibility	**High**	Low

3 BENEFITS of registry study

Registry study reflects the current clinical practices in the real world (**Major clinicians' interest**)

Registry study can provide research experiences by utilizing existing dataset (**High feasibility**)

Collaborators share clinical knowledge and experiences (**Education/ Quality improvement**)

My experience of registry study

Example of Japan Pediatric Difficult Airway Registry

(**J-PEDIA**)

- A prospective, multicenter, registry-based study in Japan

- Describe the adverse events (AEs) and risk factors during securing airway under general anesthesia in children

https://www.jpediajapan.com/

Overview of clinical research flow

Clinical question

▼

Review of previous studies

▼

Setting PICO/ Create a protocol/
Create a data-registration platform

▼

Data collection/analysis

▼

Create a manuscript/ Review process

Clinical questions

- How frequent do AEs occur when securing airway during pediatric anesthesia in Japan? (Epidemiological question)

- How much do difficult-airway (DA) features increase the risk of AEs? (Hypothetical question)

Setting PICO

Items	Contents
Patient	Children <18 years old who are secured airway during general anesthesia
Intervention/ Exposure	Difficult airway features (+)
Comparison	Difficult airway features (-)
Outcome	Occurrence of AEs

Review of previous studies
（Clarifying Knowledge gap）

- APRICOT **NOT** designed to explore AEs **SPECIFICALLY** attributed to airway management

- PeDI, 80% were children with DA

  AEs risk with DA features unclear due to **A LACK OF CONTROL**

- Prevalence of obstruction is higher in Asians
  （**Epidemiological data in Asians** is needed）

FINER	Contents
Feasibility	• REDcap system available in Japan • Sample size was approximate 17000 that can be achieved within 2-year data collection
Interest	Risk of AEs during airway management - major interest
Novelty	First large multicenter study in Japan
Ethics	Less challenging compared to interventional studies
Relevance	Results data can be utilized to improve safety of anesthesia

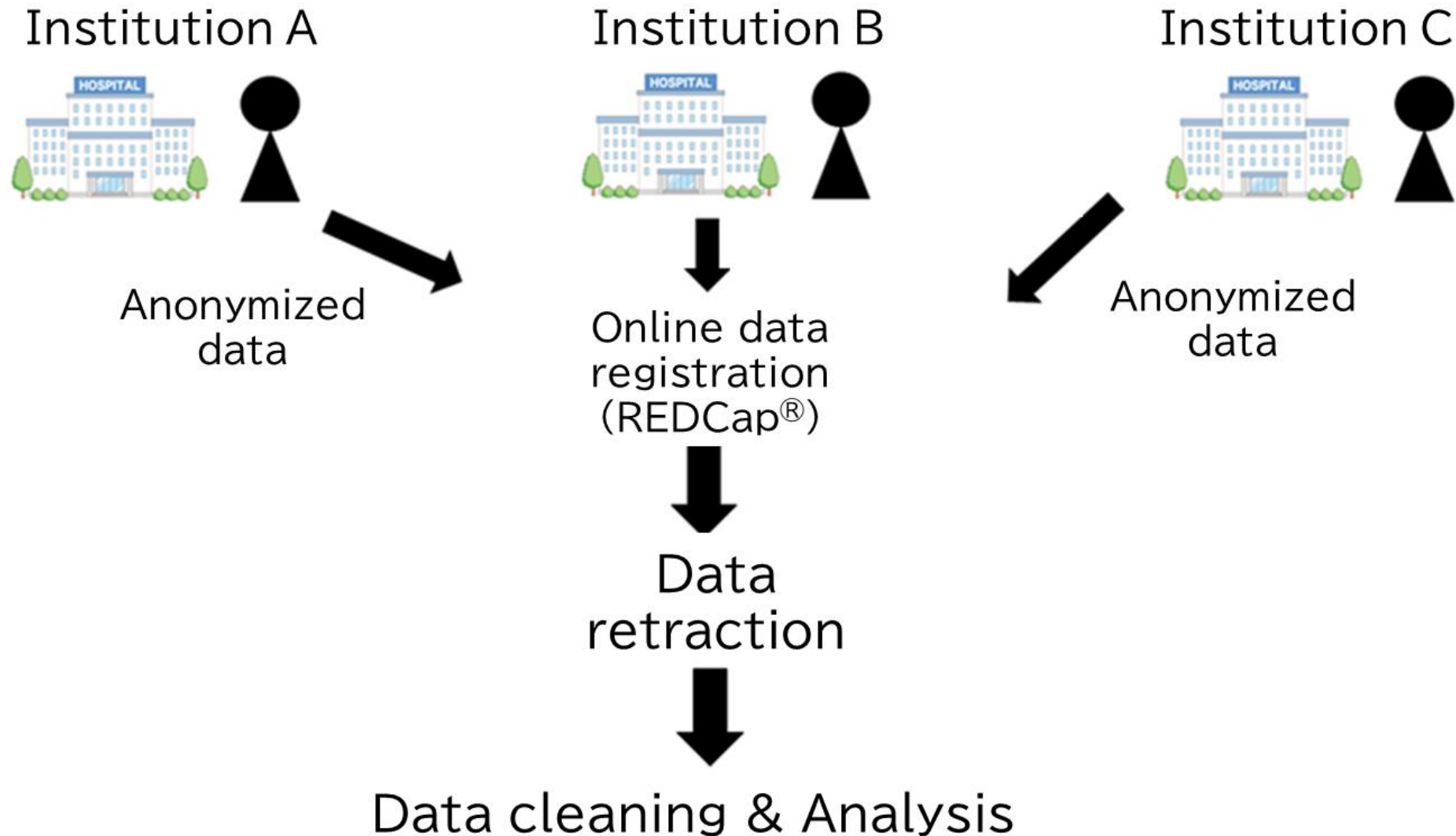# Quality control of data collection

Data collected paper-based form

⬇

- Paper-based forms **VERIFIED by site-specific research leaders**
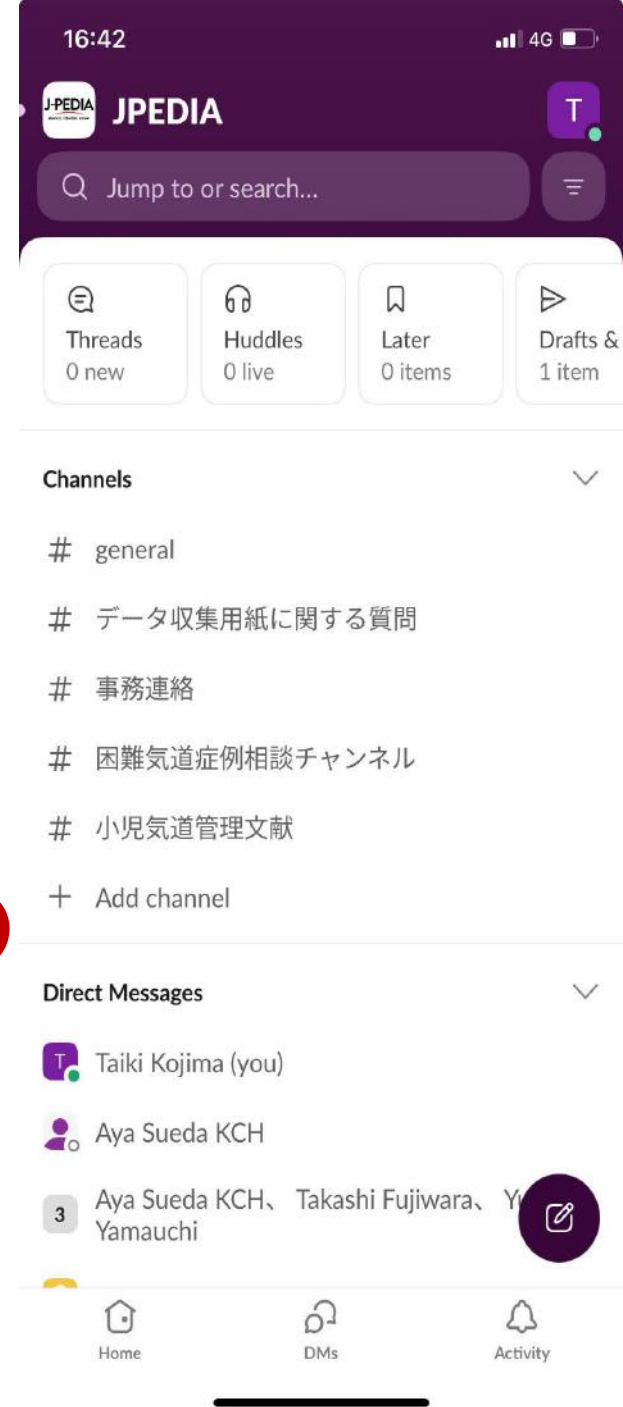- Capture rate is **≥95% of cases**

⬇

Collected data in paper-based form is registered in REDCap® system at each institution

Data Collection（REDCap®）

For **EFFECTIVE** Communication

- **Online research meetings**

  - Confirm the research terminology

  - Report research progress

- **Communication application（Slack®）**

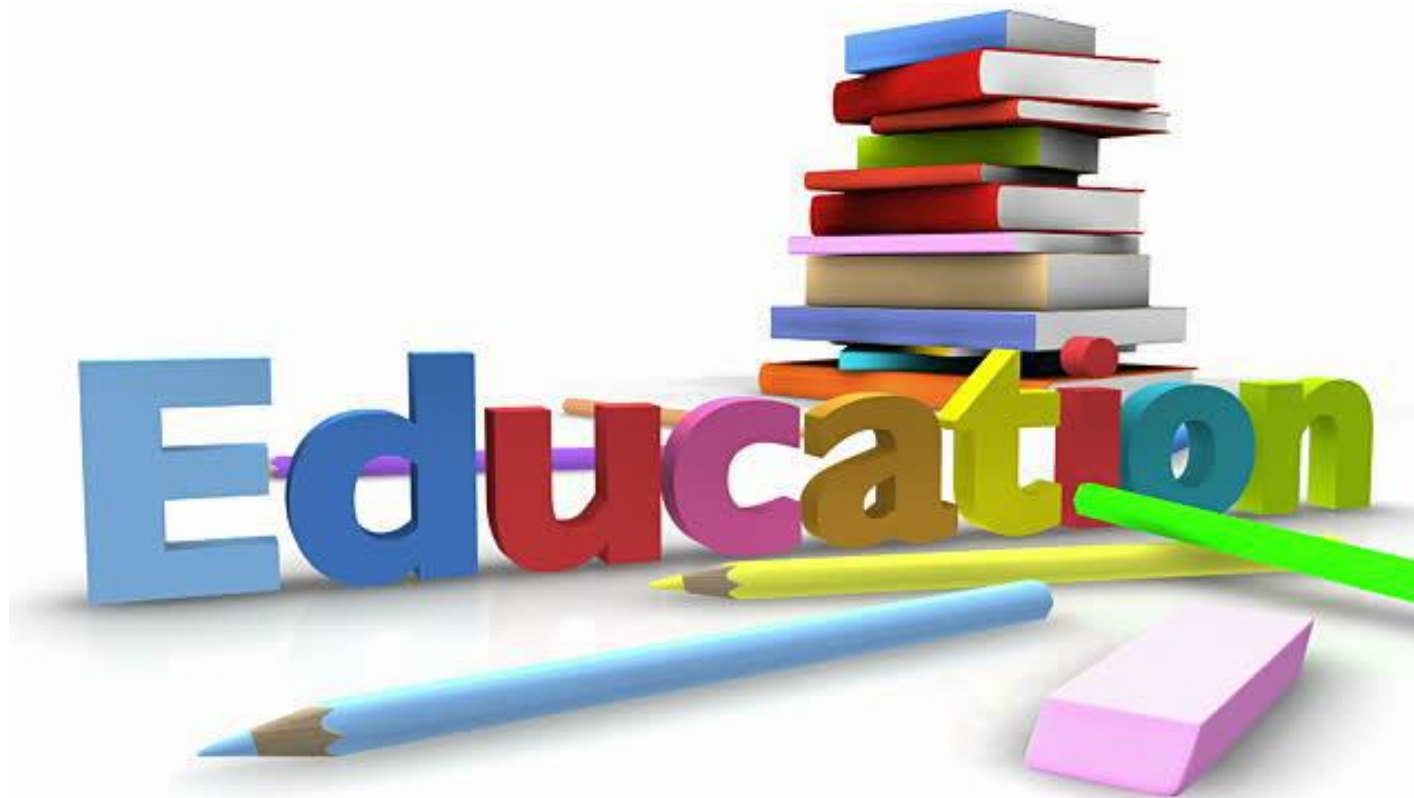 - Definition research terminology

  - Technical issues for using REDCap®

Research Mentor

FIND A MENTOR

Your mentor

- leads your research project to the **RIGHT** direction

- improves the **EFFICIENCY** in your research work

- improves your **RESEARCH SKILLS** through discussion

- helps you to create **ROBUST** study protocol

- keeps you in **GOOD MENTAL HEALTH**

J-PEDIA ⇒ EDUCATION

Real dataset is best educational material

J-PEDIA provides a dataset to conduct secondary research

- Trainees can conduct clinical research with **ALREADY EXISTED** dataset

Group mentoring system

J-PEDIA collaborators have discussion for secondary studies through online meetings

Trainees **CAN**

- Create **robust study protocol**

- Have a support of **data analysis**

- Have a support of **writing & revising manuscript**

Take-home messages

- Registry study provides **PRACTICAL** information that could be **DIFFERENT** from RCTs

- **RESEARCH MENTORS** are MUST for your success

- Registry study will **KILL TWO BIRDS WITH ONE STONE** (**Research & Education**)

References

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- Int J Appl Basic Med Res 2015;5:82

- Regulatory Science, 2017; 7: 197-203 (Japanese)

- Kojima T, et al. BMJ Open 2023;13:e067554

- Kojima T, et al. Paediatr Anaesth 2024; 34: 385-6

Thank you for coming today !!

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