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临床研究文献例句

EmpowerStats 临床科研设计与数据分析
系列教程

快速开启临床研究新世界的大门



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陈星霖/ **EmpowerStats** 技术团队

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1 选题来源

1.1 有争议

“有争议”是很好的选题，因为同行都关注并且各执一词，才需要新的证据。

(1) previous studies are inconsistent: X might have effects on Y, but results from previous studies are inconsistent. We investigated the associations of X with Y.

例文1: 2016年发表在JAMA的值夜班和冠心病的关系研究。Association between rotating night shift work and risk of coronary heart disease among women^[1].

摘要: 之前的同类研究结论**不一致**, 有局限性(随访时间短)。Prospective studies linking X to Y have been **inconsistent** and **limited** by short follow-up.

Abstract

Importance—Prospective studies linking shift work to coronary heart disease (CHD) have been **inconsistent and limited** by short follow-up.

例文2: 2017年发表在Lancet Diabetes Endocrinol的维生素D和骨密度关系研究。**25-hydroxyvitamin D concentrations** during fetal life and **bone health** in children aged 6 years: a population-based prospective cohort study.^[2]

摘要: X可能影响Y, 然而之前的研究结论**不一致**。我们研究X和Y的关系。X might have effects on Y, but results from previous studies are inconsistent. We investigated the associations of X with Y.

原文: BACKGROUND: **25-hydroxyvitamin D (25[OH]D) concentrations during fetal life** might have long-lasting effects on **skeletal development**, but results from previous studies are **inconsistent**. We investigated the associations of **maternal and fetal 25(OH)D concentrations** with **childhood bone health**.

Summary

Background 25-hydroxyvitamin D (25[OH]D) concentrations during fetal life might have **long-lasting effects on skeletal development**, but results from previous studies are **inconsistent**. We investigated the associations of **maternal and fetal 25(OH)D concentrations** with **childhood bone health**.

临床研究选题

来源于争议: 临床意义高、研究设计有模板、数据分析有参考、论文撰写有规范、拒绝意见相反的审稿人审稿。新手可能踩的坑都避开了。

- (1) 推荐优选: 同类研究有争议, 双方近年文章越来越多, 出现了Meta, 有争议的文章影响力都高。
- (2) 不推荐: 近5年没有查到同类文献, 并不表明研究创新性, 大部分情况是同行不关注, 缺乏临床意义。少数情况是同行很关注, 没有数据。

1.2 换研究人群

1.2.1 换人种

(1) *Few studied have focused on Asian*

然而亚洲的研究很少^[3]

Although studies have analyzed diabetic nephropathy (DN) in childhood T1DM, few studies have focused on Asian patients. The degree of albuminuria is not necessarily linked

(2) *however, data in nonwhites are sparse*

X has been associated with reduced risk for Y in prospective studies; however, data in 研究对象 are sparse.

OBJECTIVE: To examine the association of X with risk for Y.

期刊	影响因子	题目
Ann Intern Med, 2017	19.3	Association of Coffee Consumption With Total and Cause-Specific Mortality Among Nonwhite Populations. ^[4]
BACKGROUND: Coffee consumption has been associated with reduced risk for death in prospective cohort studies; however, data in nonwhites are sparse. OBJECTIVE: To examine the association of coffee consumption with risk for total and cause-specific death.		

1.2.2 换疾病方向

(1) *unclear...after all viable embryos*

X 和 Y 的关系已有发表。然而在某类人群中，还没有清晰的结论^[5]。

Background: Female overweight/obesity has been reported to be associated with compromised pregnancy outcomes in fresh embryo transfer cycles. It is unclear whether the cumulative live birth rate (CLBR) is adversely affected after all viable embryos are transferred from the first ovarian stimulation cycle.

(2) *whether similar associations...of patients undergoing PCI*

Background—Elevated white blood cell (WBC) count is associated with increased major adverse cardiovascular events (MACE) in the setting of acute coronary syndrome. The aim of this study was to evaluate whether similar associations persist in an all-comers population of patients undergoing percutaneous coronary intervention in the contemporary era.^[5]

Background—Elevated white blood cell (WBC) count is associated with increased major adverse cardiovascular events (MACE) in the setting of acute coronary syndrome. The aim of this study was to evaluate whether similar associations persist in an all-comers population of patients undergoing percutaneous coronary intervention in the contemporary era.

1.3 本研究用了新标准

(1) Is a set of newly

X 和 Y 的关系，已经被研究过了^[7]。POSEIDON 标准发布后，同类研究很少。创新点为采用了新的 POSEIDON 标准。

Background: Dehydroepiandrosterone (DHEA) supplementation has been reported to have beneficial effects on the *in vitro* fertilization (IVF) outcomes of patients with poor ovarian response or diminished ovarian reserve. The Patient-Oriented Strategies Encompassing Individualized Oocyte Number (POSEIDON) stratification is a set of newly established criteria for low prognosis patients. The aim of this study was to examine the potential effects of DHEA supplementation on the IVF outcomes of patients who fulfill the POSEIDON group 4 criteria.

POSEIDON 标准发布后，同类研究很少。^[8] 创新点为采用了新的 POSEIDON 标准。

3) with diminished ovarian reserve. The cumulative live birth rate (CLBR) is considered a preferable measure of success of IVF treatment (6). Until now, there have been very few reports on the CLBRs of the four patient groups defined by the POSEIDON criteria.

1.4 换研究设计类型

what is already known:

Pooling prior retrospective studies of AC-FET and mNC-FET results in comparable pregnancy and LBRs. However, these results have not yet been confirmed by a prospective randomized trial.^[9]

1.5 还没有被研究过

检索不到同类研究的SCI论文，很可能是同行不关注，临床意义低，建议及时换题目。或者同行都想做，只有你有条件做。

(1) Has not been studied yet

Has not been studied yet^[10]

Background: Elective freezing of all embryos, followed by frozen-thawed ET cycles emerged to prevent risk of Ovarian Hyperstimulation Syndrome and to allow endometrium recovery after Controlled Ovarian Stimulation, leading to better IVF outcomes. Blastocyst Freeze-all policy can minimize the number of abnormal embryos and consequently failed ETs, but its efficacy in terms of cumulative rates has not been studied yet.

1.6 科学问题：同 Y 不同 X

Z 和 Y 的关系已经被研究了，然而 X 和 Y 的关系并不清楚。因此本研究假设是：在某人群中 X 和 Y 有关系。

Neutropenia increases the risk of infection, but it is unknown if this also applies to lymphopenia. We therefore tested the hypotheses that lymphopenia is associated with increased risk of infection and infection-related death in the general population.^[11]

Background

Neutropenia increases the risk of infection, but it is unknown if this also applies to lymphopenia. We therefore tested the hypotheses that lymphopenia is associated with increased risk of infection and infection-related death in the general population.

➤ 解读

➤ 论文创新点

从数据分析角度看，有两大创新点。

1. 发现非线性关系：基于易侖软件“平滑曲线拟合”和“阈值效应分析”模块
2. 找到特殊人群：基于易侖软件“交互作用检验”和“快速扫描交互作用”模块

前言是上述内容的扩展，详细讲了有哪些争议和局限性。具体内容

1. 第一段：简要罗列与X有关的研究。突显X的重要性。Y与本研究相同或不同。
2. 第二段：简述同X同Y的研究，以及不足之处。包括：研究设计、核心结果（写出作用大小，而非单纯列出p值）。
3. 第二段：本研究如何完善上述不足。

1.6.1 换Y，X不变，人群不变

(1) *but its association with angina is unknown*

In patients with coronary artery disease (CAD), low diastolic blood pressure (DBP) is associated with increased risk of myocardial infarction, but its association with angina is unknown.

1.7 科学问题：X的变化和Y的关系

(1) remission of overweight

Childhood overweight is associated with an increased risk of type 2 diabetes in adulthood. We investigated whether remission of overweight before early adulthood reduces this risk.^[12]

BACKGROUND

Childhood overweight is associated with an increased risk of type 2 diabetes in adulthood. We investigated whether remission of overweight before early adulthood reduces this risk.

(2) change in BMI

IMPORTANCE The incidence of ischemic stroke among young adults is rising and is potentially due to an increase in stroke risk factors occurring at younger ages, such as obesity.

OBJECTIVES To investigate whether childhood body mass index (BMI) and change in BMI are associated with adult ischemic stroke and to assess whether the associations are age dependent or influenced by birth weight.

IMPORTANCE The incidence of ischemic stroke among young adults is rising and is potentially due to an increase in stroke risk factors occurring at younger ages, such as obesity.

OBJECTIVES To investigate whether childhood body mass index (BMI) and change in BMI are associated with adult ischemic stroke and to assess whether the associations are age dependent or influenced by birth weight.

1.8 科学问题：X 和 Y 变化的关系

(1) decline in eGFR

低镁血症和全因死亡以及 eGFR 降低的关系在 CKD 人群中^[13]

Hypomagnesemia predicts cardiovascular morbidity and mortality in the general population and accelerated loss of kidney function in renal transplant recipients and diabetics. **It is associated with risk factors for cardiovascular and renal injury** such as hyperaldosteronism, endothelial dysfunction, oxidative stress, insulin resistance, and hypertension. We aimed to establish the prognostic significance of hypomagnesemia for all-cause mortality and **decline in** estimated glomerular filtration rate (eGFR) in chronic kidney disease.

BACKGROUND: Hypomagnesemia predicts cardiovascular morbidity and mortality in the general population and accelerated loss of kidney function in renal transplant recipients and diabetics. It is associated with risk factors for cardiovascular and renal injury such as hyperaldosteronism, endothelial dysfunction, oxidative stress, insulin resistance, and hypertension. We aimed to establish the prognostic significance of hypomagnesemia for all-cause mortality and decline in estimated glomerular filtration rate (eGFR) in chronic kidney disease.

2 讨论的局限性

2.1 写纳排标准，结论不能外推

常见问题：“你是单中心的数据，样本代表性好吗？”

解决方案：在讨论部分强调结论的适用范围。

更多模板 1^[14]：本研究纳入的是男性人群，结论不能外推到女性。First, as our participants were predominantly men, the findings might not generalize to women.

There are limitations of this study that warrant discussion. First, as our participants were predominantly men, the findings might not generalize to women. Second, H were based on ICD-9 codes. Therefore, some misclassification may have oc

更多模板 2^[15]：本研究纳入的是中年白种人，结论不能外推到其他人群。Only middle-aged white people participated in the study, which limits the generalizability of the findings to other population groups.

早期的医学研究以流行病学调查为主，目的是为了描述疾病在人群中的分布，强调“样本的代表性”，“随机抽样”。

然而，临床医生做流调不是优势。大部分是用本科室的病例资料做研究。开展关联分析（危险因素）、诊断与预测、治疗方案与预后关系研究等。这样的研究不强调“样本的代表性”。强调结果的适用范围。论文讨论部分围绕纳排标准写：

- 只纳入了男性，所以结果无法用于女性^[14]。
- 排除了哮喘患者，所以结果无法用于此类人群^[16]。
- 只纳入了中年人白种人，结论不能外推到其他人群^[15]。

【论文实例^[16]】

X：糖皮质激素治疗（是/否）

Y：死亡

研究人群：ICU 的重症流感性肺炎

研究设计：队列研究（cohort study）

SCI 影响因子 18 分

结论：重症流感性肺炎患者使用皮质类固醇激素会增加 ICU 死亡率

疑问：本研究纳入的是重症流感性肺炎患者，发现激素和 ICU 死亡有关。他的结论能“代表”其他医院 ICU 的重症肺炎患者吗？

回答：本研究属于关联分析。“代表谁？”这个问题本来就不需要回答。关联分析的研究不强调样本代表性，强调结论的适用范围。

在讨论的局限性部分写：本研究对象为重症肺炎患者，结论不能被外推到其他人群。

**factors including the presence of competing ri
ever, we recognize some limitations. First, c
were obtained in a homogeneous population (r
with influenza pneumonia and cannot be extra**

撰写模板：First, our results were obtained in a homogeneous population of patients with （写你的研究对象） and cannot be extrapolated to other populations.

2.2 关键指标的测量不准确

【常见问题】存在测量误差，例如某指标、问卷调查等测量不精准。

【解决方案】测不准通常不影响论文发表。需要考虑“测不准”是否影响核心结果。

【论文实例^[17]】

X：夜班工作（night shift work exposure）

Y：2 型糖尿病（type 2 diabetes）

研究人群：某数据库 In the UK Biobank

研究设计：横断面研究（cross-sectional study）

SCI 影响因子 15.2 分

结论：夜班工作尤其是轮换班次与 2 型糖尿病有关，夜班次数与糖尿病有关。轮班工作不改变糖尿病的遗传风险。

本研究的 X 夜班工作情况，是通过问卷调查获取的。夜班工作状态包括：没有夜班、很少夜班、有一些、通常有夜班、永久性夜班。可想而知，问卷获取的资料不可能百分之百精准。怎么办呢？

讨论部分写：本研究中使用的问卷可能出错，因为它们涵盖了整个工作周期。值得注意的是，由此类错误导致的暴露分类错误将偏向无效假设，因此导致轮班工作与 2 型糖尿病之间的关联被低估。

The **lifetime reports** used in this study are likely to be more prone to error, as they **cover a whole lifetime of employment**. It is noteworthy that the potential exposure misclassification resulting from such errors would bias toward to the null and thus result in an underestimation of the association between **shift work and type 2 diabetes**.

意思是：测量不准只会导致不容易观察到 X 和 Y 的关系。测不准的问题，只会使结果偏向无关。混沌的状态下，不容易看到两者的关联。然而，我目前已经看到了 X 和 Y 的关系，已经是阳性发现了。言外之意：如果我能测的很精准，看的更清楚，那么 X 和 Y 的关系可能更强。如果没有错分（misclassification），研究结果更强。这句话他没写，然而我们可以体会到这层意思。

【学习体会】高手就是高手，通过对偏性（Bias）方向的思考，把缺点转化为优势，低调的夸自己。可谓讨论部分局限性写作的最高境界。

【撰写模板】

The （写你的测不准的指标 X 或 Y） used in this study are likely to be more prone to error, as they （写测不准的原因）. It is noteworthy that the potential exposure misclassification resulting from such errors would bias toward to the null and thus result in an underestimation of the association between （写 X） and （写 Y）.

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moderate to high levels of sensitivity and specificity, with the exception of reports of shift work without night shifts, which were recalled with least accuracy (i.e., 62% sensitivity). The lifetime reports used in this study are likely to be more prone to **error**, as they cover a whole lifetime of employment. It is noteworthy that the potential exposure **misclassification** resulting from such errors would bias **toward to the null** and thus result in an **underestimation** of the association between shift work and type 2 diabetes.

2.3 未收集治疗方案怎么办？关于偏性的思辨

学友提问：研究某病人群的基线（入院时）血常规某指标（X）和住院期间死亡（Y）的关系，未收集住院期间治疗方案（Z），怎么办？

回复：

首先，关联分析调整的混杂是与 X 同时发生或之前发生的。因此在 X 之后发生的通常不需要调整。

其次，目前该疾病没有标准化治疗方案，多采用激素、吸氧等对症支持治疗，这些信息在论文中需要描述清楚。

第三，如果能在讨论的局限性部分，加入关于偏性的思考就更好了。本研究目前发现 X 和 Y 是 U 型关系。通常治疗方案会使死亡的人偏向于存活，也就是说 Y=1 和 0 的人偏向于混在一起。即偏向于无效假设：不容易发现 X 和 Y 的关系。然而目前已经是阳性发现了，提示如果能考虑到 Z 的影响，X 对 Y 的作用可能更强。

论文撰写参考

It is noteworthy that the potential resulting from （写后期治疗方案的影响） would bias toward to the null and thus result in an underestimation of the association between （写 X） and （写 Y）.

值得注意的是，后期治疗方案的影响可能导致偏向无效假设，因此导致基线指标 X 与死亡之间的关联被低估。

2.4 没有收集的指标怎么办？

学友提问：论文回修审稿人问某指标 A 对结果的影响，作者是如何考虑的？

作者说没有收集 A 指标，因此计划回复：通过查阅参考文献，A 指标对结果影响不大，因此没有研究 A 指标对结果的影响。

首先要理解审稿人的言外之意：如果他认为 A 指标是关键因素，而论文的表 1 中没有列出，审稿人可以估计到作者八成没有收集（整理）A 指标。这种情况通常会直接拒稿。

然而如果给回修，表明审稿人认为 A 指标不是关键因素，没有收集到也是可以理解的。此时回修策略就非常重要。

回修策略，前提是没有收集 A 指标

下策：用参考文献回复，说 A 指标不重要。

解读：审稿人说 A 有影响，作者说 A 不重要。编辑会信谁？作者拿出 n 篇文献说 A 不重要，审稿人就能拿出 n+1 篇文献说 A 重要。争到最后通常是拒稿。不要起争执啊。

中策：承认缺陷，写在讨论的 limitation 部分

解读：没有收集到的指标，写在讨论的局限性部分，就是回复审稿人了。

参考模板

Second, we did not **review the data** of SaO₂ or appearance of critically ill at admission.^[16]

factors including the presence of competing risks. However, we recognize some limitations. First, our results were obtained in a homogeneous population of patients with influenza pneumonia and cannot be extrapolated to other populations. Second, we did not review the duration of viral shedding or appearance of drug-resistant virus in either group. Third, PS matching analysis may also be a limitation, because this method may not reflect the possible biases in observational studies, and some residual confounding may persist. However, as PS match-

上策：尽量补救，收集数据后用结果回复

解读：如果条件允许，最好收集 A 指标后做统计分析，看 A 指标是否影响核心结果。关联分析的研究通常需要做调整混杂和分层分析。如果时间紧无法收集所有研究对象的 A 指标，能收集一部分也是好的，让审稿人感觉你尽力了。

3 样本量计算

3.1 论文实例

成人髋部骨折患者术前等待时间与 30 天死亡率的关系研究，2017 年发表在 JAMA (SCI IF=51 分)^[18]。

摘要的方法写：在 2009 年 4 月 1 日至 2014 年 3 月 31 日期间，对加拿大安大略省的 72 所医院进行髋部骨折手术的成年人进行的一项基于人群的回顾性队列研究。不用写样本量估计。

Population-based, retrospective cohort study of adults undergoing hip fracture surgery between April 1, 2009, and March 31, 2014, at 72 hospitals in Ontario, Canada.

DESIGN, SETTING, AND PARTICIPANTS Population-based, retrospective cohort study of adults undergoing hip fracture surgery between April 1, 2009, and March 31, 2014, at 72 hospitals in Ontario, Canada.

正文的方法写：数据来源于医院电子病历。不用写样本量估计。

Methods

Data Sources and Setting

A population-based cohort study was conducted using administrative databases in Ontario, Canada. Ontario residents have their medically necessary health care services and hospital information, and demographic characteristics recorded in these databases. These data are linked at the Institute for Clinical Evaluative Sciences.

正文的研究对象写：收集某段时间内在某地的某类患者。不用写样本量估计。因为时间、地点和病种一确定，样本量就确定了

Patients

Adults undergoing hip fracture surgery in Ontario from April 1, 2009, and March 31, 2014, were eligible. The start and end of the accrual period was selected when a variable measuring exact surgical wait times was introduced and the study ended to allow for 1 year of follow-up (up to the final March 31, 2015) after the date of initial hospitalization (initial diagnosis). Similar diagnostic and procedure codes previously used to identify patients with a hip fracture who had experienced a hip fracture were used. 统计方法：不用写样本量估计。不用写样本量估计。

Statistical Analysis

Risk-adjusted, restricted cubic splines with 4 knots were used to model the probability of complications according to time elapsed from emergency department arrival to surgery. A nonlinear relationship between surgical delay and complication rate could be assessed using spline regression, without making any underlying assumptions about a functional form. Instead of arbitrarily dividing patients into early and delay groups,¹⁵ the association between surgical delay and

运用已有的病例资料做研究，在能力范围内当然是样本量越大越好。就像这篇 JAMA 的回顾性队列研究，纳入了 72 所医院的 42230 例患者。好处是可以做各种统计分析，从不同角度看结果，提高证据力度。例如本文做了多种敏感性分析，这是需要有样本量保障的。

4 敏感性分析

4.1 如何让审稿人相信你的结果是真实的？是高质量研究必做分层分析

【常见问题】结果稳定可靠吗？是否考虑到了其他因素的影响？对于病情轻重不同的人，你的结论都适用吗？

【解决方案】几乎所有 10 分以上的临床型 SCI 论文，在正文或附表中均会呈现分层分析的结果。表明结论稳定可靠，提高证据力度。

【论文实例^[18]】

危险因素 X：糖皮质激素治疗（是/否）

结局指标 Y: 死亡

研究人群: ICU 的重症流感性肺炎

研究设计: 队列研究 (cohort study)

SCI 影响因子 18 分

结论: 重症流感性肺炎患者使用皮质类固醇激素会增加 ICU 死亡率

疑问: 病情重的人偏向于用激素, 病情重的人死亡风险高。目前发现激素和死亡有关, 是真的有关? 还是因为病情重的人导致的假象?

解决方案: 收集体现病情的指标, 按这些指标分层, 即分别在病情轻和重的人群中, 看结果是否稳定存在。做分层分析的表, 得出各种人群中激素和死亡的关系大小。

【论文撰写模板】

讨论部分写: 调整了混杂后, 在各亚组中结果稳定存在。你的 X 和 Y 是负向关系写 **negative**, 正向关系写 **positive**。

This (写 **negative** 或 **positive**) effect was evident in all subgroups considered and after careful adjustments.

Discussion

Our results strongly suggest that administration of corticosteroids as co-adjuvant therapy to standard antiviral treatment in critically ill patients with severe influenza pneumonia is associated with increased ICU mortality.

This negative effect was evident in all subgroups considered and after careful adjustments, including a PS matching analysis.

【学习体会】

- 各层的方向要一致, X 都是危险或保护因素, 结果不能自相矛盾
- 分层的因素要多, 除了 X 和 Y 的基线指标, 都要分层看看

4.2 什么情况下需要做敏感性分析 SENSITIVITY ANALYSIS?

学友提问, 什么是敏感性分析? 什么情况下需要做敏感性分析?

回复: 敏感性分析 (sensitivity analysis) 不是一种统计方法, 而是关于证据力度的思辨。何为思辨? 思: 从不同角度看结果是否稳定存在? 辨: 对应所思的问题, 做出相应的分析进行验证。

文献实例^[19]

X: 两种治疗方案相比 (NC-FET 和 mNC-FET)

Y: 临床妊娠率 (CPR)

人群：辅助生殖人群

研究设计：队列

核心结论：NC-FET is associated with a higher CPR compared to mNC-FET.

本研究做了敏感性分析。思路如下：

思

不同人群中结果是否稳定？

例如：卵巢刺激周期和 FET 周期纳入的人不同，是否带来偏性（bias）？

In order to **assess if the results** we obtained using this full sample set were **not biased by** the inclusion of various ovarian stimulation and FET cycles in the same women,

辨

把人分为不同的层，看结果是否存在。

做法

摘要的结果部分：进行了敏感性分析，把研究对象限制在特殊人群（首次 FET 周期）中，得到了一致的结果。

A sensitivity analysis **restricting the sample only to the first FET** performed by the couple in our centre was also performed.....**remained** significantly higher.....

MAIN RESULTS AND THE ROLE OF CHANCE: The unadjusted CPR per cycle was significantly higher in the NC-FET group (46.9%) when compared with the mNC-FET + LPS groups (29.7%, $P < 0.001$) but not the NC-FET + LPS group (39.9%, $P = 0.069$). The lower clinical performance of mNC-FET + LPS remained significant even after adjusting for potential confounders [adjusted odds ratio (95% CI) compared to the NC-FET groups: 2.18 (1.64–2.90) and 1.67 (1.31–2.12) for the NC-FET and NC-FET + LPS groups, respectively]. A sensitivity analysis **restricting the sample only to the first FET** performed by the couple in our centre was also performed. The predicted CPR in this multivariable logistic regression model **remained significantly** higher in the NC-FET (53.9%) and NC-FET + LPS (44.9%) groups when compared to mNC-FET + LPS (34.2%, all Bonferroni-adjusted pairwise comparisons with $P \leq 0.01$).

人群 1: the first FET performed following a fresh embryo transfer attempt (given that the **same women** could perform **multiple fresh cycles** within our study period,.....

人群 2: the first FET performed following the first fresh embryo transfer attempt of each patient (hence, including **each patient only once**).

因为敏感性分析，只是提供侧面的支持证据，因此可以不用把表放在正文，因为表太多可能冲淡主题。可以在讨论中写：为了使本研究结果可靠，进行了敏感性分析。

参考模板

To avoid bias caused by differences in （写可能影响结果的因素，例如不同周期），we carried out a sensitivity analysis focused on the （写其中一层）of the patient: using this sensitivity analysis the improvement of （写结局指标） in （写暴露因素 X） remained statistically significant (Supplementary 写附表名称).

To avoid bias caused by differences in FET cycle rank, we carried out a **sensitivity analysis** focused on the first FET following the first fresh IVF cycle of the patient: using this sensitivity analysis the improvement of CPRs in both NC-FET and NC-FET + LPS cycles **remained** statistically significant (Supplementary Table SII). Intriguingly, the data

小结：敏感性分析不是固定的统计方法，而是关于证据力度的思辨。如果不做，也不算错。如果能做，将是高质量的研究。如果做到极致，将是顶级的研究。

4.3 结果不写(DATA NOT SHOWN)

For any diabetes, the results were much the same (data not shown).^[20]

Mediation analyses showed that 3% (95% CI 1–5; $p=0.01$) of the observational association of BMI with risk of type 2 diabetes was mediated through low plasma 25(OH)D concentration. Corresponding genetic mediation analysis using a BMI allele score instead of measured BMI, showed similar results with an estimate of 4% (0–7; $p=0.02$). For any diabetes, the results were much the same (data not shown).

Discussion

To our knowledge, this is the first study to report a relation

5 回顾性研究匿名分析不签知情同意

常见问题：用既往已有的病例资料做研究，发表论文时“患者知情同意”怎么写？无法回到过去让患者签署。

常识：如果要补每个研究对象的知情同意书，那么不少发表在顶级期刊的回顾性研究论文就要撤稿了，因为实际工作中很难做到。

学习规范：

例1. 新英格兰医学杂志2016年发表的某药物与心力衰竭的多中心观察性研究，在方法部分写到：数据是匿名的，因此无需知情同意。

(1) A Multicenter Observational Study of Incretin-based Drugs and Heart Failure. N Engl J Med, 2016. The data are anonymous, and the requirement for informed consent was therefore waived.^[21]

sponsored by large U.S. employers. The study was approved by the institutional review board at each participating site and by the Independent Scientific Advisory Committee of the CPIC (protocol 14_119R). The data are anonymous, and the requirement for informed consent was

例2. 2014年发表的孕妇服用抗抑郁药和新生儿心脏病的研究。收集既往医院病历系统的数据，患者知情同意豁免。

Antidepressant use in pregnancy and the risk of cardiac defects. *N Engl J Med*, 2014. ^[22]

STUDY CONDUCT

The study was approved by the institutional review board of Brigham and Women's Hospital, and the need for informed consent was waived. The authors vouch for the accuracy and completeness of the analyses reported as well as for the fidelity of the report to the study protocol.

The study was approved by the Joan XXIII Hospital Ethics Committee (IRB#11809). Patie remained anonymous, and the requirement for consent was waived due to the observational

要点

- (1) 回顾性分析既往病例资料，只要做到匿名（anonymous），可以不需要每位患者签署参与本研究的知情同意书。
- (2) 伦理和知情同意是两回事，伦理是一定要过的。
- (3) 过伦理时要写清楚研究设计是回顾性收集既往已经发生的病例资料，匿名分析，数据采集、数据分析和论文撰写等过程，没有暴露患者隐私信息，包括：姓名、电话、住址等。

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