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Original Article

CROSS-SECTIONAL SURVEY OF MULTI-CENTRE PATIENT REGISTRIES IN MALAYSIA

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ABSTRACT
Objective: This survey set out to describe patient registries available in the country, to determine their security features, data confidentiality, extent of outputs produced and data quality of the registries.
Methods: A cross sectional survey was carried out via a self administered questionnaire.
Results: There were 21 patient registries which covered important chronic diseases in health. There was a wide variety in duration since development, size, numbers of centre reporting, funding source and outputs but not much difference in data security and patient confidentiality amongst the registries. There were impressive outputs seen (reports, presentations and journal articles) and high quality data despite most registries being recently developed.
Conclusion: The quality of registries in Malaysia is of high standard but its' major benefits have yet to be realised.
Keywords: Confidentiality, databases, data security, registries.
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BACKGROUND

Patient registry is an organised system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition or exposure, and that serves a predetermined scientific, clinical or policy purpose.[1]

Well-designed and well-performing patient registries can provide real-world view of clinical practice, patients' outcomes, safety and comparative effectiveness, as well as provide evidence for clinical and healthcare decision making.

Many developed nations utilize patient registries in their health care system. For example, in England, there are 250 clearly identified registries with possibly more than 400 in existence.[2] As of 2005, there were 60 registries in Sweden with another 30 to 40 being planned[3] and Norway has more than 60 disease registers. The first disease register came up in Europe in 1856 but the majority of today's disease registers sprung up around the 1950's. The development of disease registers in medical and health then were driven by an urgent need; increasing incidence of chronic disease and failure of the traditional methods of infectious disease epidemiology to provide an adequate framework for the study of chronic diseases.[4]

Irrespective of the original purposes for patient registries, currently there are 4 main reasons why they are important in clinical and health management systems.[1] They are to:

1. Describe the natural history of a disease.
2. Determine the clinical or cost effectiveness of specified health care products/services.
3. Measure or monitor safety and harm of products and services.
4. Measure quality of care.

Natural history of disease
Natural history covers the progression of characteristics, management and outcomes of disease. Patients have a variety of clinical presentations and can respond differently to treatment. This can change according to ethnicity as well as geographical location. Registries which track patients, their management and outcomes allow for documented natural history of a disease in question.

Clinical or cost effectiveness
Clinical effectiveness involves determining if the treatment provided is effective in practice. Most new therapeutic products are introduced into the market after rigorous clinical trials. However, clinical trials are done under rigid settings and do not reflect the real life conditions of all patients affected by the disease. This leads to reduced clinical effectiveness in real life. Cost effectiveness is a means to describe the comparative value of a health care product or service in terms of its ability to achieve a desired outcome for a given unit of resources.[5]

Monitoring safety and harm
Patient registry can serve as an active surveillance system

for the occurrence of unexpected or harmful events for products and services.[6]

Measuring quality of care
Quality of care can be determined by assessing the differences between health care providers or patient populations based on performance measures. These performance measures compare treatments provided or outcomes achieved with 'gold standards' (e.g. evidence-based guidelines) or other benchmarks.[1]

Based on the reasons above, the Ministry of Health (MOH) has developed many new registries in line with the desire to assess our patients' needs and to make decisions based on evidence of our own health care situation and outcomes. These registries utilize Malaysian patient data to address the issues of:

1. Providing clinicians with accurate estimates of treatment outcomes that can be shared with patients.[7]
2. Providing information to the MOH programme planners for the planning of clinical and health services.
3. Opportunities for research and clinical audit (on quality of care rendered).

However, in the enthusiasm to set up patient registries, key factors should not be forgotten; namely patient data confidentiality, data security and quality of the registries itself. The setting up of a patient registry requires considerable sums of financial and human resources and in encouraging the development of registries, it is important that the above key aspects be covered. In the United Kingdom (UK), a survey of the registries showed that there was considerable scope for improvement in terms of data security and ensuring patient confidentiality.[7] Aside from this, 50% of databases only produced 4 or fewer peer reviewed research articles.

With this in mind, this study was undertaken to describe the patient registries in Malaysia and to determine if they have acceptable patient data confidentiality, security and high quality outputs.

METHODS

Study design
This was a cross-sectional survey using a self administered questionnaire.

Objective
The objective of this study was to:

1. Determine the characteristics of patient registries in Malaysia.
2. Determine the security features and level of data confidentiality.
3. Determine the extent of registry data use.
4. Determine the data quality of registries registered in Malaysia.

Study population
All registries were identified via the National Medical Research Register (NMRR). The Registries which were multi-centre and functioning for at least 1 year as of 1st of May 2009 were invited to participate. This is because registry set up requires at least a 1 year time period before it can be fully functioning. Registries or databases involved in products or drug therapy and harm were excluded. The main respondents were the custodians or managers of the clinical registries and database administrators who were responsible for data security.

Study instrument
The questionnaire used was modified from the "UK Directory of Clinical Databases" data collection manual. It covered the following aspects; management team, sources of funding, geographical area, clinical speciality, duration of registry coverage, numbers of notification, linkages to other databases, data confidentiality, storage and security, use of data and data quality. The quality of data in the registries was measured using 8 criterias; representativeness of patient population, completeness of patient recruitment, completeness of data collected, use of clear definitions for variables, use of rules for recording of data, reliability of data coding, independence of observations to main outcome measures and the extent of data validation.

Ethical issue
This study did not require ethical approval because there were no patients or actual data involved and questionnaires were answered by registry managers.

Statistical analysis
This study used descriptive analysis. Statistical software used was SPSS version 15.

RESULTS

Organization and management of patient registries
Out of the 24 registry managers invited, 21 responded (88% response rate). Most of the registries covered both Peninsular and East Malaysia (16 registries) while the rest covered only Peninsular (Table 1). All except 4 are set up for continuous reporting of data. Follow up periods for individual patients ranged from every clinical visit to yearly visits. The team members involved in the day to day management of the registries are mainly doctors, nurses, project managers and information technology specialists. Those involved for each registry vary in terms of numbers and designation.

18 registries are funded solely from government grants while only 3 have more than one source of funding; industry,

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professional bodies and non governmental organisations. The amount required to manage a registry annually ranged from RM 100 000 to RM 400 000. There was no correlation between the funding amounts per year and numbers of data collected or the number of centre's participating in the registry, as most of the cost incurred was for information technology (IT) infrastructure set up.

Table 1: Organisation and management of patient registries

Features	No. of registries (%) n=21
Geographical area covered:	
Whole of Malaysia	16 (76)
Peninsular only	5 (24)
Time trend for data collection	
One off	4 (19)
Follow up	17 (81)
Day to day management team	
Doctors	19 (91)
Allied health professionals	7 (33)
Statisticians	13 (62)
General/project managers	17 (81)
Nurses	19 (91)
Epidemiologists	6 (29)
IT Specialists	18 (86)
Research assistants	3 (14)
Funding source	
Government	21 (100)
Industry	1 (5)
NGO	2 (10)
Professional body	2 (10)
Funding amount per annum (RM)	
100,000 – 199,999	10 (48)
200,000 – 299,999	8 (38)
300,000 – 399,999	2 (10)
≥ 400,000	1 (5)

Characteristics of patient registries

Although the oldest registry has been functioning for 9 years, the majority are under 3 years of age (76%). All registries emphasize on measuring the quality of care (Table 2) and most of them (63%) were established to cover the 4 main functions of a registry. 70% of registries were designed for degenerative diseases. All pathological aspects in medicine are covered such as allergy, infections, congenital diseases, drug induced pathologies, injuries and psychopathological problems. More than half of the registries capture patient records from all age groups and all of them included both genders.

All registries receive MOH data. However, majority (62%) have more than 1 type of health sector reporting to them. 1 registry has all sectors involved; MOH, armed forces, universities, non governmental organisations and private centres. It is also one of the 2 registries with more than 50 centres as data providers, 180 in total. 50% of the registries receive first patient notification within 1 month of initiation while the rest within 12 months. Only one required 36 months from initiation for their first patient notification.

Table 2: Characteristics of patient registries

Characteristics	No. of registries (%) n=21
Objectives	
To determine natural history of disease	18 (86)
To determine clinical/ cost effectiveness of health care product/services	17 (81)
To measure or monitor safety and harm	17 (81)
To measure quality of care	21 (100)
All 4 of the above	14 (67)
Pathogenesis	
Allergy	1 (5)
Infections	8 (38)
Drug induced	5 (24)
Degenerative	15 (71)
Congenital/ genetic	6 (29)
Injury	4 (19)
Psychopathology	1 (5)
Age groups	
Neonatal	1 (5)
Children	1 (5)
Adults	7 (33)
Older people	1 (5)
All age groups	11 (52)
Type of centres reporting	
Ministry of Health	21 (100)
Armed Forces	1 (5)
University	10 (48)
NGO	1 (5)
Private	7 (33)
Number of centres reporting	
< 50	19 (90)
≥ 50	2 (10)
Level of data collection	
Individual	21 (100)
Aggregate / census	8 (38)
Number of patient notifications for year 2008	
0 - 99	2 (10)
100 – 999	7 (33)
1000 – 9999	6 (29)
10000 and above	5 (24)
Duration from initiation of registry to 1st patient notification	
Within 1 month	15 (71)
1- 12 months	5 (24)
More than 1 year	1 (5)

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Security and confidentiality of data
Data capture is mainly via web application. Data storage is 100% electronic with majority (18 registries) having an off site data centre. All of them have their data backed up; 50% ensuring backup is done on a daily basis (Table 3). 67% of registries have data back up located both on site and off site.

All registries have antivirus software and firewalls installed at every workstation, server and network perimeter. The antivirus software is updated hourly. Full scans are done weekly and firewalls have an alerting mechanism for security incidents. 100% of the registries have the following security features installed in their network perimeter; gateway antivirus, intrusion prevention and web filtering. They also have policies for IT security, password protection, screen lock and patch management in place. Each registry has designated personnel in charge of IT security and a disaster recovery plan in place. Disaster recovery plan testing is conducted yearly and the network assessment 6 monthly.

Confidentiality of data stored is mainly anonymised but is reversible to become identifiable (65%). This is much higher compared to only 33% of the registries in UK.[7] The rest have identifiable data stored on the registry databases.

All except 1 registry inform their patients about participation in the registry collectively via a public notice. However, 30% of them do not provide an option to opt out of having their details collected.

Uses of patient registries
All registries have planned outputs (Table 4). Patient registry data is used to produce journal articles, oral papers and poster conference presentations as well as reports (planned or ad hoc basis).

Most registries (65%) produced journal articles and poster presentations. Although poster presentations were a more favoured method of information dissemination, the number of oral paper presentations presented per registry reached as high as 31.

Majority of the registries (62%) produce planned annual reports covering all centres under their purview. Almost all registries make some form of information available to the public, with the majority having 'internet downloadable' annual reports. In terms of other reports, only 10% conducted planned analyses daily. The rest conducts them at quarterly or yearly intervals. Every single registry can perform ad hoc analysis at the central level. Only 1 registry reported that it does not cater for ad hoc analysis at the local level.

Table 3: Data capture, storage, security, and confidentiality of patient registries

Characteristics	No. of registries (%) n=20
Data capture	
Paper-base (post or fax)	11 (55)
Electronic via CD/Diskette	1 (5)
Electronic via web	19 (95)
Auto download/ linked with hospital data	1 (5)
Data storage	
Register book/ paper forms	6 (30)
Electronic – offsite data centre	20 (100)
Back up devices	
CD Rom	1 (5)
External hard drive	2 (10)
Back up tapes	17 (85)
Same server	3 (15)
Separate server	4 (20)
Frequency of back up	
Daily	10 (50)
Weekly	7 (35)
Monthly	2 (10)
Confidentiality	
Anonymised (but reversible if need arose)	13 (65)
Identifiable	5 (25)
Patients informed of data collection	
Collectively informed	19 (95)
Not informed	1 (5)
Patient consent for data collection	
No signed consent but option to opt out	14 (70)
No signed consent or option to opt out	6 (30)

Quality of data
In two thirds of registries, there were at least good evidence that the patient population was representative of the population in the country (Table 5). 70% reported at least 80% in completeness of patient recruitment. At least 60% could confirm that at least 80% of data collected was complete. All registries had explicit definitions for at least 50% of the data variables. 90% had explicit rules for how most of their variables were recorded. Of the registries that had outcome variables, at least one third had observers not independent or blinded to the outcome. Objective patient outcomes were the main outcome for only 1 registry (e.g. laboratory based results).

Data in all registries underwent either range or consistency checks or both during data validation. None had independent or external validation from other sources such as source data (original medical records) verification etc.

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Table 4: Usage of patient registries

Uses	No. of registries (%) n=21
Planned analysis	
Daily	2 (10)
Quarterly	7 (33)
Annually	12 (57)
Annual reports produced	
No	3 (14)
Yes	9 (43)
In the process of 1st report	9 (43)
Reports	
Centre specific	3 (14)
Multi centre	10 (48)
Centre specific and multi centre	3 (14)
Level of information sharing	
Share data via hardcopy documents	5 (24)
Share contact details via web	5 (24)
Share annual reports via web	8 (38)
Share anonymised raw data via web	1 (5)
Outputs (total cumulative)	
Oral Paper presentations	9 (43)
Poster presentations	13 (62)
Reports	8 (38)
Journal articles	14 (67)

Table 5: Quality of data

Quality criteria	No. of registries (%) (n=20)
Patients in registry representative of the population	
No evidence or unlikely	6 (30)
Some evidence	12 (60)
Good evidence	2 (10)
Total population of country included	
Completeness of recruitment	
Few(<80%) or unknown	6 (30)
Some (80-89%)	6 (30)
Most (90-97%)	6 (30)
All or almost all (>97%)	2 (10)
Completeness of data	
Few (<50%) or unknown	1 (5)
Some (50-79%)	7 (35)
Most (80-97%)	10 (50)
All or almost all (>97%)	2 (10)
Use of explicit definitions for variables	
Most (50-97%)	11 (55)
All or almost all (>97%)	9 (45)
Use of explicit rules for deciding how variables are recorded	
Some (<50%)	2 (10)
Most (50-97%)	8 (40)
All or almost all (>97%)	10 (50)
Reliability of coding	
Not tested	4 (20)
Fair	1 (5)
Good	15 (75)
Independence of observations to primary outcome	
Outcome not included	1 (5)
Observer neither independent nor blinded	7 (35)
Independent observer not blinded	11 (55)
Independent observer is blinded or outcome is objective	1 (5)
Extent of data validation	
Range or consistency	12 (60)
Range and consistency checks	8 (40)

DISCUSSION

Patient registries in Malaysia currently cover all the critical chronic medical diseases and conditions. They range from various age groups covered, number of records, patient and geographical coverage. Their potential uses also varied. Despite this variety, a few characteristics on data security and confidentiality were very similar.

Most of the registries used personal identifiers as it is required during record linkage within and between databases and to ensure completeness of recruitment. Hence, data confidentiality becomes an integral part of registries especially when it has personal identifiers. Data confidentiality ideally should be reversibly anonymised so as to minimise risk of disclosure of patient identities but maximise potential use of data.[7] In the registries we surveyed, 65% fulfilled this criterion. This can be explained by the fact that most registries in Malaysia have requested assistance from 1 organisation i.e. Clinical Research Centre (CRC) during its set up. CRC imposes strict criteria on data confidentiality and data security. It imposes stringent information security policies and procedures in controlling access, disclosure control, monitoring access logs, physical protections and data handling. Since we do not have a Malaysian Data Protection Act yet, the security measures taken were done in compliance with the United States (US)[8] and European Standards.[9,10] Therefore, the robust security measures found are to be expected. CRC also plays a role in providing dedicated specialised support to assist clinicians in establishing and maintaining uniform and standardised methods for patient registries. It is what has been recommended for registries in the UK.[7] Currently, funding of all registries is mainly through a special Registry Grant generously set aside by the Deputy Director General (Research & Technical Support) MOH Malaysia. It would be ideal if more professional bodies and other sectors involve themselves in co funding of patient registries. It would lead to long term financial viability and stability.

The registry outputs found here are acceptable as more than 52% of registries are less than 2 years old. Most registries are able to produce reports only after their second year of establishment.

Limitations of study

This study used the NMRR to obtain the number of registries in the country. The NMRR was introduced in 2007 under the directive of the Director General of Health which states all research have to be registered. This may not be all encompassing because there may be independent registries that might have been started earlier on and missed registration. Some may also perceive that patient registry is not research and hence do not need NMRR registration. Also, private sector registries may not feel the need to register themselves if public sector data is not used. Thus, most of this study's findings are limited to public sector registries. The questionnaires are self administered therefore open to possible bias in reporting from the administrators.

CONCLUSION

The quality of registries in Malaysia is of a similar standard and is mainly due to the standardized criteria they fulfil prior to the development of a registry. Despite registries amazing potential for the future of patients in the country, the benefits of many registries are still in its infancy. It is recommended that more clinicians and researchers involve themselves in patient registries to enhance and attain its full potential.

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3 out of 10 clinical students are either overweight or obese

Boo NY, Chia GJ, Wong LC, Chew RM, Chong W, Loo RC. The prevalence of obesity among clinical students in a Malaysian medical school. *Singapore Med J*. 2010;51(2):126-32.
30.1% of clinical students in a private medical school were found to have body mass index exceeding 23.0 kg/m^2. The overweight/obese students were more common among males, and Malays and Indian (versus Chinese). 31% and 7.1% of those who were overweight and obese, respectively, perceived themselves to have normal weight.