

旨在实现更好医疗照护的循证医学声明

针对患者照护研究中存在系统偏倚、浪费、错误和欺诈的回应

Evidence based medicine manifesto for better healthcare

A response to systematic bias, wastage, error, and fraud in research underpinning patient care

来源:BMJ 2017;357:j2973 doi: 10.1136/bmj.j2973

知情决策需要临床医师和患者识别并整合相关证据。但是,当前众多证据的可信度值得怀疑,较少研究真正能够解决患者的重要问题,可用于医患知情共同决策(inform shared decision)的证据缺乏,他们如何能实现知情决策呢?

大量研究存在设计不合理或实施不规范的问题。这些研究的结果很多被选择性报告或未报告¹。随着临床研究数量增多²,证据质量往往会降低³,从而导致医疗从业人员为患者提供可支付、有效、高质量医疗照护的能力受到影响。

*The BMJ*与牛津大学循证医学中心共同举办一年一度的“证据直播(Evidence Live)”会议,旨在“发展、推广、应用更好的证据以提供更佳的医疗照护”。通过这项工作及其他项目,我们发现了横跨整个证据生态系统、涵盖基础研究到临床实践的大量问题,同时也获知了众多进展及解决方案。

本文提出的循证医学声明源自于对

上述内容的认识。该声明以公开的方式邀请所有人加入并共同推动更好地生产证据。通过制定路线图,实现优先目标并从取得的成绩中获取经验。最终能与已有的工作形成互补和统一,并有新的突破。

为什么我们不能相信证据?

临床研究中出现严重的系统性偏倚、错误以及浪费,已有较多报道(框图1)⁴。不少已发表的研究在一定程度上存在误导,影响了这些研究的结果在实践中被接纳和应用。并受到多种原因影响,包括:商业和学术利益存在冲突、管理不善¹⁵;研究议程存在偏颇(常常因为未从患者角度出发考虑研究问题及结局)¹⁶⁻¹⁷;设计不合理、缺乏透明度或缺乏独立审查;研究人员不遵循研究方案¹⁸或研究提前终止¹⁹;代笔作者²⁰;发表偏倚和报告偏倚⁵⁻²¹;研究结果被过度解释或误用²²;存

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框图1 当前证据存在的问题

- 一篇里程碑式的综述显示:一半以上的试验结果从未被发表;结果阳性的试验被发表可能性是阴性结果试验的2倍
- 药物临床试验的成本在过去10年增加了5倍,阻碍了新药的研发
- 当前约有85%的研究花销被浪费
- 在一项针对系统性综述的研究中,92个Cochrane系统性综述中86%未纳入主要的危害结局数据
- 一项纳入39个研究的系统性综述中,未发现研究有力地评估了共同决策
- 2009至2014年,制药行业因犯罪行为 and 民事侵权行为受到共130亿美元(折合100亿英镑;120亿欧元)的罚款——而体制上几乎没有为防止此类问题再次发生做出改变
- “尽管一再呼吁禁止或限制存在于临床指南作者和赞助商之间的利益冲突,但问题仍然存在”
- 三分之一(34%)科学家的研究实践存在问题,包括:为发现具有统计显著性的效应而开展数据挖掘、选择性结果报告、改变结局指标、发表偏倚、偏离研究方案及隐藏利益冲突
- 2012年,一项针对9 036名*The BMJ*作者及审稿人的调查发现,在2 782名(31%)应答者中,有13%目睹或亲身经历英国的科学家或医生为了使研究发表,在他们的研究中做了不恰当的调整、更改、甚至捏造数据
- 基于一项630篇文章的调查发现,有8%的作者承认他们在作者申明中撒谎

框图2 循证医学声明,实现更好的医疗照护

- 扩大患者、医疗保健专业人员和政策制定者在研究中的作用
- 增加对现有证据的系统使用
- 为最终用户提供相关、可重复和可获得的研究证据
- 减少有问题的研究实践、偏倚和利益冲突
- 确保药品和设备监管的健全、透明和独立
- 制定更好的可用的临床指南
- 通过更好地使用真实世界数据,支持创新、提升质量和安全性
- 对专业人士、政策制定者和公众开展循证医学教育,实现知情抉择
- 鼓励新一代的循证医学领袖

在没有被纠正的错误¹⁴或隐藏未被发现的欺诈⁹⁻²³。

低质量证据会导致低水平的临床决策。现在已有许多机构如雨后春笋般产生,帮助临床医师解

释已发表的证据,并为他们提出行动建议。但这些机构仍存在问题,如生产不可信的指南¹⁰、监管上的失败²³,以及延迟撤市有害药物²⁴。这些过失共同导致了治疗费用快速攀升²⁵、过度医疗(包括过度诊断,过度治疗等相关概念)²⁶,以及本可避免的伤害²⁴。

生产更可信的证据:循证医学声明

我们已通过一系列同利益相关者开展的活动,优化了生产可信证据的步骤(框图2),包括组织讲座、圆桌讨论、在线咨询和直接反馈。解决这些问题需要花费时间、资源和精力。从事循证医学的群体应承担起此项重任。然而,这是一个巨大的工程,正在由分散在世界各地的团体负责实施,未来也将同样如此。我们希望将注意力集中于能更高效地带来改变的工具和策略上,以便我们能一同致力于使用更高质量的证据来改善医疗照护。本声明文件和优先选项是一个动态文件,将随着时间的推移不断进化以促进可靠证据用于医疗照护。如果您想表达自己的观点并参加讨论,可以访问以下网址:<http://evidencelive.org/manifesto/>。

The manifesto has been developed by people engaged at all points in the research ecosystem engaging in fixing the problem, including patients and the public, who indirectly fund and are directly affected by the outputs of the current system. We thank all those who have provided feedback: partners who hosted round tables and seminars and those who gave feedback are listed across www.evidencelive.org. We also thank Ruth Davis and Alice Rollinson for their support in facilitating the broader engagement of the evidence based medicine community with the manifesto. The BMJ's late patient editor, Rosamund Snow, was a coauthor of early versions of the manifesto. We are seeking other inputs to continue her work and our commitment to patient involvement.

利益竞争(Competing interests): We have read and understood BMJ policy on declaration of interests and declare that all authors have both academic and financial conflicts of interest that inform this manifesto. Academically, all of the authors believe that improving the quality of evidence, its transparency, involving patients, and improving the communication of research is essential for providing informed treatment decisions. Financially, the BMJ and the Centre for Evidence Based Medicine run a non-profit conference (Evidence Live) together that focuses on better evidence for better health. Our respective institutions are involved in research, education, and publishing in many of the areas outlined in the manifesto. In addition, individually we do media work, books, training events, and talks. We consider all of these conflicts may have biased our opinions and therefore have sought a wide range of input to offset our preconceptions.

来源及同行评议(Provenance and peer review): Commissioned; not

externally peer reviewed.

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