

Patient Registry

دکتر اسماعیل فخاریان

استاد

گروه جراحی مغز و اعصاب و

مرکز تحقیقات تروما

۲۷/ اردیبهشت / ۱۴۰۰

معاونت تحقیقات و فن آوری اطلاعات دانشگاه علوم پزشکی کاشان

Definition

A patient registry is:

- An organized system, based on
- Observational study methods, for
- Collection of uniform data, to
- Evaluate a specific outcome for
- A population (with a disease, condition or exposure), &
- Serves scientific, clinical or policy purposes

Major Purposes of Registry

Pt registries should contribute to improvement of:

- Pt care
- Healthcare planning
- Social, Economical, &
- Quality of life outcomes

Types of Pt Registries

Registries are classified according to **definition** of their **populations**:

- **Disease or Condition** Registries
- **Product** Registries
- **Health Services** Registries

Category	Diseases and conditions	Products	Services, events
Object type	chronic, acute communicable, rare diseases, disabilities, cause of death	medicines, devices, equipment	diagnostic, curative, preventive, discharges, births, abortions
Purposes / objectives (primary and secondary)	disease surveillance, control, natural course of disease	post-market surveillance	intervention evaluation, quality of care
	health outcomes (objective, patient reported)		
	effectiveness (clinical, comparative, financial)		
	safety and harm (HTA, vigilance)		
	intervention (planning, guidelines, reminders)		
Coverage (geographical and organizational)	health care unit (GP, hospital)		
	local (counties, districts, insurers, professional associations, NGOs)		
	national (MS, non-MS)		
	international (regional, EU, European region, global)		
Population definition	population (geographically based) ³		
	population based (exposition dependent) ⁴		
	patient (user, client, insured party)		
Observation unit	person with a characteristic of observation	person related device, equipment item	person related event (birth, death, service)

Table 2.2: Distribution of identified registries across European countries

Country	N	Country	N
Spain	191	Latvia	17
UK	139	Estonia	16
France	82	Slovenia	15
Portugal	66	Netherlands	14
Ireland	65	Multi-country	13
Germany	41	Czech Republic	11
Hungary	40	Switzerland	10
Austria	38	Malta	9
Italy	38	Cyprus	8
Finland	32	Greece	7
Sweden	29	Romania	6
Croatia	28	Lithuania	4
Poland	24	Serbia	2
Norway	23	Albania	1
Belgium	19	Bulgaria	1
Denmark	19	Georgia	1
Slovakia	18	Turkey	1
		Total	1028

Disease or Condition Registries

- Disease or condition registries include pts with the same diagnosis, e.g. cystic fibrosis or heart failure, or the same group of conditions such as disability.
- It could be hospital/clinic-based or population based.

Primary purpose

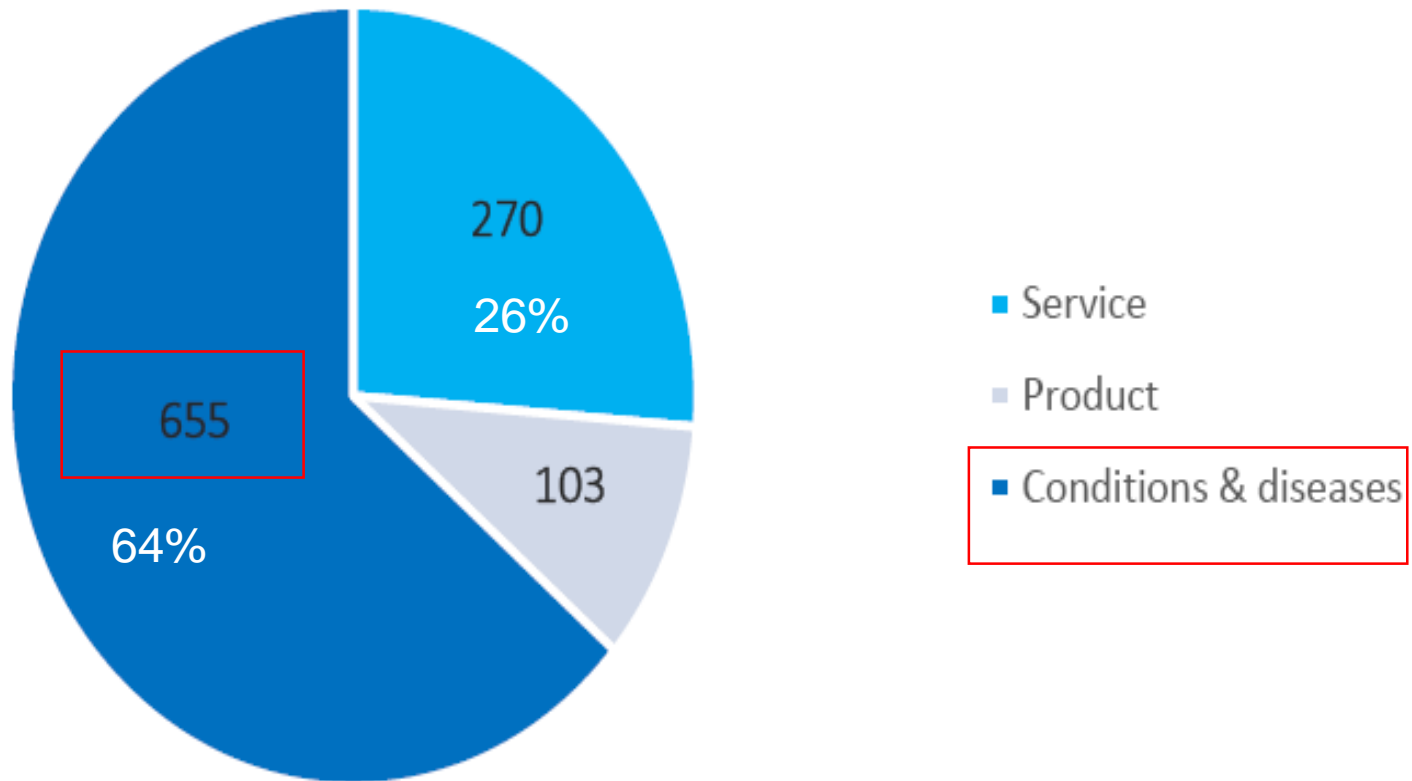
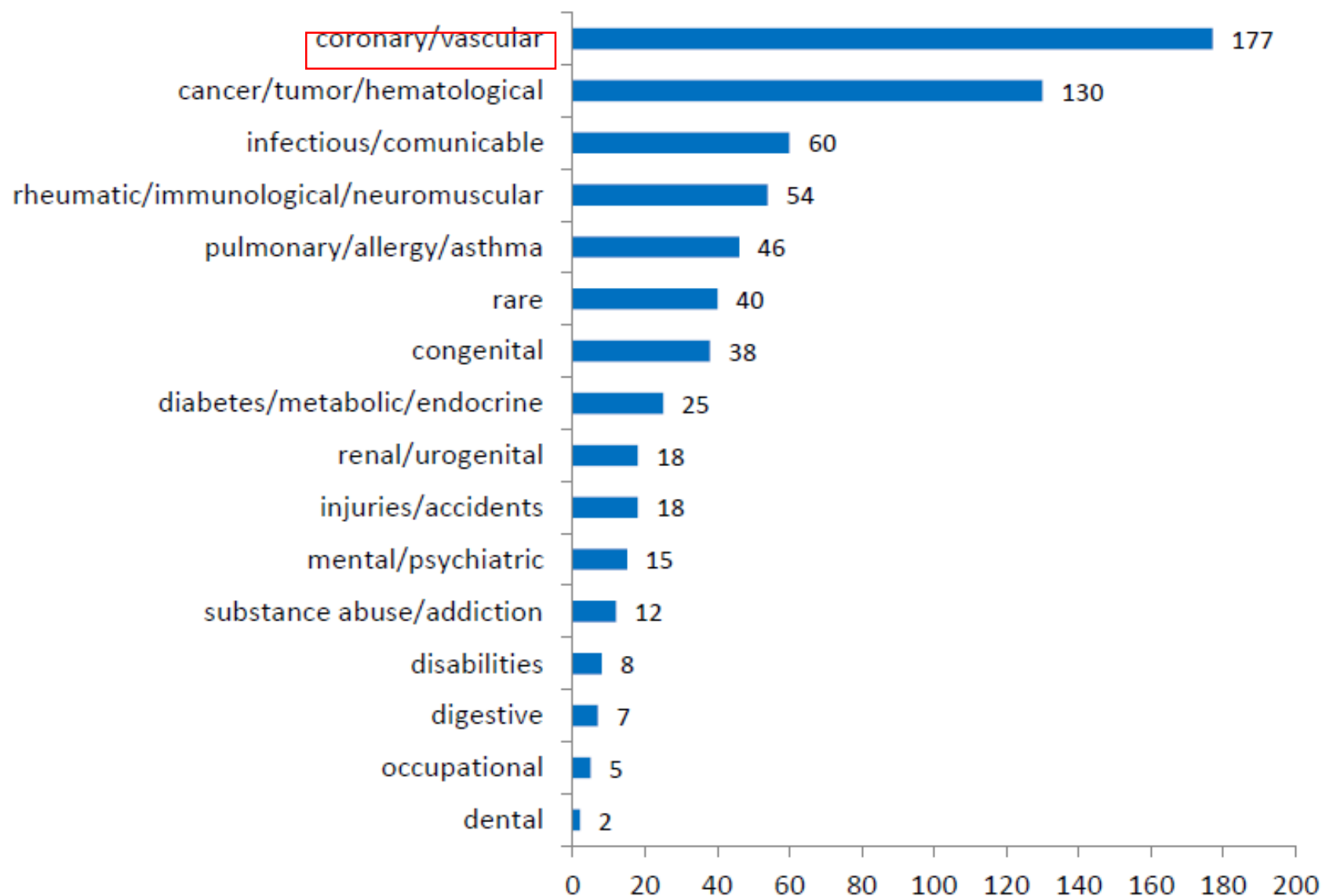


Figure 2.2: Breakdown of all registries based on primary purpose (N=1028)

Disease based registries



Product Registry (Post Marketing Surveillance)

- Once a drug or device is approved for use by an authority, it requires quality assessment for post approval phase.
- Registry is used for identifying & understanding of product safety.

Product Registry

Registries aim to **assess safety or harm** associated with the use of various products (drugs/devices) need to anticipate & assess the need for adverse event detection, processing & reporting.

Device Registries

- Providing helpful information on the long-term effectiveness of devices & their safety
- Keeping track of the impact of factors such as type of surgical technique, surgeon, hospital, & pt characteristics.

Swedish Hip Arthroplasty Register (SHAR) www.shpr.se/en

Started in 1979, web-based recording since 1999, measuring pt reported variables since 2002.

It had 98% pt coverage & 100% hospital coverage in 2009.

Revision rates for hip implants in Sweden declined over the years & the survival of the implants in age>65 is *3 higher than US.

These are due to registry's success in follow up of the patients

The Swedish Hip Arthroplasty Register (SHAR) (www.shpr.se/en) is presented as illustrative example of registry effectiveness.

The registry started in 1979, a web-based reporting system has been in place since 1999, and since 2002 it has measured patients reported variables. in 2005 the registry has excellent coverage (patient coverage 98% and hospital coverage 100 % in year 2009).

the registry is governmentally funded, and no device-manufacturing industry funding is present (although the registry sells data to industry, without identifiers).

The Swedish legal context enables undisturbed data collection.

The data are collected after surgery and reported to SHAR through the internet.

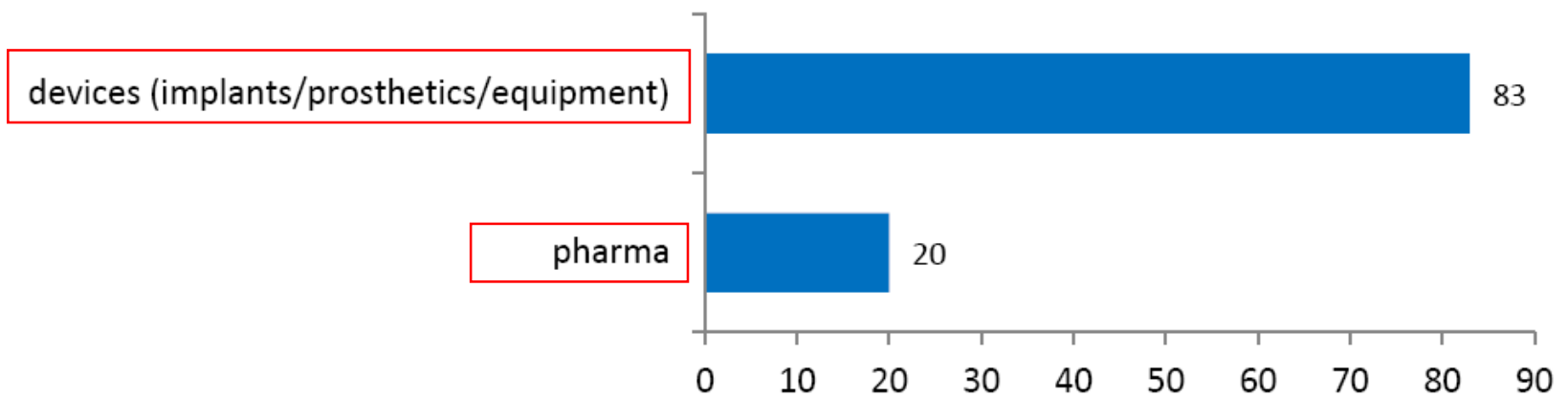
In accordance with Swedish Data Act, all patients are informed about the registry and are free to give up their participation in the registration at any point.

Analyses of registry data focus primarily on re-operations, short term complications revisions (surgeries to replace devices) and patient reported outcomes.

Revision rates for hip implant in Sweden declined substantially over the years, which is largely due to registry's success in detecting devices for hip replacement surgery which have longer survival rates.

Judging by the registry success, for instance in comparison with other countries such as the U.S., the survival of hip replacement implants among the Medicare patients in the united state (1997-2005) and patients aged 65 and older in Sweden, the failure rate is about three times higher in the U.S.

Product based registries



Health Services Registries

Health services registries includes pts undergoing a **common procedure, clinical encounter, or hospitalization.**

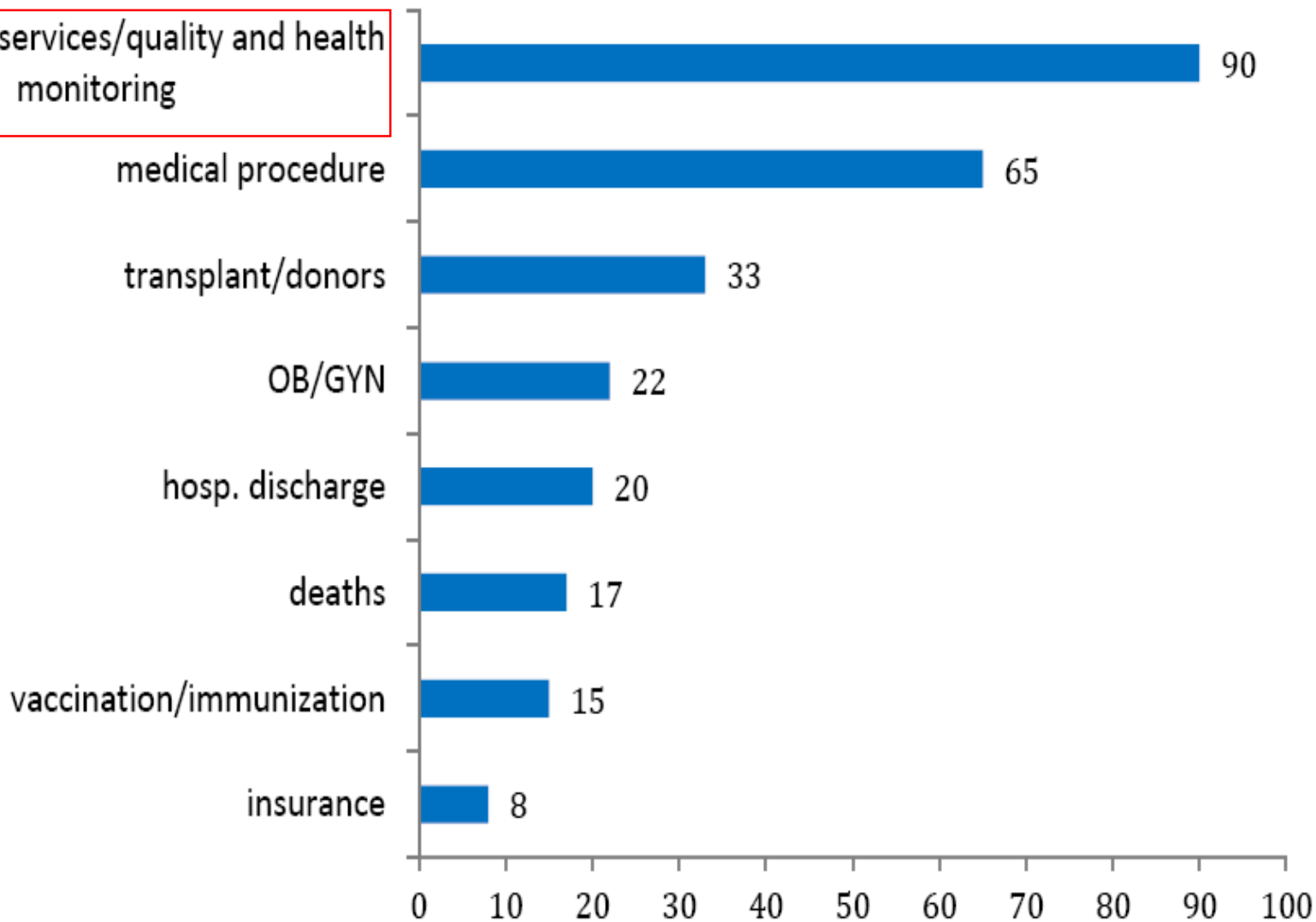
The **focus** of health service registries is on **providing information** used in the **management of health services.**

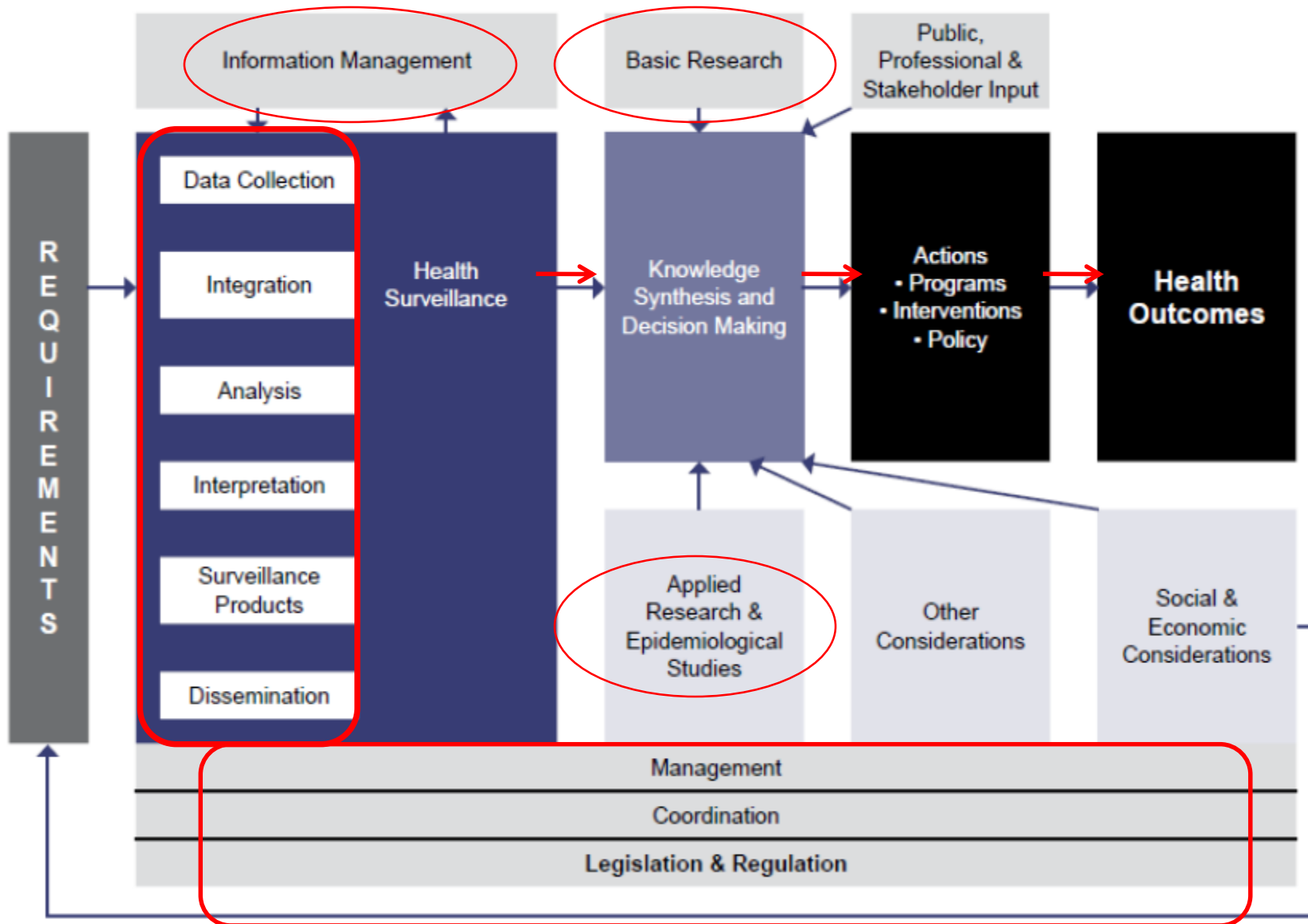
Health Services Registries

Health care service registries are sometimes used to **measure & improve the quality of care**, defined as “the degree to which health services for individuals & populations increase the likelihood of desired health outcomes & are consistent with current professional knowledge.

Service based registries

preventative services/quality and health monitoring





مشکلات موجود

- افزایش موارد درخواست برای ایجاد مراکز ثبت از طرف ا.ه.ع با این تصور و تلقی که صرف وجود یک کارشناس و اقدام برای ثبت برخی داده ها کافی است.

- در مواردی که برخی داده ها در حال ثبت است مکانیسم تعریف شده و منظمی برای نظارت بر کم و کیف آن وجود ندارد.

مشکلات موجود

- موضوع دسترسی به اطلاعات و به اشتراک گذاری آن با سایر ذینفعان از مشکلاتی است که نیاز به توجه خاص دارد.

و بالاخره

- یکپارچگی ثبت داده ها در مراکز که امکان استفاده از آنها را تسهیل و یا دشوار می نماید.

Take Home Message

Pt registry is a data based process with:

- clear objectives;
- legal & economical supports, &
- oriented toward **Health Outcome**

Thank you for your attention