

表3. アウトカム論文執筆の有無に対する多変量ロジスティック回帰分析

筆頭著者もしくは責任著者として論文執筆				
多変量解析モデル				
(R ² 0.19; n=319)				
	オッズ比	95% 信頼区間		P*
		下限	上限	
勤務機関				0.229
病院	2.31	0.89	6.01	
その他	2.26	0.28	18.10	
診療所	1.00	—	—	
診療科				0.104
外科系	0.98	0.54	1.78	
基礎系・その他	4.15	1.07	16.03	
内科系	1.00	—	—	
医学博士				0.004
取得	2.44	1.33	4.45	
取得無し	1.00	—	—	
認定医				0.690
取得	1.15	0.58	2.29	
取得無し	1.00	—	—	
専門医				0.345
取得	1.58	0.61	4.04	
取得無し	1.00	—	—	
一週間の労働時間, 平均±SD	1.01	≈0.99	1.03	0.0818
メンター				<.0001
有り	6.78	3.64	12.63	
無し、もしくは不明	1.00	—	—	

* 値はカテゴリーもしくはトレンドPに対して算出

Title

Having a research mentor is a key factor for Japanese physicians to write an original paper in peer-reviewed journals

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Abstract

Background: The number of paper published in top clinical journal has been short in Japan and physician researchers are expected to actively publish scientific papers to international journals.

Objective: To investigate the characteristics and profiles of Japanese physician researchers who have written an original paper in peer-reviewed journals as a first or corresponding author.

Design: A cross sectional study

Participants: Japanese physicians in their 30's - 40's (238 men and 81 women, mean age 41 years old) who were recruited by an email to participate in a Web survey in March 2015.

Main measures: How many original papers the participants had written in English as a first or corresponding author within one year prior to the investigation.

Key Results: In total, 78 physicians (24.5%) had published an original paper as a first author and 39 physician (12.2%) had published as a corresponding author. There were only 72 physicians (22.6%) who reported that they had a research mentor. Significant variables in univariable logistic regression model were work place, clinical departments, DMSc, board, fellow, weekly working hours, and an existence of a research mentor. After adjusting for these variables, multivariable model showed that a physician who had a research mentor compared to those who did not have [Odds ratio (OR) 6.78, 95% Confidence Interval (CI): 3.64-12.63], and a physician who obtained DMSc compared to those who did not (OR 2.44, 95% CI: 1.33-4.45) were more likely to write an original paper published in peer-review journals. Comparing to a physician majoring in general internal medicine, those in basic medicine (OR 4.15, 95% CI, 1.07-16.03), and surgical departments (OR 0.98, 95% CI, 0.54-1.78) were less likely to write an original paper.

Conclusions: Having a research mentor is a key factor for physician researchers to publish an original paper in peer-reviewed journal.

INTRODUCTION

There appears to be no argument that biomedical research has been dominated by the U.S.A. for the past several decades with 52-70% representation in the top general medicine and basic science journals during 1991-2000.¹ Nevertheless, during 1991-2010 Japan had contributed to the top basic science journals a great deal but the contribution to the top general medicine journals had been very small and stagnant.² Apart from basic research, clinical research does not merely indicate clinical

trials but ultimately increases quality of patient care through interesting research question embedded in clinical research.³ Research conducted by physicians resulted in hundreds of innovations that offers patients to access to cutting edge therapy and earlier diagnosis of illness, result in better outcomes, and maximize health.

In spite of such important area, the number of physician researchers has seriously declined. Because Japan faces sever physician shortage (the number of medical doctors per 1000 persons in Japan, 2.3 in 2012 versus average number among OECD countries, 3.2),⁴ and medical doctors are chronically exposed to overwork. According to Japan Federation of Medical Worker's Unions' report in 2007, 30.9% physician respondents worked more than 80 hours per week. In the same survey, more than 95% physician respondents could not take day-off after over night duty and continuously had taken regular day shift.⁵ Hence, it is critically important to improve working environment for such a busy physicians to be involved in academic research activities.

Hence the purpose of this study is to investigate the characteristics and profiles of medical doctors in their 30-40's who have an experience of writing an original paper in peer-reviewed journals as a first or corresponding author. The result of this study is meaningful in that how we should improve research environment to encourage physician to be involved in long-term research activities that contributes medical standard of this country.

METHOD

Participants

This study is a part of the research team "Development of epidemiological education program and infrastructure for medical doctors with research mind" funded by the Ministry of Health, Labor, and Welfare. Because the research team particularly focused on young medical doctors, we recruited 250 men and 250 women medical doctors in their 30's - 40's from a website survey company. After these subjects provided informed consent, they sequentially answered to the self-administered questionnaire. Then we randomly sampled 82 women from the 250 women to match with the ratio of gender in total number of medical doctors in Japan. Among 332 participants (i.e., 250 men and 82 women), 139 researchers (41.9%) reported that they were involved in research at the time of investigation. Because we especially focused on clinical research, we excluded 13 participants who were involved in research activities but their research area was basic medicine. Thus 319 participants became our sample for analyses in this

study.

The study was approved by the institutional review board at St. Luke's international Hospital (倫理委員会の番号あれば教えてください).

Measures

Outcome of interest is how many numbers of original papers published in peer-reviewed journals. The participants was asked whether they had written as a first or a corresponding author within one year prior to the investigation.

Items investigated in this study were baseline characteristics, working conditions, items related to qualifications, research and mentor. Baseline characteristics included gender, age, marital status, occupation of partner (physician/others/unemployed), number of children, and household income in previous year (\leq US\$100,000/ $<$ US\$100,000-US\$200,000/US\$200,000). Working conditions included clinical department (medicine/surgery/basic and others), work place (hospital/clinic/others), and weekly working hours. Items related to qualifications included, the period of physician experience, Doctor of Medical Science (DMSc), board certified, and fellow. Items related to research included research type, and timing of first experience of any conference presentation and writing academic papers. We asked our participants to choose one of four types of research to be involved in which included basic medicine, clinical research, social science, and others. We defined "a research mentor" in our study as "a person who is more experienced or knowledgeable to lead or guide you in a certain research area of expertise". And then we asked if they had a research mentor or not, and asked gender or position (chair, professor, or director at same department /other faculties or members at same department/others) of their research mentors if the participant answered they had research mentors.

Statistical analysis

Numbers of original papers to be written as a first or a corresponding author were divided at a median of its distribution and grouped into binary outcome (i.e., 0 vs. 1+). Characteristics of young medical doctors were assessed between those with no papers and those with at least one paper. All tests were assessed by a t-test for continuous variables or chi-square or fisher's exact test for categorical variables. A logistic regression analysis was applied to investigate what characteristics and profiles of mentees were associated with having an original article as a first or a corresponding author. Odds ratios (OR) were estimated along with 95% confidence interval (CI).A multivariable logistic regression model was performed adjusting for variables selected

at $p < 0.1$ in univariable logistic models.

All analysis were conducted using SAS software version 9.3 (Cary, NC), and statistical significance was set at $p < 0.05$.

RESULT

Table1 showed baseline characteristics. The most of our participants were young male ($n=238$, 74.6%; mean age, 41.0years), married ($n=266$, 83.4%) and had at least one child ($n=243$, 86.2%). In total, 78 physicians (24.5%) had written an original paper as a first author and 39 physician (12.2%) had written as a corresponding author during 1 year prior to this study. There were only 72 physicians (22.6%) who reported that they had a research mentor.

Table2 showed factors associated with writing an original paper as a first or corresponding author. Participants were more likely to write an original paper, if they worked at hospitals compared to the other places ($p=0.036$), or if they majored in basic medicine compared to general internal medicine or surgical departments ($p=0.084$), or if they obtained DMSc compared to those who did not have ($p=0.004$). Averages of weekly working hours were 56.1 hrs among people who wrote an original paper, and 48.4 hrs among people who did not, respectively ($p=0.002$). Participants who had a research mentor were more likely to write an original paper compared to those who had no research mentor or those who did not know if they had research mentors ($p < 0.001$). This trend was consistently observed among all types of work places including teaching hospitals ($p < 0.005$), hospitals other than teaching hospitals ($p=0.013$), and clinics ($p < 0.001$). In contrast, gender of mentor or positions of research mentor made no difference for participants to write an original paper.

Table 3 showed multivariable logistic model for factors associated with writing an original article as a first or a corresponding author. Variables selected at $p < 0.1$ in univariable model were work place ($p=0.036$), clinical departments ($p=0.084$), DMSc holder ($p= 0.004$), board holder ($p=0.093$), fellow holder ($p=0.081$), long weekly working hours ($p= 0.002$), and having a research mentor ($p= <0.001$). After adjusting for these variables, the multivariable model showed that participants who had a research mentor had 6.78 (95% CI, 3.64-12.63) times more likely to have an experience of writing an original paper in peer-reviewed journals compared to those who did not have a research mentor or those who reported they were not sure if they had a mentor. Participants who obtained DMSc had 2.44 times (95% CI, 1.33-4.45) more likely to write an original paper compared to those who did not have. Comparing to participants majoring in general internal medicine, those who majoring in surgical departments

(OR 0.98, 95% CI, 0.54-1.78), and basic medicine (OR 4.15, 95% CI, 1.07-16.03) were less likely to have an experience of writing an original paper. There were no statistical interactions between mentor and other variables.

DISCUSSION

This study demonstrated that having a mentor and DMSc are significantly associated with a skill to publish an original paper in peer-reviewed journals as a first or corresponding author. Previously there are very few studies to investigate what factors were associated with research activities among physicians in western countries. Nevertheless some studies shed light on the importance of the mentorship in academic medicine, but how mentorship affects or influences which academic productivities of mentees is not still articulated. Indeed, mentorships are not prevailed even in United States.⁶ According to three systematic reviews in mentoring in academic medicine,⁶⁻⁸ the effects of mentorship varies among individual studies including scientific merits on specialty choice, career choice in researcher, career satisfaction, gender equalities, promotion of leadership and career development.^{9, 10} In fact, six studies reported a mentor's academic role that mentorship has positive effects on publishing a research paper,¹¹⁻¹⁴ completing a thesis,^{15, 16} and having a grant,¹²⁻¹⁴ which is consistent with the result of our study.

In Japan, there were very few reports except for one study which reported very high prevalence of a research mentor (91% of 683 respondents) due to very biased sample of medical faculties who belong to large sized teaching hospitals.¹⁷ Compared with such high research mentor prevalence, the prevalence is only 23.2% in our study in total, and 41.7% among participants who were involved in research at the time of investigation. This value is quite shocking and indicates at work place other than teaching hospitals, there are very few mentors available. Nevertheless our study demonstrated that even at clinics or hospitals other than teaching hospitals, if a research mentor was available, the likelihood of being able to write an original paper increased for clinicians. This finding suggests that having a mentor is a powerful factor to encourage physician to be involved in research activities.

Mentorship is mutual personal development for both mentors and mentees.¹⁸ But the role of mentor is very limited and in the above mentioned study with high prevalence of research mentor,¹⁷ research mentors' roles specifically focused on research methodology (i.e., writing manuscript, research design, research management,

and etc.) only, but not on career development including served as role model, promoted your career to networking, and served as advocates. A systematic review reported that the barriers for clinicians to be involved in research activities included time constraints due to lack of staff and training, worry about the impact on the doctor-patient relationship, and difficulties of formulating interesting questions.¹⁹ Indeed core skills in research methodologies broadly applicable to clinical research is important, but negotiating protected research time, obtaining grants, gaining promotions, and taking leadership roles in academic medicine is more important and concrete for clinicians to be involved in long-term research career.

There are several limitations should be addressed in our study. In addition to sample size we did survey on the internet with some incentive between March 20 and 26 2015, which means people those who were busy seeing patients could not participate in this study. Thus the generalizability of our result should be carefully interpreted. In our study we randomly sampled 82 women from the 250 women to match with the ratio of gender in total number of medical doctors in Japan. Some critiques might argue that such a sampling scheme might have resulted in biased sample. In this regard, we confirmed our participants similar to characteristics of medical doctors including average age, the working population at hospitals and the work districts who were registered in Survey of Physicians, Dentists and Pharmacists.²⁰ Thirdly, we did not measure research mentors' roles including grant support, advice on work-life balance, and future vision, and the frequency of mentor-mentee's meeting. The role of the mentorship should be more explored in the future studies.

Future implication

Clinical researchers are endangered species worldwide. In Japan, the reason for such small numbers of physician researchers who committed a clinical research may be explained by the current medical education system. In Japan a person goes to medical school right after high school graduation as age of 18 years old. During 6 years in medical school a student learn basic science for 2 years then the clinical science another 4 years including bedside learning. Unlike U.S., medical students in Japan seldom have research experiences before and throughout medical school years. Japanese medical education system does not give high priority to research training in medical curricula even for residents. A newly certified physicians started residency under Japanese typical apprentice system, especially in surgical specialties where clinical skills are taught from senior to junior surgeons hand to hand. This paternalistic mentorship in Japan should be explored in terms of scientific evidence.

Our research shows that 54.9% of respondents who have DMSc do not research at the time of investigation. Basically DMSc which is equivalent to Doctor of Philosophy in U.K and this qualification issued by a university in Japan is supposed to be given to an independent researchers. To improve current situation in Japan, we have to develop research environment where physician scientist or physician who obtained DMSc are able to pursue their long-term research career.

In conclusion, having a research mentor is likely to encourage clinicians to be involved in clinical research in Japan. In addition university should take a leadership to provide educational curricula for both medical students and physicians.

ACKNOWLEDGEMENT

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疫学研究への導入とその構造

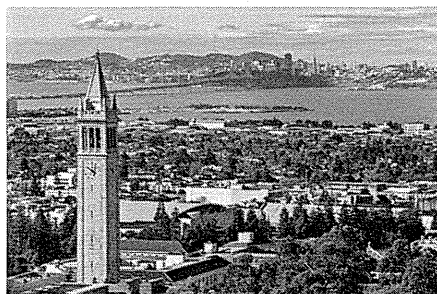
～臨床研究計画書作成～
ワークショップ

July 2015

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St. Luke's International University
Center for Clinical Epidemiology



A view of SF Bay from UC Berkeley

BRITISH MEDICAL JOURNAL

LONDON SATURDAY SEPTEMBER 30 1950

SMOKING AND CARCINOMA OF THE LUNG PRELIMINARY REPORT

BY
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AND

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In England and Wales the phenomenal increase in the number of deaths attributed to cancer of the lung provides one of the most striking changes in the pattern of mortality recorded by the Registrar-General. For example, in the quarter of a century between 1922 and 1947 the annual number of deaths recorded increased from 612 to 9,287, or roughly fifteenfold. This remarkable increase is, of course, out of all proportion to the increase of population—both in total and, particularly, in its older age groups. Stocks (1947), using standardized death rates to allow for these population changes, shows the following trend: rate per 100,000 in 1901-20, males 1.1, females 0.7; rate per 100,000 in 1936-9, males 10.6, females 2.5. The rise seems to have been particularly rapid since the end of the first world war; between 1921-30 and 1940-4 the death rate of men at ages 45 and over increased sixfold and of women of the same ages approximately threefold. This increase is still continuing. It has occurred, too, in Switzerland, Denmark, the U.S.A., Canada, and Australia, and has been reported from Turkey and Japan.

Many writers have studied these changes, considering whether they denote a real increase in the incidence of the disease or are due merely to improved standards of diagnosis. Some believe that the latter factor can be regarded

whole explanation, although no one would deny that it may well have been contributory. As a corollary, it is right and proper to seek for other causes.

Possible Causes of the Increase

Two main causes have from time to time been put forward: (1) a general atmospheric pollution from the exhaust fumes of cars, from the surface dust of tarred roads, and from gas-works, industrial plants, and coal fires; and (2) the smoking of tobacco. Some characteristics of the former have certainly become more prevalent in the last 50 years, and there is also no doubt that the smoking of cigarettes has greatly increased. Such associated changes in time can, however, be no more than suggestive, and until recently there has been singularly little more direct evidence. That evidence, based upon clinical experience and records, relates mainly to the use of tobacco. For instance, in Germany, Müller (1939) found that only 3 out of 86 male patients with cancer of the lung were non-smokers, while 56 were heavy smokers, and, in contrast, among 80 "healthy men of the same age groups" there were 14 non-smokers and only 31 heavy smokers. Similarly, in America, Schrek and his co-workers (1950) reported that 14.6% of 82 male patients with cancer of the lung were non-smokers,

Conducted a case-control study followed by a cohort study a few years later.

✓ Results received a lot of criticism:

"the evidence is purely circumstantial..."

"the only known carcinogen is arsenic..."

21 August 2013, 3:53pm AEST

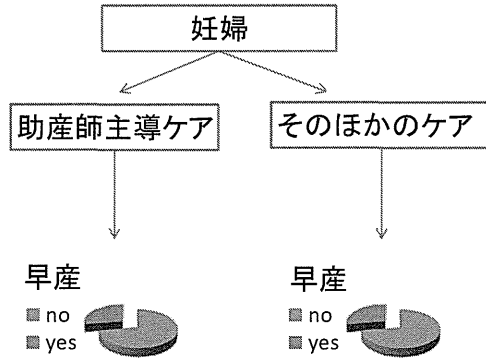
One-on-one midwife care linked to lower risk of premature birth

(助産師主導によるケアは、早産リスクの低下に関連しているか)



Sandall et al., *Cochrane Database Syst Rev*, 2013

リサーチクエスチョン: 助産師主導によるケアを受けた妊婦には、早産例が少ないのではないか?



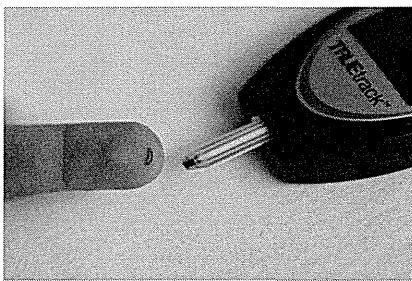
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Independent high-quality evidence for health care decision making

August 8, 2013, 12:27 pm | 167 Comments

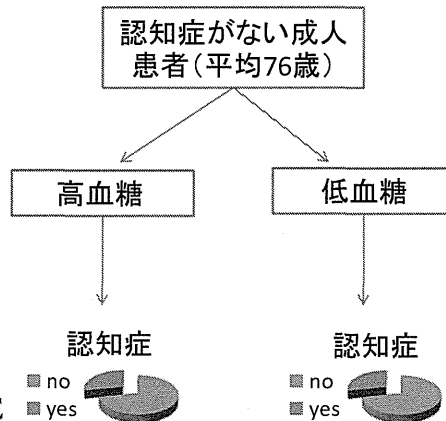
High Blood Sugar Linked to Dementia

By PAULA SPAN (高血糖は認知症に関連している)



Crane et al., *NEJM*, 2013

リサーチクエスチョン: 高血糖の患者は、認知症発症のリスクが高いか?



The NEW ENGLAND JOURNAL of MEDICINE

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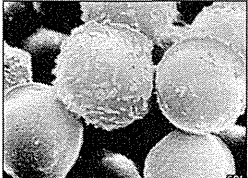
Playgroups 'cut leukaemia risk'

Children who attend daycare or playgroups cut their risk of the most common type of childhood leukaemia by around 30%, a study estimates.

Researchers reviewed 14 studies involving nearly 20,000 children, of which 6,000 developed acute lymphoblastic leukaemia (ALL).

It is thought early infections may help the body fight off the disease.

The University of California, Berkeley study will be presented to a leukaemia conference in London.



Childhood leukaemia is linked to infection

Research Question: Is exposure to infections early in life associated with a reduced risk of childhood leukemia?

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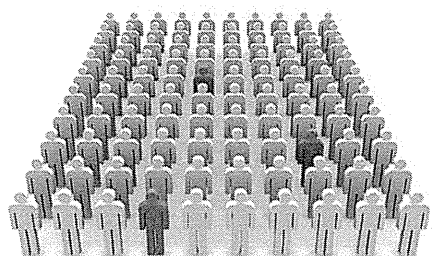
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      A[Children aged 0-15 years] --> B[Leukemia]
      A --> C[No leukemia]
      B --> D[% Daycare attendance]
      C --> E[% Daycare attendance]
      D --> D1[no]
      D --> D2[yes]
      E --> E1[no]
      E --> E2[yes]
  
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5 Urayama et al., *Int J Epidemiology*, 2010

基本要素

Diseases do not occur at random

- 人を調査の対象とする。
- 集団の中で、ある問題と人の特徴の関連を考察する。
- ここでいう「問題」は、健康、医療に関わる問題。
- 関連を量的に評価するために統計学と情報学を道具として活用する。



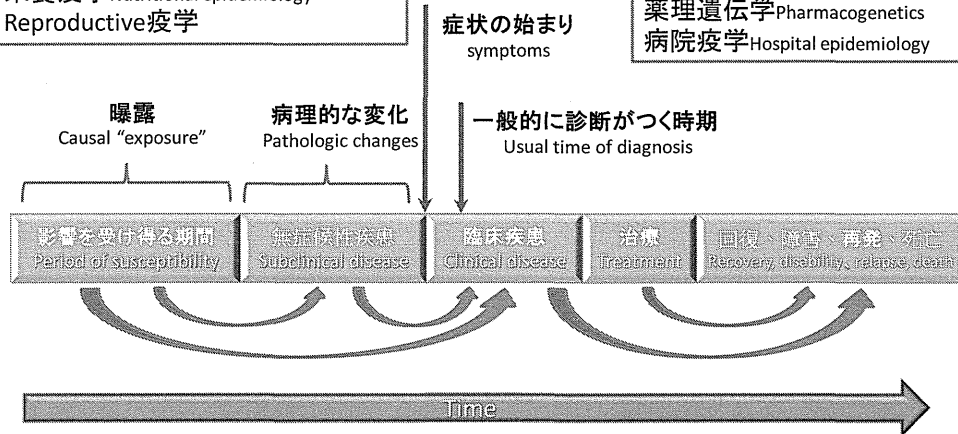
疫学とは、健康アウトカムの発生とその決定要因／原因について検討する学問である

6

疫学の種類

環境疫学 Environmental epidemiology
 社会疫学 Social epidemiology
 産業疫学 Occupational epidemiology
 感染症疫学 Infectious disease epidemiology
 分子疫学 Genetic epidemiology
 栄養疫学 Nutritional epidemiology
 Reproductive 疫学

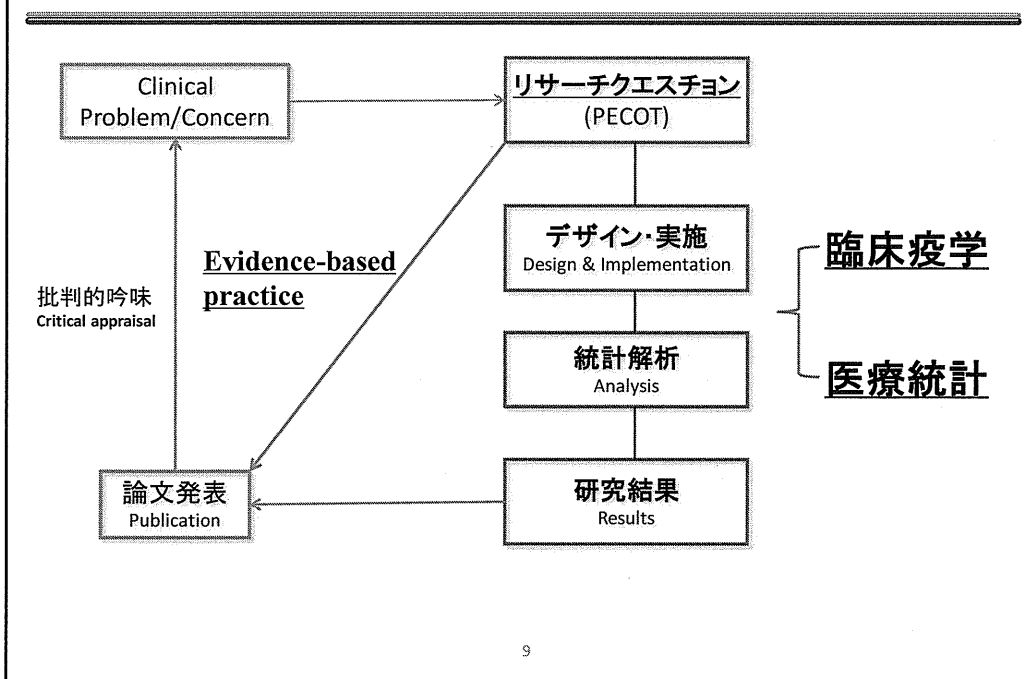
臨床疫学 Clinical epidemiology
 看護研究 Nursing research
 薬剤疫学 Pharmacoepidemiology
 薬理遺伝学 Pharmacogenetics
 病院疫学 Hospital epidemiology



講義のアウトライン

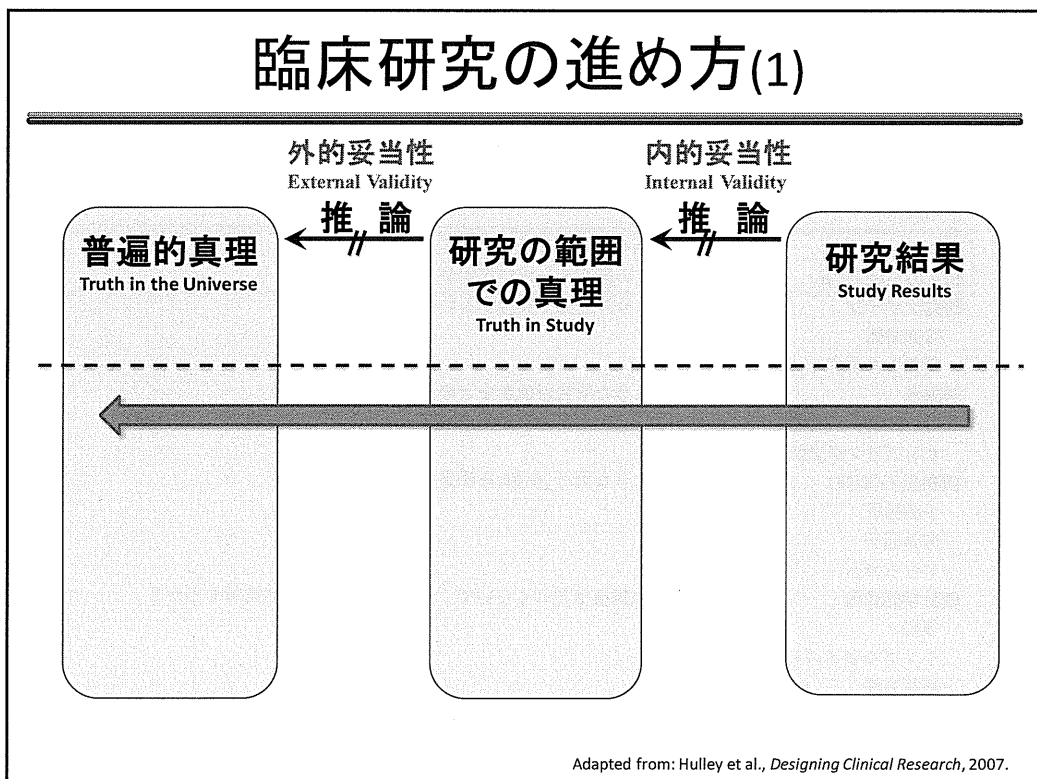
- 疫学とはなにか
- リサーチクエスチョンの作成 (PECOT)
- 集団の定義 (P- population)
- 興味のある変数の定義 (E- exposure, O- outcome)
- 疾患／アウトカムの数量化

臨床研究とEBMサイクル



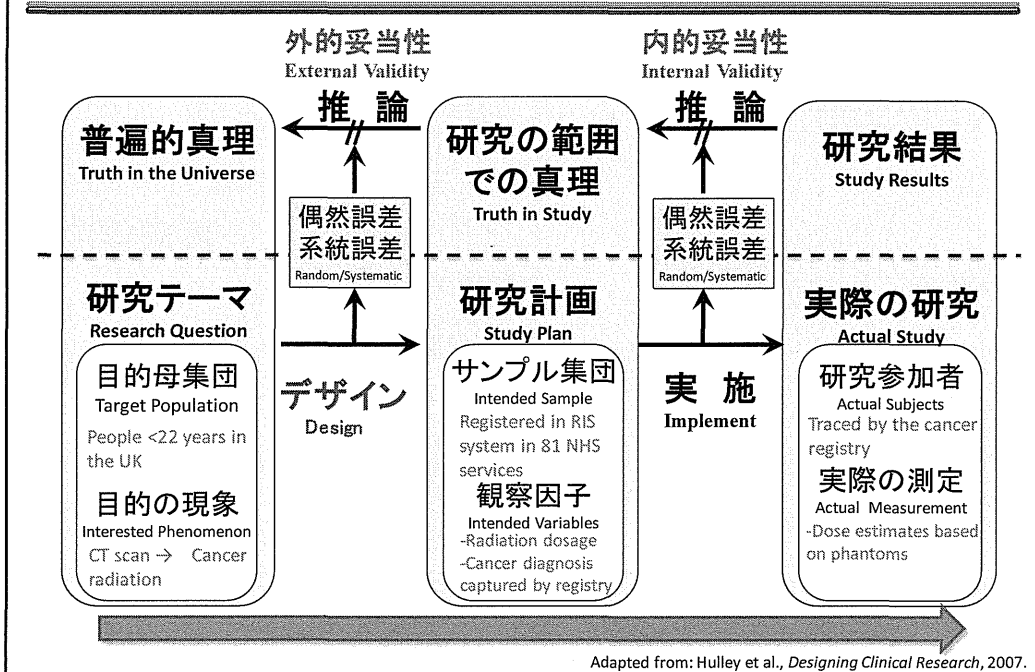
9

臨床研究の進め方(1)



Adapted from: Hulley et al., *Designing Clinical Research*, 2007.

臨床研究の進め方(2)

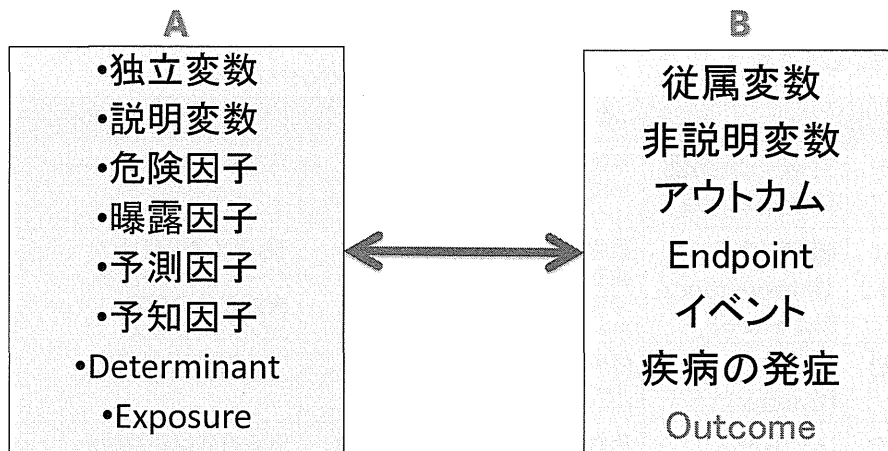


研究計画書の構造

表 1-1 研究プロトコルのアウトライン

構成要素	目的
研究テーマ	どういうテーマを研究しようとしているか？
研究の意義(背景)	なぜその研究テーマが重要か？
研究デザイン	どのように研究を実施するか？
研究期間	
研究のタイプ	
対象者	どのような研究対象者をどのように獲得するか？
選択基準	
サンプリング方法	
観察因子(変数)	どのような因子(変数)を測定するか？
予測因子	
交絡因子	
アウトカム	
統計学的事項	研究の規模はどれくらいで、データをどのように解析するか？
仮説	
サンプルサイズの推定	
解析方法	

リサーチクエスチョン



Aがない患者に比べて、Aがある患者は、Bの発生率が高い、または低いかな？

研究テーマのタイプ

カテゴリー	説明
病 因 Pathogenesis	ある疾患の原因や危険因子 cause/risk factor
頻 度 Frequency	ある疾患の罹患率や発症率 Prevalence/Incidence
診 断 Diagnosis	ある診断法の診断能 Diagnostic Performance
予 後 Prognosis	ある疾患の平均生存期間など Survival, etc
治療・予防 Treatment Prevention	ある治療法の治療効果や予防効果 Therapeutic/preventive effect
害 Harm	ある治療法による副作用や不利益な 影響 negative effects of treatment

疑問の定式化 (formulate a question)

PECOT

臨床的な疑問を解決可能な形であげる
research question

	要素	ヒント	吟味
P	対象一母集団 (Population)	目的とする母集団 intended pop. 研究可能なサンプル集団 study population	代表性? Representativeness?
I (E)	曝露/介入 (Intervention/ Exposure)	薬物療法、カウンセリング 検査、スクリーニング 環境因子への曝露など Therapy, screening, env. exposures, etc.	ランダム割り付け? ベースラインの調整 交絡因子の測定 コンプライアンス
C	比較対象 (Control)	標準治療、プラシーボ Standard treatment, placebo Non-diseased, non-exposed	Randomization, adjustment, confounding, compliance, etc.
O	アウトカム (Outcome)	死亡、無病生存、検査値・症状 の改善、診断、疾患の発症 Mortality, survival, onset of disease, response to therapy, etc.	測定方法は客観的か ブラインド化? Objective measurement methods, blinding
T	観察期間 (Time)	アウトカムを評価するのに適切な 観察期間 appropriate observation period to evaluate outcome	フォローアップ率 Follow-up rate

例: PECOT

(P) Population

- In patients who received a CT scan before the age of 22 years, is there a higher incidence of leukemia or brain tumors in adulthood among patients receiving greater estimated radiation doses compared to lower estimated radiation

(O) Outcome
doses?

(E) Exposure

(C) Comparison

(T) Timing of assessment

22歳になる前にCT検査を受けた患者の中で、推定放射線量が高い群は低い群と比べて、白血病または、脳腫瘍の発症率のリスクが増加するか？

文献検索 (Literature Search)

Using PICO - x MEDLINE/Pu... x lgdata.s3-... x

pubmedhh.nlm.nih.gov/nlmd/pico/piconew.php

Search MEDLINE/PubMed via PICO with Spelling Checker
Patient, Intervention, Comparison, Outcome
so.usa.gov/x/...

Patient/Problem:

Medical condition:

Intervention:
(therapy, diagnostic test, etc.)

Compare to:
(same as above, optional):

Outcome:
(optional)

Select Publication type:
Not specified

[\[Home\]](#)

<http://pubmedhh.nlm.nih.gov/nlmd/pico/piconew.php>

Information databases:

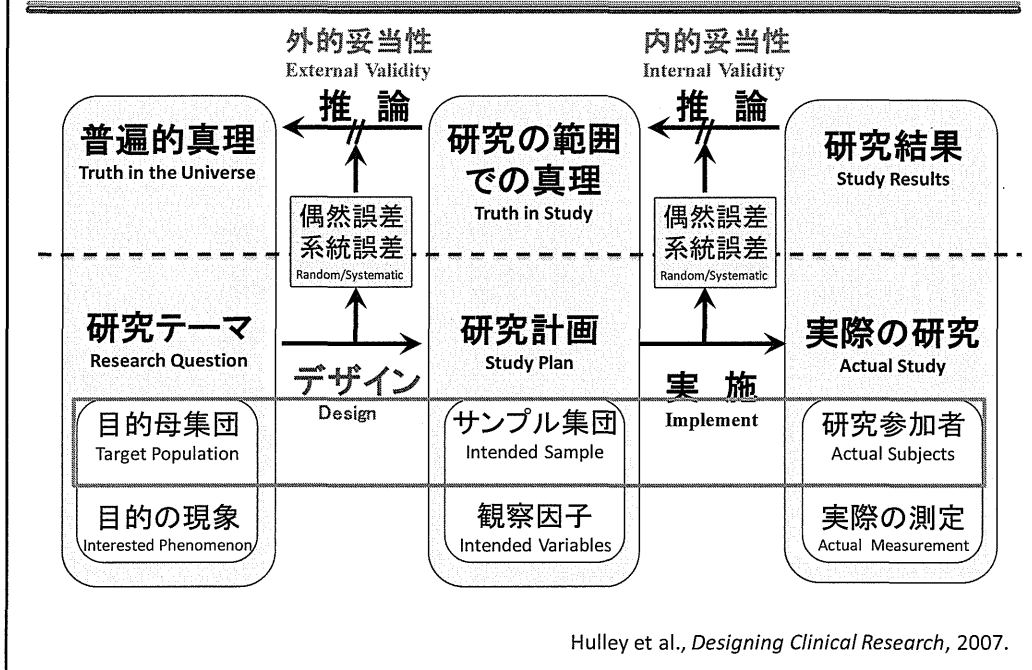
- PUBMED
- Up To Date
- DynaMed
- eMedicine
- Ovid
- Medline

研究計画書の構造

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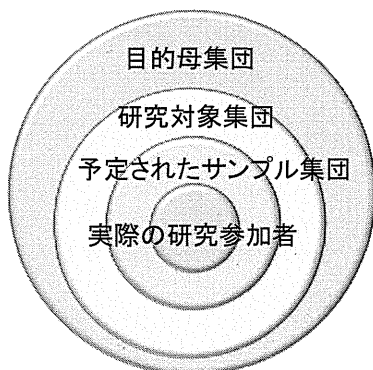
集団について



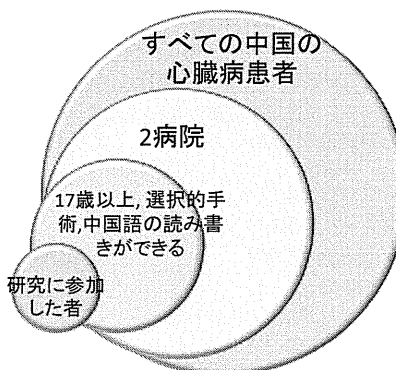
階層集団

Hierarchy of Populations

- 目的母集団 (Target population) - 研究結果を一般化できる外的集団
- 研究対象集団 (Accessible population) - 実際にアクセスが可能なグループで、研究結果が適用される集団
- 予定されたサンプル集団 (Intended population) - 集団を代表する標本グループ
- 実際の研究参加者 (Actual population) - 研究データが取得できたグループ



*Nested circles indicates representativeness with respect to basic characteristics



*Questionable generalizability and possible selection bias