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目录

编者寄语

第一期正式出版!

如果你有幸经历过一个孩子出生的那一刻，你就会知道它改变了你所知道的生活。如果你还没有经历过这辉煌的时刻，我希望不久的某一天，你会有机会去经历。这种感觉很难用语言表达，但这是一个荣耀的时刻，尤其是当新生儿成为你自己家庭的一员时。

我们自己的杂志终于出现了！在某种程度上，你可以把《国际临床工程杂志》看作是一个孩子，它将培养全世界临床工程师的自豪感——发出壮丽的光环，让新父母在养育他们美丽的孩子时感到高兴。

这个婴儿（这本杂志）有年长的兄弟姐妹——所有的职业家庭成员一起努力获得成功。在最近一系列重要的成就中，让我们的家庭感到自豪的是：

- 唯一的临床工程领域大会——国际临床工程和卫生技术管理大会的召开——第三届大会定于2019 年 10 月在意大利罗马举行 (www.icehtmc.com)。
- 今年 10 月 21 日，全球临床工程日庆祝活动全球将在中国成都发起 (http://global.icehtmc.com/)，以表彰临床工程师对改善医疗成果的贡献。
- 临床工程奖（the Clinical Engineering Awards Program）的启动 (http://cedglobal.org/awards/)。
- 在临床工程部网站 (www.globalced.org) 免费发布《医疗技术的人为因素安全手册》(http://cedglobal.org/human- factors-forhealth-technologysafety/); 并且现在
- 我们自己出版的《国际临床工程杂志》(www.GlobalCE.org) 正式出版了。

将这本杂志感觉像你的孩子一样，这一点非常重要，因为这将是由你的创造，它的发展将直接与你个人的参与和投入相关。我们知道，养育一个孩子“需要一个村庄”。这本杂志也不例外，它需要一个村庄，在适当的呵护下，它将成长为一个成熟的、有影响力的出版物。只有在你（村庄）的照顾、关心、鼓励并与它分享你的知识时，它才会茁壮成长。

我们确实有一些优势，值得你们骄傲。举个例子，例如，我为我们杂志的编委会成员感到骄傲，他们来自广泛的学科领域，包括临床工程师、医生、外科医生、麻醉师、研究人员、卫生信息学、技术评估专家、医疗器械孵化器专家、法医工程师、院士、研究人员、成人和儿科医院工程师、工业界、政府、世界卫生组织、联合会、协会、非政府组织和病人护理等。他们都是各自专业领域的知名领袖，出版发表过很多文章。此外，他们代表着来自世界各地的专家，从非洲和美洲，到欧洲和亚洲。谁还能要求更多？我们的另一个优势是，我们选择和部署了一个开放的平台，这有利于及时、系统和一致的双盲审查提交过程，在线存档，以及在世界任何地方安全获取高质量的文章。杂志有幸拥有一位敬业的管理者，她就是拥有生物医学工程博士学位的 Stavrianou 女士。对于我们高质量的杂志来说，这是多么合适的专家啊。

我们以志愿者为基础的审稿人代表了许多相关主题的广泛知识。这些审稿人提供他们的时间和专业知识来促进和促进公平，高质量，和提交的科学建设性的审查过程，从而支持编辑的目标。

你可能知道，抚养孩子需要资源，我们在这方面也有优势。通过临床工程部 (CED) 的早期支持，我们成功地采取了最初的几小步。现在，在《中国医疗设备》杂志社的大力支持下，我们已经逐渐变成了行军。

这是一个重要的时刻，你们的投稿和学术贡献将把我们的梦想变成现实。该期刊还旨在鼓励年轻工程师和资深科学家投稿。

如果您想以审稿人的身份加入，或者提交你的稿件，请登录 www.GlobalCE.org 网站。一旦你注册了，你可以选择您想成为的角色——一个读者，一个审稿人，或者投稿。我在这里诚邀您一起行动起来，成为这个家庭的一员。这本杂志是给您和您的同事的。您有一个独特的机会来参与“提升”我们的专业。期待您的投稿。

让我们一起让它成为最好！

Dr. Yadin David

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应用人为因素方法降低医疗器械风险

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摘要

本文描述了人为因素方法可以帮助加强建立的临床工程团队的工作，将新的重点放在减少错误和病人安全。这种方法在许多方面代表了各部门的自然发展过程，这些部门正在寻求增强其对医疗保健的有用性和相关性。通过文中的几个例子，说明采用人为因素方法可以揭示与医疗设备的安全使用有关的问题，而这些问题是不容易通过其他方法获得的。这些方法的采用和实施为临床工程部门在确保最佳患者安全方面加强其作用提供了更多的潜力空间。

【关键词】人为因素，医疗器械，错误调查，患者安全。

引言

对于临床工程团队来说，管理与医疗设备相关的风险是他们工作的核心。对医疗设备的有效维护给予适当的重视，以确保它们在规范范围内运行，并按要求进行检查，以支持持续良好的性能。一个理想的方法是考虑医疗设备生命周期的所有阶段，从采购计划到最终退役。目的是通过正确选择和维护设备，将有助于确保良好的患者治疗期间的结果。

1999 年，美国医学研究所 (the Institute of Medicine,IOM) 发表了一份具有里程碑意义的报告，题为 : To Err is Human: Building a Safer Healthcare System (人非圣贤孰能无过 : 建设一个更安全的医疗保健系统)[1], 它警示到，每年至少有 44000 到 98000 人死亡发生在美国医疗体系的医疗差错。这一爆炸性的统计数据在美国和其他国家的医疗界引起了许多争论和分析，随后在其他司法管辖区进行的研究显示，在人口规模标准化下，错误率惊人地相似 [2]。这些信息带来的结果之一是对病人的安全给予了新的重视，相关组织开始寻找方法来研究目前的安全水平，抓住错误，并做出改进，从而对病人的安全结果产生更持久的影响。

在寻找可能对医疗有益的方法和途径的过程中，注意力转向航空和核电行业，这两个行业都经历了重大的灾难性事件，导致人们明确要求采取行动。人为因素准则结合了心理学和工程学的原理和方法来理解人类如何与周围的世界互动，考察认知问题以及人与周围环境之间的互动。该领域的领导者，如 James Reason 和 Jens Rasmussen，已经开发出了一些模型，通过提出一些问题来帮助确定一个系统是否设计的可以安全地供人使用，例如：操作是否清晰合理？它的行为方式是否与操作员遇到的其他系统相似？它是否以简洁明了的方式揭示了它的运行状态？

这些方法已被证明在提高航空和核电站的安全性

方面非常有效。在过去的 40 年里，由于各种程序的标准化以及清单和安全联锁等工具的使用，商业航空变得更加安全 [3]。这些方法也为改善医疗保健的安全性提供了巨大的潜力，但迄今为止，结果参差不齐 [4]，在这一点上，也有必要考虑为什么在医疗保健中实现真正显著的错误率降低如此困难。医疗保健提供者接受多年的培训为病人提供尽可能最好的护理，当诊断或治疗过程中出现错误时，他们的痛苦是可以理解的。

由于安全做法的标准化和规范化，航空和核电安全得到了有效改善，第一反应会是在医疗保健方面可能会有类似的效果，但也有一些重要的差异，使得对改善错误率的产生变得更加困难。

(1)医疗保健流程远比飞机起飞前驾驶舱的流程多样化，例如 (J Ruiter-Ligeti，医学博士)。它们不一定能标准化到同样的程度，而且许多医疗保健提供者会在临时突发的复杂情况下采取不同的行动。“变通”一词是在病人护理环境中经常听到的，因为一线护理提供者会将一些善意但有限制性的协议进行修改，试图为每个病人提供最佳护理。

(2)为了努力提高安全性，医疗保健系统规划者往往试图强加标准化水平，限制一线工作人员提供最佳护理的能力，这会导致挫折感和必须以“单干”的形式去提供更好的护理。当系统被强加给用户而没有完全了解在床边所做的工作的细节时，这种情况常常会发生。例如，对于管理者来说，为避免早期错误，相对于去理解采用某种护理方式的原理，去制定一个针对某种护理方式的政策更为简单。每个人都想为病人做到最好，但是要想理解什么是最好的需要对实际护理环境有非常详细的了解。

(3) 医疗保健不是一个静态的实体。事实上，自 IOM 报告发布以来，在过去的 19 年里已经发生了巨大的变化，包括计算机化的广泛采用和新型医疗设备的引入。这两种有用的力量都增加了本已复杂的环境的复杂性，使安全成为越来越大的挑战。此外，采用这些系统和设备的方式往往没有考虑到护理环境和用户的技能、能力和培训水平，导致出现新的错误可能性。

在所有这些问题上都可以采用人为因素的方法，而且有一些早期令人鼓舞的迹象表明，这些方法正在逐步发展。有趣的是，人因方法在医疗保健领域的应用并不新鲜。波士顿的 . Jeff Cooper 博士和他的同事在麻醉安全性方面的工作就是一个很好的例子 [5]。与医疗保健的其他领域相比，这项工作远远领先于它的时代，它对麻醉期间病人的安全有着深远的积极影响。可惜的是 , 这种方法在许多其他领域的护理并没有获得一个重要的立足点 , 所以我们现在面对的挑战是在今天的复杂的卫生环境如何实现广泛应用 , 如今设备联网，各类信息都在复杂的 IT 系统进行整合。

临床工程师和技术人员有充分的理由支持在医疗保健中应用人为因素法，至少就医疗设备在错误中所扮演的角色而言。ECRI 研究所的 Jim Keller 表示，他们的数据显示，75% 的医疗设备故障不是由于设备本身，而是由于使用错误 [6]。在下一节中 , 临床工程团队可以如何通过哪几种人为因素应用方法进行说明 , 希望我们作为专业人员，抓住机遇 , 利用这些工具确保医疗设备尽可能安全有效地使用。

人为因素在临床工程中的角色

虽然认为临床工程能够解决医疗保健中的所有系统性错误问题是不合理的，但很明显，其中一些问题以某种方式与医疗设备和 IT 系统的使用相关。医疗设备支持临床工程的传统领域 , 近年来 , 临床工程越来越多的参与基于 IT 系统的部署 , 因为在很多方面带来的问题这些模仿的医疗设备本身造成的 ; 诸如技术规范、网络连接、接口能力和总体用户满意度等问题。IT 系统通常是患者数据收集的扩展，其中大部分是由前端的医疗设备发起的，因此这种活动扩展是合理的。

临床工程很适合引入系统工程方法来帮助减少误差，这有一个优势，是的方法远离意见和推测，更接近可测量的参数和结果 ; 是一种经典的质量改进的方法。关于全面分析临床工程如何将人因方法带入医疗保健的方法超出了本文的范围，但是可以在网上找到关于这个主题的相关内容 [7]。以下是一些简要的重点总结，鼓励您可以进一步阅读。世界上有少数但越来

越多的团队专注于这些方法，希望随着时间的推移，这些方法将更加普遍，成为常规，因为它们提供巨大的潜力，去提高安全水平与医疗设备和IT系统的使用。

评估和采购的应用

长期以来，医疗器械的评估和采购一直被认为是临床工程的一项关键任务，其所做的决定会产生多年的影响。技术选择不当会导致设备不可靠或难以操作。在大多数国家，对新技术的需求超过可用的资金，因此需要谨慎地做出决定。一旦完成，所选择的设备是长期承诺，理想情况下应该满足医疗保健系统的需要。很多时候，医疗设备的决策并不涉及到很多，甚至是任何终端用户，他们最终的任务是试图从所选择的系统中获得良好的性能。在临床领域，传统的用户评估常常是主观的、随意的，而且容易产生偏见。在受控的模拟或真实环境中使用工作流分析和可用性测试的人为因素方法，可以对来自多个供应商的竞争产品进行高度客观的评估。

代表性的最终用户最初被观察到与可比较的技术进行交互（如果有的话），以获得对该技术适合环境和相关工作流的方式的彻底理解。然后，用户被招募到一系列与竞争技术的受控交互中，使用脚本描述了观察到的临床工作流程中的典型任务的场景。人为因素团队成员被动地观察每个参与者的表现，特别关注用户在与设备交互时遇到的困惑，或者在使用过程中出现的错误。如果多个参与者在使用的特定阶段遇到了问题，这就强烈表明正在测试的设备的某些方面对整个用户来说都存在问题，应该对问题的潜在严重性进行评估。例如，它会导致不正确的治疗或诊断吗？它可以忽略或以某种方式修改吗？

这种安装测试需要一些努力和对所使用的评估方法的知识，但是为获得一个主要设备所投入的时间是值得的。机构必须选择哪些设备领域要接受这种严格的评估，作为一般指南，可以采用以下筛选条件：该设备是否与过去的事故和错误有关？设备是否广泛分布在组织中，会被各种不同的人使用？是否进行了重大的金融投资？如果其中一个或多个问题的答案是肯定的，那么前期成本和基于人为因素的购买前评估可能会在设备的使用寿命中获得收益。要考虑的另一个重要的问题是，当终端用户直接参与这种类型的评估，他们会更好地了解设备的功能和限制，而且更偏向于自己所选的产品，当然前提是假设他们的经验足以帮助他们做出一个最佳的采购决定。

用于预测和调查错误

即使精心选择了设备，错误仍然会周期性地发生，因此，下一个可以发挥辅助作用的领域就是不良事件的预测和调查。故障模式和影响分析（Failure Mode and Effects Analysis，FMEA）等工具可用于预先评估在设备或系统使用过程中发生某些事件的可能性。每一种潜在的失效模式都被识别出来，每一种失效的相关影响都被分类，询问发生的概率是什么，以及发生后的影响是什么。一旦制定了这些措施，就可以确定一系列的缓解战略，并决定哪些是切实可行的。请注意，所有这些工作都是前瞻性的。它是在实现特定设备或系统之前完成的，如果分析是彻底的，它提供了显著降低与特定系统相关的总体错误率的潜力。临床工程团队通常非常适合领导这种分析，因为他们了解技术实现的细节，并且很好地掌握了与使用相关的潜在问题领域。

假设事件已经发生，机构已经开始调查，根本原因分析（the Root Cause Analysis，RCA）方法是基于人因理论的一个强有力的工具，可以用来尝试理解事件背后的根本原因。除了非常罕见的例外情况，医疗工作者都本着对病人负责的态度，当不良事件发生，对其病人的护理过程中会受到创伤。有时，人们对不利事件的最初反应是批评相关人员，并将其归咎于判断力差。这样做有两面性：快速识别出“罪魁祸首”，并让系统确信这是一次性事件，从而产生一种错误的安全感，认为根本问题已经得到有效解决。人为因素方法帮助我们了解这些假设背后的原因，试图理解其中的根本原因。也许医疗保健提供者在一个非常关键的任务中被打断了。也许系统本身太复杂，许多用户不知道如何正确地操作它。可能向用户提供的信息似

乎证实了系统的运行符合预期，但用户没有注意到由于他们的行动而出现的潜在不良事件正在演变。RCA有助于发现这些问题，一旦这些问题被发现，就有助于指导系统负责人对系统进行必要的更改，以尽量减少复发的可能性。再一次，临床工程在这方面的分析中处于主导地位，与来自其他学科的同事一起发现这些根本原因。通过识别和减轻这些问题，系统在长期内真正变得更安全。

查找未发现故障的维修报告

正如本文开头所提到的，临床工程部门担负着有效维护本机构所用医疗设备的责任。询问任何临床工程师，他们是否曾经从临床收到一件贴有“损坏”标签的设备，结果发现当他们在试验台上测试时，它的性能符合规范。这些通常被称为“未发现故障”，因为服务团队没有检测到任何故障[8]。最近的一项研究提取了与未发现故障的服务事件相关的数据，确定了一系列显示未发现故障报告发生率较高的设备。当对这些设备的可用性进行评估时，发现用户的困难与无故障事件发生的可能性之间存在相关性。

换言之，用户在使用设备时遇到了困难，其中一些人选择放弃，他们认为设备本身一定出了问题，或者干脆采取了这样的方法：如果我不能让这个设备工作，也许我应该再采购一个，把这个送去“修理”。从中可以看出，在临床工程部门没有发现故障的报告在某种程度上是一个设备难以操作的信号。进一步的调查可以揭示，诸如进一步的用户培训这样的干预措施是否能够有效地帮助减少操作问题，或者这些问题是否已经嵌入设备的设计中，使得唯一有效的补救措施就是彻底更换设备。

结论

虽然并非所有上述方法都可以由一个机构的临床工程团队单独执行，但这些人为因素方法的应用可以很容易地由IT部门开发和支持。凭借他们的技术背景，该团队非常适合采用和推广这些方法，并且经常会在临床人员、管理人员和风险管理人员中找到伙伴，这些人以对尽可能减少护理过程中的错误为目标。随着临床工程的适应和发展，这一领域代表着对他们目前所做工作的高度影响的延伸，可以说，推广人为因素方法是一个挑战，与10年前临床工程在参与信息技术系统方面所面临的挑战一样。这场争论基本上得到了解决，人们希望在未来10年里，在临床工程中采用人为因素的方法方面也能看到类似的结果。为了获得这些知识，我们鼓励用户通过阅读和与已经在这一领域工作过的同事接触来了解更多关于这个主题的知识。临近大学的工业工程和心理学系可能拥有对人的因素有很丰富认知的教员，他们有兴趣与在实际临床环境中工作的人合作。此外，越来越多的实验室专门致力于将人为因素方法应用于医疗保健，这些实验室代表了专家的信息来源和潜在的协作。

总而言之，临床工程部门有一个绝佳的机会，通过在工作中采用和应用人为因素方法，在帮助提供更安全的医疗保健方面发挥重要作用。鼓励临床工程专业人士抓住这个机会，做出贡献。医疗保健专业领域的发展将有助于将临床工程从技术支持角色提升为确保患者最佳安全的重要角色。

利益冲突

作者声明本论文的发表不存在利益冲突。

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不良事件数据的派生使用：原因和方式。美国食品和药物管理局（FDA）的制造商和用户设施设备体验（MAUDE）案例

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摘要

目标：本文试图衡量美国食品和药物管理局（FDA）制造商和用户设施设备体验（Manufacturer and User Facility Device Experience, MAUDE）数据库第二阶段开发对患者安全、技术评估等科学领域的影响。

方法：已经在五个文献数据库对术语 “制造商和用户设施设备体验数据库”和“FDA AND MAUDE（美国食品和药物管理局及制造商和用户设施设备体验）”进行了查询。将一些资格标准应用到研究结果上，最终形成了 117 篇论文。通过对这些发表论文的广泛研究得出了一些有趣的发现。

结果：研究结果涉及数据库开发随时间的演变，根据被识别的论文中提到的设备组、这些论文的研究目标、这些论文作者使用制造商和用户设施设备体验（MAUDE）数据的原因以及这些数据在他们的研究方法中是如何使用的，来检查研究结果。

结论: 制造商和用户设施设备体验（MAUDE）数据库影响最大的两个科学领域是患者安全与技术评估。平均而言，每年有超过 10 篇经同行评审的论文将制造商和用户设施设备体检（MAUDE）数据作为实现研究目标的手段。这就证明了制造商和用户设施设备体验（MAUDE）是一个可开发的、有价值的数据源，可用于这些科学领域的研究。

【关键词】医疗设备、制造商和用户设施设备体验（MAUDE）、不良事件报告、患者安全、卫生技术评估。

引言

患者安全、卫生技术评估和医疗设备警戒是严重依赖数据可用性的领域。他们需要来自各种来源的有效数据以便提取有用的信息。医疗设备（MDs）数据的一个重要来源似乎来自于世界大部分地区相关监管系统实施的医疗设备警戒和上市后监测机制。而美国食品和药物管理局（FDA）制造商和用户设施设备体验（MAUDE）数据库就是这样的一个来源。现今，数以百万计的医疗设备在各个地方（医院、诊所、住

宅等）使用，每年有数以千计的新型号设备进入市场。毋庸置疑，这些医疗设备对改善医疗服务做出了重大贡献。然而，医疗技术，与其他技术一样，并不是毫无风险的。在许多的案例中，设备由于出现损害患者健康的不良事件而被召回，或者在一些案例中，一个“有前途的”创新方法因为未被证明如预期的那样安全，在经过较短时间的使用后不得不被撤回 [1][2][3][4]。

当今最大的医疗设备（MDs）市场（美国、欧盟、日本等）是由监管框架（条例、法律、指令、指导方针）管理的，根据这些框架，医疗设备必须遵守特定的安全规定，才能进入这些市场 [5][6]。所有的这些框架都有一个共同的安全要求，即在中、高风险设备进入市场后，跟踪它们的不良事件报告系统或警戒系统，并进行上市后监测 [5][6][7]。

医疗设备（MDs）警戒报告系统的目的是通过防止报告的不良事件的再次发生来提高患者的安全性。这是通过命令医疗设备的用户和制造商向卫生主管部门报告医疗设备在事故中造成的不良事件来实现的。根据这一机制，每当医疗设备可能会造成患者或使用者死亡或受伤时，制造商都必须报告这一事件，并评估是否应该采取纠正措施。同时，用户报告系统鼓励用户向制造商和 / 或主管部门报告他们所注意到的任何此类事故。医疗设备警戒和用户报告系统的主要目的是通过减少将来在其他地方再次发生类似事故的可能性来提高患者、用户和其他人的安全。要做到这一点，就要评估所报告的时间，并酌情传播信息，这样可用来防止这种重复，或减轻这种事件的后果。

美国是最大的医疗设备市场 [8][9]，作为市场监测的相关机构，美国食品和药物管理局（FDA）也负责医疗设备的警戒。

自上世纪 90 年代以来，美国食品和药物管理局（FDA）建立了一个名为“制造商和用户设施设备体验数据库”[10] 用于报告与不良事件相关的医疗设备。现在，该数据库每年收到超过 800.000 多份报告 [11]。

现今，制造商和用户设施设备体验（MAUDE）包含 400 多万份医疗设备报告（MDRs），其中包括疑似与设备相关的死亡、严重受伤和故障，以及其他不符合规定的问题，如包装和标签问题、未经消毒的递送等。制造商和用户设施设备体验（MAUDE）包含制造商和进口商从 1996 年 8 月到现在提交的医疗设备报告，从 1991 年到现在提交的所有强制用户设施报告以及 1993 年 6 月后提交的自愿报告 [12]。数据库的一部分对公众开放，提供有关医疗设备（MDs）安全的重要信息。这可以通过美国食品和药物管理局（FDA）的官方网站（www.fda.gov）查阅，也可以通过搜索框查询。此外，所有主要数据集都会以可导入公用数据库的文本文件的形式提供给公众。

经过评估程序后，大量的医疗设备报告（MDRS）或涉及死亡的报告由食品和药物管理局（FDA）进行调查，很多情况下，这种调查导致了纠正措施，这对患者和使用者的安全都有明显的好处。在第二阶段，这些大量的数据似乎为进一步的研究提供了有价值的来源。回顾性分析研究、数据提取技术和对这些数据的其他科学使用，为患者安全、医疗设备技术评估以及其他科学领域提供了附带利益 [13][14]。

本研究试图定量和定性地衡量制造商和用户设施设备体验（MAUDE）的第二阶段开发和以及这种开发对科学研究的影响。

资料和研究方法

已经在五个国际文献数据库（ScienceDirect 数据库、Journals@Ovid Full Text OVID 公司医学期刊全文数据库、Pubmed 文献数据库、Web of Science 数据库、Scopus 数据库）对术语“制造商和用户设施设备体验数据库”和“FDA AND MAUDE（美国食品和药物管理局及制造商和用户设施设备体验）”进行了查询，以便查找到所有包含这些术语的出版物。2015 年 1 月对数据库进行了查询。这些查询的结果是通过删除重复项进行了合并，从而产生了最初的 1.016 个独特的出版物。（来自每个数据库的结果见表 1）。

这一系列的结果是根据出版类型、语言和出版时间进行筛选的，以便只保留 2005 年至 2014 年间用英语撰写的同行评审的论文。书籍、社论、评注、信件、论文评语、会议论文集刊物等等，均被排除在最后的

选择之外。经过筛选，剩下 381 篇科学论文。

表 1. 文献搜索结果

文献数据库	MAUDE 以及 FDA	“制造商和用户设施设备体验数据库”
ScienceDirect	322a	269
Journals@Ovid Full Text	196a	175
Pubmed	54	42
Web of Science	49	41
Scopus	209a	322
总计（无重复记录）	631	604
[a] 已用间接指标完成搜索 (MAUDE w/10 FDA) or (MAUDE ADJ10 FDA)		

下一步是从这 381 篇论文中提取出那些直接使用了来自制造商和用户设施设备体验（MAUDE）数据的论文。筛选后，形成最后一组 117 篇论文。在这些论文中，有 4 篇论文的作者搜索了制造商和用户设施设备体验（MAUDE）数据库，但发现结果与这项工作无关。但是，我们仍然决定将这 4 篇论文列入最后一组，因为尽管他们最终并没有使用来自制造商和用户设施设备体验（MAUDE）的任何数据，但他们考虑了数据库的内容。这 117 篇论文的名单出现在参考文献部分（参考文献：14-25、28、31、33-135）。

应该指出的是，在被排除在外的 264 篇论文中，有 50 多篇论文引用了制造商和用户设施设备体验（MAUDE）数据，但这种引用要么局限于对一两个案例的单一评论，要么是间接地引用了使用了原始数据的其他论文的结果。

最后一步是又详细地研究了最后一组的 117 篇论文，专注于这些论文提到的设备组，随着时间的推移数据库开发的发展，这些论文的研究目的，导致这些论文作者使用制造商和用户设施设备体验（MAUDE）数据的原因，他们最终如何在他们的研究方法中使用这些数据，等等。查询方法的流程图如图 1 所示。

文献搜索结果最初使用的是 Mendeley 桌面参考资料管理软件处理的，后来使用的是 Microsoft Excel 进行处理。

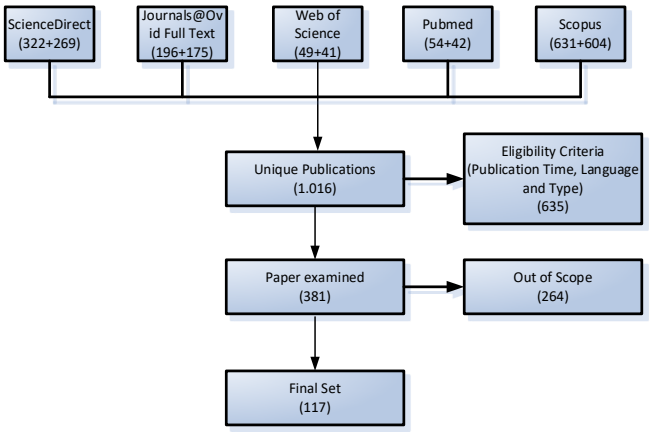

图 1. 用于 FDA MAUDE 系统搜索的 PRISMA 流程图 .
注：
Eligibility Criteria (Publication Time, Language and Type): 资格标准（出版时间、语言及类型）
Paper examined: 筛选后的论文；
Out of Scope: 超出范围；
Final Set: 最终组。

结果

最后一组 117 篇论文的分析结果如下：

A）由于制造商和用户设施设备体验（MAUDE）是一个包含医疗设备报告（MDRs）的数据库，每条记录都与一个医疗设备相关。因此，用于第二阶段使用的数据的检索也与医疗设备有关。进行的分析确定了在论文中作为参考的设备组。这些设备组在适用的情况下被分组为更通用的设备类别。应该指出的是，尽管有 24 篇论文专门针对一种设备类型，而不是针对整个组，但在本分析中只考虑了设备组问题。

表 2. 每个设备组的论文数量

心脏病学设备	29
支架类	9
植入式心律转复除颤仪	7

腔静脉滤器	6
自动体外除颤仪	2
血管成形术导管	1
动脉闭合设备	1
导管引入鞘	1
导管	1
血液闭合系统	1
植入式设备	**22**
网孔类	6
间隔封堵器	4
人工电子耳蜗	4
骨形态发生蛋白 2	3
乳房植入物	1
脑脊液阀门	1
心脏瓣膜	1
硅氧聚氨酯共聚物	1
脊髓电刺激仪	1
内窥镜检查设备	**14**
内窥镜检查 - 一般	4
子宫内膜去除设备	3
内窥镜吻合器	1
经内镜胰胆管造影	1
胃肠内窥镜检查	1
微波子宫内膜去除	1
粘膜消融设备	1
射频消融	1
其他	1
腹腔镜检查设备	**6**
Hem-o-lok 结扎锁	3
腹腔镜粉碎器	1
腹腔镜套管针	1
其他	1
输液设备 - 泵类	**5**
输液设备	2
胰岛素泵	2
输液泵	1
假体	**4**
人造脊椎	1
髋关节假体	1
腰椎总椎间盘	1
肩关节假体	1
机器人辅助外科手术	**4**
经子宫颈绝育	**4**
患者自控镇痛	**3**
取石球囊和网篮	**2**
取石网篮	1
取石球囊和网篮	1
体外氧合	**2**
体外膜肺氧合	1
氧合器	1
激光 - 一般	**2**
美容激光	1
激光	1
救护车担架	**1**
床护栏	**1**
吸乳器	**1**
隐形眼镜	**1**
乙烯 - 乙烯醇共聚物	**1**
饲管	**1**
血糖检测仪	**1**
核磁共振	**1**
手术显微镜	**1**
腹腔透析	**1**
背驮式	**1**
日光浴设备	**1**
涉及各种设备组的论文	**8**

根据所做的分析，最常被提及的是一般类型的心脏病设备（29 篇论文），其次是植入式设备（22 篇论文）和内窥镜检查设备（14 篇）。关于设备组，支架组（9 篇）、植入式心律转复除颤仪组（7 篇）、网孔组（6 篇）、腔静脉滤器组（6 篇）、间隔封堵器组（4 篇）、人工电子耳蜗组（4 篇）的数量比较领先。最后，有 8 篇论文并没有包含在这部分分析中，因为他们使用了与不同设备组相关的数据组合。每组的论文数量见表 2。

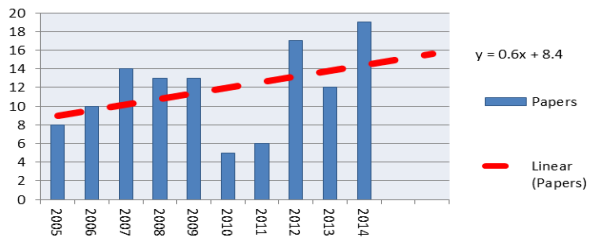

图 2. 每年发表的论文数量。

B）关于这写论文的发表时间，2014 年、2012 年和 2007 年为论文发表最多的年份（分别为 19 篇、17 篇和 14 篇）。线性趋势线显示，随着时间的增加，使用制造商和用户设施设备体验（MAUDE）数据的论文数量在增多（斜率 =0.6）（见图 2）。

C）虽然将涉及各个科学领域和主题的论文的研究目标归纳分类为几个通用的目标类别是很困难的而且可能是会有风险的，但是，为了概括使用制造商和用户设施设备体验（MAUDE）数据库数据的论文的研究方向，我们还是做了这样的尝试。

在这些论文中，最常见的研究目标是“审查 / 确认与某一设备组或类型相关的已报告的不良事件 / 并发症”（31 篇）、“评估不良事件”（22 篇）、“评估某一设备组或类型的设计特性”（15 篇）、“解释这些事件发生的原因”（14 篇）、以及“评述一项医疗技术和 / 或其性能”（10 篇）。表 3 展示了此次分析的结果。

表 3. 制造商和用户设施设备体验（MAUDE）数据使用的目的

论文的目标	论文数量	目标的例子
审查 / 确认已报告的不良事件 / 并发症	31	整理世界范围内关于泌尿外科激光手术不良反应的报告 [15]
评估不良事件 / 并发症	22	提高对耳科手术中使用显微镜可能导致耳廓烧伤的认识 [16]
检查 / 评估医疗设备的设计特性	15	我们试图确定穿孔率是否与套管设计有关 [17]
解释特定不良事件 / 并发症发生的原因	14	本研究旨在分析无张力阴道带（TVT）手术出血的问题 [18]
评述一项医疗技术和 / 或其性能	10	本研究试图确定输液器事件日志是否可以支持事故调查 [19]
评估不良事件 / 并发症的频率和 / 或严重程度	8	本研究的目的是使用大数据库评估此类并发症的频率和严重程度，并与外科房间隔缺损闭合术进行比较 [20]
评估 / 检验一种方法或假设	7	本文的目的是评估一个新的系统和程序，专门用于氧合器的更换 [21]
审查一种新技术 / 程序	7	本文将评述目前在美国市场上可以买到的胆道和胰腺取石设备 [22]
讨论监管问题	2	本分析的目的是根据每组批准的设备数量来比较 510(k) 和 PMA 的批准和召回 [23]
估算成本	1	从医院或综合卫生系统的角度估算静脉患者自控镇痛（IV PCA）错误的发生率和成本 [24]

D）同样困难的是试图审查和分类这些论文中使用制造商和用户设施设备体验(MAUDE)数据的目的。这一分析的结果与论文目标分析的结果相似。简而言之，使用制造商和用户设施设备体验（MAUDE）数据的主要原因是“总结或审查不良事件”（53 篇）以及“解释这些事件发生的原因”（42 篇）。此外，结果表明，有 36 篇论文涉及了不良事件或并发症的评估，有 32 篇论文直接提出了患者安全措施的建议。最后，要注意的是，在每一篇论文中，这些数据可以用于多种目的。本次分析的所有结果见表 4。

讨论

被发现使用了制造商和用户设施设备体验（MAUDE）数据的最终的 117 篇论文并不能被认为涵盖了各自研究活动的全部范围。如果将在本研究排

表 4. 制造商和用户设施设备体验（MAUDE）数据使用的目的

制造商和用户设施设备体验（MAUDE）数据被用来：	论文数量
总结与某一设备组或类型相关的不良事件	53
解释特定不良事件发生的原因	42
评估不良事件或并发症	36
提出患者安全措施	32
评价某一设备组或类型	30
预估不良事件的发生频率或计算趋势	30
评估一项技术或医疗程序的安全性	24
评估不良事件 / 并发症的严重程度	15

除的出版物考虑进去的话，制造商和用户设施设备体验(MAUDE)数据使用的实际范围应考虑得还要广泛，有很多这样的论文：a）参考了来自制造商和用户设施设备体验（MAUDE）数据的特例，b）使用了来自制造商和用户设施设备体验（MAUDE）数据的部分或补充数据，c）参考了其他基于制造商和用户设施设备体验 (MAUDE) 数据分析的论文。此外，还发现，制造商和用户设施设备体验（MAUDE）数据上还使用了许多其他类型的出版物，例如书籍、社论和会议论文集刊物。

论文关注的设备组主要有心脏病设备（支架类和植入式心律转复除颤仪）、植入式设备（网孔类和人工电子耳蜗）、内窥镜检查和腹腔镜检查设备。令人惊讶的是，在医院中广泛使用的高危设备组，如呼吸器、麻醉机、心电图等，并不在这个列表中。一个可能的原因是，研究人员已经将他们的注意力转移到了那些在测试期间或临近测试期间已经进入市场的设备（药物洗脱支架、机器人辅助技术、经子宫颈绝育等）上，或那些包含卷入严重召回事件的产品（支架类、封堵器、复律器、除颤仪等）的设备组上 [1]。

使用制造商和用户设施设备体验（MAUDE）数据的论文数量似乎随着时间的推移而增加，且有比率为 0.6 的时间趋势（见图 1）。考虑到美国食品和药物管理局（FDA），结合新的或改进的大数据管理和分析技术的出现，不断努力提高数据的质量和可访问性（设备唯一识别码、完全生病周期、Open FDA 公众健康项目等）[2][3][11][25][26]，预计在不久的将来制造商和用户设施设备体验（MAUDE）数据的第二阶段开发将会进一步增加。

对论文研究目标的审查清楚地表明，通过复查或总结与特定设备组或类型相关的不良事件 / 并发症 (31 篇），评估不良事件或并发症（22 篇），解释这些事件发生的原因（15 篇），评估不良事件发生的频率和严重程度（8 篇），正在审议中的大多数论文直接或间接地有助于患者安全。此外，通过评估设备的设计特性（14 篇）、概述一项医疗技术及其性能（10 篇）以及审查新技术和 / 或医疗程序（7 篇），对技术评估的贡献也很重要。这些存在问题的论文在其他领域也有贡献。例如，7 篇论文使用制造商和用户设施设备体验（MAUDE）数据来测试或评估一种方法，2 篇论文讨论了医疗设备的监管问题。

通过对这些数据在论文中使用的方式的检查进一步证实了制造商和用户设施设备体验（MAUDE）数据库对保障患者安全来说是一个有用的信息来源这一事实。结果表明，制造商和用户设施设备体验（MAUDE）数据被用来总结与设备或医疗程序相关的不良事件，解释不良事件发生的原因，并提出具体的措施。上述用途的最终目的是让医学界及医疗设备设计师和制造商了解可能会出现的问题，这些问题发生可能性，导致这些并发症的潜在机制，避免和处理

这些事件的方法以及消除其后果的措施。此外，制造商和用户设施设备体验（MAUDE）在技术评估方面似乎也是一个有用的工具，因为其数据被用来评估医疗技术和医疗设备的使用，以及评估使用某一设备或程序的风险。还值得一提的是，通过这次分析发现，有 14 篇论文使用 MAUDE 数据库作为信息来源来测试或评估一个方法、一个程序或一个假设。例如，MAUDE 数据被用来评估在紧急护理设备决策中人为因素的作用 [27]，以及检验日志文件是否有助于事故调查 [19]。

在论文的分析过程中，还收集了其他有用的信息，包括说明使用制造商和用户设施设备体验（MAUDE）数据插入的研究限制以及这些数据的质量和完整性。在许多论文中都提到了制造商和用户设施设备体验（MAUDE）数据和不良事件报告数据使用的一般情况，插入了处理报告率的某些局限性和分母问题 [28]。关于报告率，人们普遍认为，不仅不良事件被少报，而且关于反应不良事件数量与实际发生事件数量比率的信息也缺乏。同样地，缺乏可以用作分母的基线数字（例如，与产品相关的外科手术的总数、所使用的特定设备的总数等）。这两个限制使得数据不适合用来确定比率 [29][30]。

此外，有人对制造商和用户设施设备体验（MAUDE）数据的一致性和质量提出了批评。一些研究人员对它们的质量表示怀疑，认为美国食品和药物管理局（FDA）提供的数据结构不统一、不完整，其准确性存在争议，从而阻碍了分析过程。另一些人评论说，这些报告中包含的信息和详细程度是参差不齐的，就这使得对报告的解释变得困难，且使得因果关系常常不确定 [29][31]。

在 2005-2014 年期间，制造商和用户设施设备体验（MAUDE）数据既可以通过美国食品和药物管理局（FDAs）官网提供的在线搜索表单进行搜索，也可以通过将他们下载为 txt 格式文件后进行搜索。大多数的研究都使用了在线搜索表单。只有少数几个使用了以 txt 格式提供的制造商和用户设施设备体验（MAUDE）数据。这可能是因为考虑到数据量（一些表有 300 多万行）将这些 txt 文件插入关系数据库中并不是一件容易的事情，而且因为 txt 文件需要一些技术上的准备工作以便为插入做准备。openFDA 官方网站（http://open.fda.gov/）提供了更方便、更全面的数据访问功能，且随着具有当代大数据分析工具或数据挖掘技术的数据库的进一步使用，预计这将导致对制造商和用户设施设备体验（MAUDE）数据库的更大程度的开发。

最后，值得一提的是，与欧洲医疗设备数据库（European Databank on Medical Devices, EUDAMED）相比，制造商和用户设施设备体验（MAUDE）数据库的透明性带来了积极的影响。在欧盟（EU），立法修改对公告机构和国家主管当局实施了更严格、更详细的监控和执法要求，以应对日益增加的安全问题。最近，欧洲议会（European Parliament）投票通过了一项以两项法规形式实施的更为严格的新立法 [136][137]。欧洲医疗设备数据库（EUDAMED）的使用，包括召回事件，都得到了加强。该数据库包含有在欧盟（EU）市场上可获得的关于医疗设备（MDs）的监管信息。然而，关于欧盟医疗设备不良事件用户报告系统，并没有全面收集向国家主管当局提交的报告。这是由欧盟（EU）监管体系的分散化结构造成的，再加上并没有规定要求集中收集到欧洲医疗设备数据（EUDAMED）中。此外，欧盟（EU）政策不允许公众访问所有这些数据，包括召回事件，禁止独立研究人员进行分析。

一项研究比较了 2004-2015 年期间欧盟（EU）警戒系统的透明度和美国食品和药物管理局（FDA）的透明度的影响，该研究发现没有基于欧洲医疗设备数据库（EUDAMED）的论文或报告，甚至是来自于主要欧盟（EU）机构的 [138]。但是，事实上欧洲医疗设备数据库（EUDAMED）可以提供类似的信息。举个例子，根据 1995 年至 2002 年间美国食品和药物管理局（FDA）的数据，Bliznakov 等人 [139] 对医疗设备召回事件进行了调查，该调查仅涉及使用软件的设备。调查发现，大约 25% 的召回事件经过研究是由软件故障引起的。正如所料，由于软件问题而导致的这些

召回事件的比例从 1995 年的 17% 上升到了 2002 年的 34%。后续研究表明，这一比例在 2012 年上升到了 40%[140][141]。这些作者同时使用欧洲医疗设备数据库（EUDAMED）数据对软件故障导致的召回事件进行了调查，并发现了非常相似的结果。遗憾的是，由于欧洲医疗设备数据库（EUDAMED）数据的使用受到限制，导致这些结果无法发表。

结论

FDA 向公众提供部分其上市后监测数据库的访问权限，从而允许 FDA 以外的研究员可以基于原始数据进行分析和研究，由此也为公共卫生带来了附带利益。尽管有这些限制，但每年有超过 10 篇经同行评审的论文使用制造商和用户设施设备体验（MAUDE）数据，这一事实表明，制造商和用户设施设备体验（MAUDE）是一个可开发的、有价值的数据源。

根据对这些论文的分析，与其他科学领域相比，制造商和用户设施设备体验（MAUDE）数据库主要用于与患者安全和技术评估相关的研究工作。我们还注意到，制造商和用户设施设备体验（MAUDE）数据主要用于评估市场上相对较新的设备，或调查与这些设备相关的问题。此外，研究发现，当需要总结与某一设备相关的不良事件以及需要检查可能导致不良事件的原因时，制造商和用户设施设备体验（MAUDE）是一个有用的数据源。最后，制造商和用户设施设备体验（MAUDE）数据的开发随着时间的推移而增加，预计在未来将会更加的密集。

毫无疑问，有些改进可以增加对制造商和用户设施设备体验（MAUDE）数据库的开发利用。然而，尽管有局限性、有限制条件以及批评，但在研究的大多数论文中有一个共同的结论：制造商和用户设施设备体验（MAUDE）数据库是对患者安全和技术评估的一个有用的且有价值的工具。欧盟应考虑到使用制造商和用户设施设备体验（MAUDE）所带来的好处，以便朝着加强和改进警戒系统的数据收集程序的方向前进，同时也增加了法规中明确规定的欧洲医疗设备数据库（EUDAMED）的透明度：“……应大力加强警惕和市场监督，同时应引入确保医疗设备的透明度和可追溯性的规定，以改善健康和安全……该数据库的目的是提高整体的透明度，包括为公众和医疗保健卫生专业人员提供更好的信息获取途径……”[136][137]。此外，应该允许个别研究人员访问相关数据，以便能够进行对设备改进和患者安全做出重大贡献的类似研究。

利益冲突

作者声明，本篇论文的发表没有任何的利益冲突。

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做出改变——全球卫生技术成功案例：125 个国家提交的 400 多篇论文的概述

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摘要

卫生技术（HT）对全球卫生保健至关重要。医疗、康复和保健程序在提供服务方面对技术的依赖程度越来越高。因此，必须对卫生技术进行更好的管理。临床和生物医学工程师已被世界卫生组织（WHO）认可，是提供卫生技术管理至关重要的一部分。

2015 年在中国举办的第一届国际临床工程与卫生技术管理大会（ICEHTMC）上，多个国家的参会者通过了一项关于全球临床工程（CE）的决议，以识别和推广临床工程的独特资质，并记录临床工程对改善世界卫生状况的贡献。回顾已发表的论文和提交的案例研究的结果，得出了第一批临床工程案例。共收集了来自 90 个国家 / 地区的 150 篇文章，时间跨度涵盖了过去十年。其结果在 2016 年世界卫生组织举办的世界卫生大会（World Health Assembly,WHA）上提交给了相关卫生领导人。去年，增加了来自 125 个国家在 2016-2017 年期间的 250 个案例研究。本文介绍了在检阅这些案例的过程中所确定的证据、来源以及它们所代表的 6 种类别。

【关键词】医疗保健，临床工程，技术管理，安全性，功效，结果，创新，成功故事。

引言

卫生技术（HT）对健康至关重要，因此，医疗，康复和保健对卫生技术的依赖度越来越高。因此，合格和训练有素的专业人员，通过最佳和安全的方式进行管理，以更好地应对疾病和资源的负担显得更加重要。经过培训的临床工程师在学术上已有充足的准备，负责卫生技术生命周期的管理，专注于安全有效技术和成果的可用性和可靠性，在医疗团队中扮演着至关重要的角色。

在过去的 50 多年里，临床工程（CE）专业人员对在政府机构和关键利益相关者间仍缺乏了解的现状表示担忧，另外他们对安全和有效地创建和部署卫生技术的巨大贡献仍未得到广泛的认可。为改善这个现状，该项目应运而生。这也将有助于吸引更多的学生

IFMBE-CED 是国际医学与生物工程联合会（IFMBE）- 临床工程部（CED），目前代表 165 个国家的临床工程师（就职于医院的生物医学工程师）。更多关于 CED 的信息，您可以登录官网 cedglobal.org/organization-and-teams/ 查看。

和未来的从业者加入临床工程这一重要行业中。临床工程的实践对医疗、康复和保健是否重要？他们的贡献是否得到认可？本文分享了在对已发表的证据进行三年审查后所使用的方法和相关发现。

继 2015 年在杭州召开国际临床工程与卫生技术管理大会上举行的全球临床工程峰会上，确定了某些地区面临的问题是否也是在全球其他国家面临共性问题，归纳总结了各国面临的共同挑战，以及优先处理这些关键问题所需采取的全球战略。通过对全球临床工程峰会中总结的问题进行排序后，与会成员投票认为存在两个主要问题：（1）缺乏对临床工程对改善医疗保健服务贡献的认识和认可，（2）对于想要进入该领域的人员和正在从事这一领域工作的人员缺乏足够的教育和培训。为了解决这些问题，一系列行动方案制定完成。2017 年在巴西圣保罗举行的第二届全球临床工程峰会上，与会人员讨论并总结了问题解决的进度和结果，并整理更新完成需要继续解决的问题和挑战。所提出的行动计划侧重于数据收集，以确定临床工程的贡献是否符合改善世界健康的标准和目标，以及这些贡献是否可以通过循证记录加以证实。

研究方法

基本原理

由 IFMBE / CED（国际医学与生物工程联合会 - 临床工程部）的资深认证临床工程师组成的工作组在全球范围内呼吁提供证据支持临床工程对改善医疗服务或患者结果的贡献的案例研究。此外，2016 年进行了文献调查，从文献和提交的案例两个来源中，对来自 90 个国家的 150 份反馈进行了审查，并能作为相关的证据（请参阅 http://global.ice htmc.com/publication/healthteachnology）。

再将结果进行评分并分类（创新，卫生系统，卫生技术管理，安全与质量，以及电子技术），并纳入提交给世界卫生组织 WHA 的文件（http://global.icehtmc.com/publication/globalsuccess）。

随着收集到越来越多提交的论文和出版物，随着 2017 年继续扩大范围，通过增加 IFMBE 主办的活动中使用发布的相关数据等，又额外收集到了来自超过 35 个国家 / 地区的 250 个故事。在 2 年的时间里，我们一共收集到来自 125 个国家 / 地区的 400 多篇案例。这些临床工程的成功案例指出了从卫生技术中获益的改善结果，并展示了为实现最佳和安全的临床相关工作时所需要的进行有效管理的集成系统等。临床结果包括人们生活质量的变化，护理管理决策支持，实现无时无刻、365×24×7 的准备状态以及提高操作效率。

定义

在本研究中，我们将收集的数据分为 6 类，定义如下：

- **创新** (Innovation)

通过提供新的卫生技术（HT）解决方案，改善现有的解决方案或组合的使用来解决多个问题。

- **增加获取途径** (Improved Access)

在地点、时间和便利性等方面，更容易获得与卫生技术有关的医疗服务或设施。

- **卫生系统** (Health Systems)

在国家或政策层面更有效和高效地部署卫生技术，产生积极影响。

- **安全与质量** (Safety & Quality)

通过卫生技术人力资源开发，卫生技术对健康服务安全或质量结果的积极影响。

- **医疗技术管理**（HTM）

建立或改善医疗技术管理（HTM）方法，从而改善人口健康状况。

- **电子技术** (E-Technology)

由于部署了基于因特网的卫生技术工具而进行的改善。

措施

在 2015 年的首届全球临床工程峰会期间，人们提出了一个问题，即能否确定成功进行卫生技术的创新，管理，获取途径，电子技术应用，安全性和质量等成果的证据。为此，项目（或提案）是否成功被定义为是否满足制定的至少 2 个客观指标。这些指标包

括及时性、成本节约、护理提供者的部署或采用、对服务的影响以及对成功的总体预测。每个指标使用 3 分制来评估，并对代表代表成功的陈述进行评估（1= 强烈不同意；3= 强烈同意）。

- 及时性是指项目 / 提案是否及时实施。这就是所谓的“提案将影响当前的结果”这句话。
- 成本指标是指成本是否在预算限制范围内以及对该区域的条件是否合理来进行评估。这是通过“该地区能够满足成本目标”的声明进行评估的。
- 接下来的两个指标被合并到“提案将由它的目标用户部署”和“提案将对采纳它的人产生积极的影响”这样的声明中。
- 最后，通过陈述“全面考虑，提案将是成功的”来评估整体提案的成功预期。

创新是技术生命周期的开始，在这个生命周期中，新的想法为医疗保健提供者或他们的患者所面临的当前问题提供解决方案。临床工程师可以很好地理解当前的问题，并提供不同或新的解决方案。在我们的分类中，创新意味着从团队的概念和原型设计，到继续进行临床试验，以及证明符合标准，法规和预期结果的过程，展示团队合作的方法来解决问题。与安全与质量类、电子技术类和 HTM 一样，服务获取的改善紧随创新阶段。产品和应用程序得以成功应用的情况将被评为高级，并被列入循证类别总计数。

结论

这 6 类数据的摘要如下。它们来自 CED 提交给世界卫生大会的 2016 年卫生技术资源 (Health Technologies Resources) 文件 [1]，世卫组织于 2017 年 5 月第三届全球医疗器械论坛 [2]；(3) 2017 年 9 月圣保罗举办的第二届 ICEHTMC 大会 [3]（S），和其他 2016-2017 IFMBE 发布的资源（O）[4]：

一份新的调查结果汇总文件 (以下附链接) 表明，6 个类别已在世界各地有所受益。总的来说，这项审查从 125 个国家的 400 个案例研究中找到了证据，并在过去 12 年中，对这些国家医疗设备的管理 (卫生技术的主要组成部分) 产生了积极的影响。

2007 年世卫组织世界卫生大会第 60.29 号决议（https://www.who.int/medical_devices/resolution_wha60_29-en1.pdf）敦促会员国与生物医学工程师合作制定国家卫生技术管理计划。世卫组织在 2017-2018 年全球调查中与 IFMBE CED（国际医学与生物工程联合会 - 临床工程分会）协作，进一步明确了对这一职业的定义 [5]（http://www.who.int/medical_devices/support / en /）。

“设计，评估，控制，维护和管理医疗设备，并对其在全球卫生系统中的安全使用进行培训，这些都需要训练有素且合格的生物医学工程专业人士”[5]。这个职业在不同国家 / 地区有不同的名称，例如临床工程师，医学工程师，……以及相关专业人员和技术人员。【WHO 和 IFMBE CED 的调查显示，2018 年全球有超过 80 万的专业人士。】

案例研究分为 6 类，旨在制定国家战略和计划，以改善卫生技术的使用并更好地控制成本。在一些国家，实现这一目标的最好办法是在卫生部一级建立一个临床工程师领导的卫生技术部门。研究提供了明确的证据，证明卫生技术是有益的；有时，需要通过对复杂的系统进行有效指导和管理，以实现最佳效果。

- 创新
- 获取途径
- 管理
- 卫生系统
- 电子技术
- 质量与安全

案例研究实际上是“卫生技术成功案例”，在有限的资源环境中，在国家决策中纳入诸如临床工程师等专业卫生技术专长是可取的，可以最大限度地扩大卫生系统的服务。以下各页链接的案例研究说明了这些益处：

- **获取途径：**在阿尔巴尼亚卫生部领导的项目，将关键诊断服务所需的获取途径增加了一倍，如计

算机断层扫描、磁共振和血管造影成像，同时将设备停机时间减少到零，并显着降低了成本。

- **卫生系统：**在卫生部和临床工程师的领导下，工程师与来自学术界和工业界的专家合作，使得国家实验室各利益攸关方的协调得到改善。
- **质量与安全：**由临床工程师领导的上海地区覆盖 122 所医院的计划，通过与政府，行业和学术机构的合作，提高了设备用户的满意度，跟进新兴技术，并与行业建立了更紧密的合作伙伴关系。

结论

卫生技术（HT）对于健康至关重要，健康、康复和保健计划对卫生技术的依赖性越来越强。除了持续的人口增长、政治和经济不稳定、疾病管理、灾害、难民危机、事故和恐怖袭击等产生的卫生保健的负担外，世界卫生保健技术系统还面临着创新和最佳管理方面的挑战。21 世纪实现针对健康方面的规划需要经过培训的合格的临床工程专业人士。如果提供适当的工具，疾病预防、治疗和康复就会更有效率和效力。IFMBE CED 与 WHO 认识并强调使用适当、集成和安全的卫生技术对于每个医疗保健系统的成功结果非常重要。在为世界卫生大会（WHA）编写的 2016 年 5 月的卫生技术资源文件中，提出了一项建议：卫生技术必须进行有效管理以确保充分发挥临床作用，并得到预期的投资回报。

因此，非常重要的一点是，在资源有限的情况下，必须对卫生技术进行专业管理，并在其整个生命周期中对其部署进行适当指导。本文描述了通过对已发表的数据进行广泛研究，表明临床工程师们的贡献对患者的治疗效果产生了积极的影响。这项研究表明，世界上每个地区，包括资源匮乏的地区，都面临着改善卫生服务的挑战，同时也面临着基础设施和人力资源能力水平的挑战。临床工程师在卫生技术生命周期管理的所有阶段都发挥着至关重要的作用。从创建到规划，从调试到利用和集成，以技术为基础的系统必须而且能够得到最佳性能的管理。在每个技术生命周期阶段，对经过培训和胜任的临床工程师的需求都会产生关键性差异，这一点在本文所进行的分析证据中已经表明。我们希望，政府机构和其他相关方能够更好地理解临床工程师的作用，从而支持他们加入到专业医疗团队中。

建议

我们希望能在您所在国家卫生体系中，去鼓励有更多的临床工程师积极参与并得到更多认可 [2]。

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- WHO HQ: http://www.who.int/medical_devices/en/
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- WHO Digital Health: http://www.who.int/medical_devices/global_forum/Thedigitalhealthaltas.pdf
- WHO Assistive Devices-GATE: https://mednet-communities.net/gate/
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- WHO NCD Kit Refugees: http://www.who.int/medical_devices/global_forum/NCDkitrefugees.pdf

- IFMBE, CED, HTA: http://ifmbe.org/, http://cedglobal.org/ http://htad.ifmbe.org/
- PATH: https://www.path.org/ (Belgium, China, DRC, Ethiopia, Ghana, India, Kenya, Malawi, Mozambique, Myanmar, Peru, Senegal, RSA, Switzerland, Tanzania, Uganda, Ukraine, Vietnam, Zambia)
- AWHP: www.ahwp.info; Asian Harmonization Working Party - 30 countries, 3/17 Regulatory Authorities
- HTAi: https://www.htai.org/

RESOURCES REVIEWED

Focus Area	***Title,*** authors, with active links
Afghanistan, Iraq, Libya, Occupied Palestinian Territory, Somalia, Sudan, Syria, and Yemen	***Medical Devices for Emergency Kits (NCD Kit)***, Laura Alejandra Velez, Slim Slama
Australia	***Phototherapy to Reduce Exchange Transfusions,*** Luciano Moccia, Gaston Arnolda, Daniele Trevisanuto
Australia	***FREO2 oxygen solutions: the Low-Pressure Oxygen Storage system and FREO2 Siphon,*** Roger Rassool, Jim Black
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Bangladesh	***Health Technology enhancing rural Primary Care and eHealth***, Ahmed Raihan Abir
Brazil	***Dynamical Orthostatic Chair Development of a new method of lifting and locomotion for physically disabled people***, Walef Robert Ivo Carvalho
Brazil	***A multiband reflectance photometric device for reveal gestational age at birth***, Rodney Guimaraes, Zilma Reis
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Brazil	***Digital Storage and System Management for Video surgery Records in a Network Platform***, Benedito Fernandes De Lima et al
Brazil	***Early stage strategic effectiveness evaluation of high flow nasal therapy (OPTIFLOW®) in the treatment of Acute Pediatric Respiratory Failure***, Graziela de Araujo Costa et al
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Brazil	***Remote Equipment Monitoring System***, A. Ricardo Maranho
Brazil	***Model fitting and simulation of the respiratory control system under incremental exercise and altitude in healthy subjects***, C. A. Sarmiento, A. M. Hernández, L. Y. Serna
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Peru	***Heavy-Metals Point of Care Detection HT to improve care***, Herb Voigt, Fred Hosea
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Argentina	***HT improving Provincial Access***, 2015, German Giles
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Romania	***Telemonitoring Systems and Technologies for Independent Life of Elderly***, S. B. Sebesi
Slovakia	***Telemedicine and mHealth System for Complex Management in T1DM and T2DM Patients: Results of 6 Months Study***, Fedor Lehocki, Tomas Bacigal
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Benin, Burkina Faso, Burundi, Cameroon, DRC, Ethiopia, the Gambia, Ghana, Ivory Coast, Kenya, Nigeria, South Africa, Tanzania, Uganda, Zambia	***THET NGO & South Africa enhancing 15 African HTM societies***, Anna Worm & Mladen Poluta
Australia	***In-house Endoscopy support, 2016,*** Anne-Louise Smith
Bangladesh	***Clinical Engineering Approach to Improve Healthcare Technology Management for Enhancing Healthcare Delivery System in Middle Income Countries,*** A. Hossain et al
Benin	***Evaluation of medical devices in Benin,*** Charles Pascal Soroheye, Adjaratou Seidou Maliki, Marc Myszkowski
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Botswana	***Using HTM to improve care delivery***, Bonnie Tlhomelang
Brazil	***Impact of clinical engineering in primary healthcare***, Priscila Avelar, Renato Garcia, Carlos Alberto Silva
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Costa Rica	***HTM in Costa Rica,*** G Murillo, M. Ingeana, (***part2***)
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Ethiopia	***Managing Successful Medical Device Warranty Period Maintenance,*** Demeru Yeshitla Desta, Tegbar Yigzaw Sendeke, Sharon Kibwana, Mihereteab Teshome Tebeje
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Spain, France	***Integrating an EHR Graphical User Interface into Nanoelectronic-Based Biosensor Technology,*** Ana Maria Quintero et al
Uruguay	***CAMACUA: Low Cost Real Time Risk Alert and Location System for Healthcare Environments,*** I. Decia et al
USA	***Assessing Risk in the Kaiser Permanente CE Program,*** C Davis-Smith, F Painter, M Baretich
USA	***Medical Device Cybersecurity,*** Steve Grimes, HIMSS 2016

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USA	***Biomedical Device Integration into an Electronic Health Record,*** Michael Fraai
Venezuela, Ecuador	***Intelligent System for Identification of patients in Healthcare,*** Ricardo Silva, (***part2***)

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Australia	***Medical Air Mis-connections,*** Anne-Louise Smith, Mark McEwen, 2016
Brazil	***An observational study of the high incidence of false and nuisance alarms in an intensive care unit,*** LG Vaz, GC Vivas
Brazil	***Evaluation of waste disposal inadequate management from health services,*** Larissa Teixeira de Oliveira, Ana Claudia Patrocínio
Brazil	***Improving Health Technology Assessment in Cold Chain by Applying Clinical and Industrial Engineering,*** LFM Brito et al
Brazil	***Improving Operational Reliability in Medical Washer Disinfector with the Use of FMEA Tool: A Quality Improvement Report,*** Marcelo Espinheira et al
Brazil	***Medical devices proactive surveillance – trends and impact from field and enforcement actions in Brazil,*** MG Vincente
Brazil	***Structuring the Radiological Report,*** D.M. Rocha et al
Brazil	***Development of an ubiquitous management platform in air compressors used in primary healthcare,*** I.L. Santos, F.S. Rosa, R. Garcia
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Brazil	***Clinical Engineering/Health Technology regulation, evaluation & training to improve care delivery,*** Murilo Conto, Zeev Katz, (***part2***)
China	***A Hospital-based Dynamic Warning System Medical Consumables Regarding Adverse Event Management,*** Sun-Lv-Feng
China	***Case Study and Management Improvement of Medical Devices,*** Jing-ying Gao, Lei Wei, Yin-chun Lu
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Dominican Republic	***Medical – Surgical Vacuum and Anesthetic Residue Extraction Policy in the Dominican Republic,*** Diogenes Hernandez
Germany	***Technological Surveillance and Integrity Monitoring of Infusion Systems,*** D. Grosse-Wentrup, U. M. Hoelscher
Global	***A pneumonia prevention system,*** Peter Young; Maryanne Mariyaselam
Global	***Global Professional Credentialing Project,*** Yadin David, Mario Medvedec, Jim Wear
Global	***Adoption of medical-technologies in infrastructure-poor environments,*** Gisela Abbam, Vikram Damodaran, Sally Lee
Global	***Hospital Integrated Networks Risk Management - Issues and Recommendations,*** Yadin David, (***part2***)
Global	***Skill development for growth in emerging markets,*** Gisela Abbam, Marut Setia

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Global	***Clinical Engineering Risk Management,*** Frank Painter
Global	***CE Certification globally to improve care delivery,*** Jim Wear, Mario Medvedec
Global	***Human Factors Engineering book - global resource,*** Tony Easty et al
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Global	***Promoting the Image of Biomedical Engineers and Improving Safety,*** Michael Cheng
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Italy	***A new digital era of Clinical and Biomedical process,*** Giulia and Stefano Marchesi
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Taiwan	***Actions of medical device post-market surveillance,*** KP Lin, Y-T Hung, Shiu- Huei Yeh

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USA	***Application of Quality, Risk & Asset Management Principles to Clinical Engineering,*** Binseng Wang, (***part2***)
Cape Verde, Senegal, The Gambia, Guinea Bissau, Guinea, Sierra Leone, Liberia, Mali, Ivory Coast, Ghana, Togo, Benin, Burkina Faso, Nigeria, Niger	***The West African Health Organization, Biomedical Engineering Curriculum,*** Bobo-Dioulasso et al, (***part2***)