

## 美国临床药学的发展与实践

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**摘要** 目的: 介绍美国临床药学的发展史及其实践领域的拓展。方法: 简要总结20世纪美国临床药学发展史及其临床实践领域从住院部拓展到门诊, 并描述临床药师的主要职责。结果与结论: 美国临床药学的重心已从用药和药物调剂向“以患者为中心”、以提高用药安全和有效为目标的临床实践上倾斜。20世纪初, 在大多数医院尚无雇佣药师时, 一些药师中的有识之士就已开始参加患者监护查房。此后, 出现了更多开创性临床实践模式, 昭示着药学职业的巨大潜力。这一系列改变也催生了药学博士项目发展, 将药师更好地培养为临床人员, 运用其药学专长优化患者监护。虽然临床药学的进步并非一蹴而就一帆风顺, 但经过药师和专业组织的努力, 临床药学发展方向发生转变, 药师已成为多学科团队中不可或缺的一员。

**关键词** 美国; 临床药学; 医院药学; 门诊监护

### Development and Practice of Clinical Pharmacy in the United States

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**ABSTRACT** **OBJECTIVE:** To introduce the development of clinical pharmacy in the United States, and to develop practice field. **METHODS:** Some highlights of the history of clinical pharmacy practice over the past century were summarized briefly, and clinical pharmacy practice expanded from inpatient department to outpatient department; some typical responsibilities of clinical pharmacists in the United States were described. **RESULTS&CONCLUSIONS:** The practice of clinical pharmacy has evolved from a focus on medication and product delivery to “a patient centered”, with the goal of improving the safe and effective use of medications. Beginning in the early 1900s, during a time when most hospitals did not employ a pharmacist, forward-thinking pharmacists first participated in patient care rounds. This was followed by the other innovative clinical practice models, which demonstrated the potential of the pharmacy profession. These changes led to the development of the Doctor of Pharmacy degree program to better train pharmacists to be clinicians, using their expertise of pharmacy to optimize patient care. This evolution did not occur quickly or without challenge, but through the effort of pharmacists and professional organizations to change the direction of pharmacy practice, pharmacists are now recognized as an essential component of a multidisciplinary care team.

**KEYWORDS** USA; Clinical pharmacy; Hospital pharmacy; Outpatient care

20世纪初, 临床药学在美国是一项以药品为中心的专业(Product-centric profession), 其主要任务是有偿供应药品。之后, 临床药学开始逐渐发展为更多地以患者为中心的监护。通过参与临床监护决策, 患者成为了药师工作的核心<sup>[1]</sup>。工作中心的转变凸显出药师在医疗护理团队中的角色转变, 药师也因其专长而逐渐被认可。美国临床药学会(The American College of Clinical Pharmacy, ACCP)将临床药理学定

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义为以药物合理使用的科学与实践为中心的药学领域<sup>[2]</sup>。若我们延伸这一定义, 可以认为临床药师是经过执业资格认证, 为患者提供监护服务以提高药物治疗效果, 保障卫生、健康和疾病预防的专业人员。

临床药师最初在医院住院部门工作。实践证实, 临床药师服务可减少用药错误, 提高医疗机构的患者监护水平<sup>[1]</sup>。公众对临床药师与日俱增的敬意促使药学领导者扩展临床药学的实践领域, 将药师整合到美国不断发展的卫生保健系统中。在这一背景下, 美国医疗体系的关注重点转移到加强门诊患者的监护上来, 其目标是通过预防保健和改善慢性疾病

的管理,提高民众的健康状况,并最终通过预防初次和复发性住院以降低医疗成本<sup>[3]</sup>。

本文介绍美国临床药学的发展史及其临床实践领域从住院部拓展至门诊,并描述临床药师的主要职责。

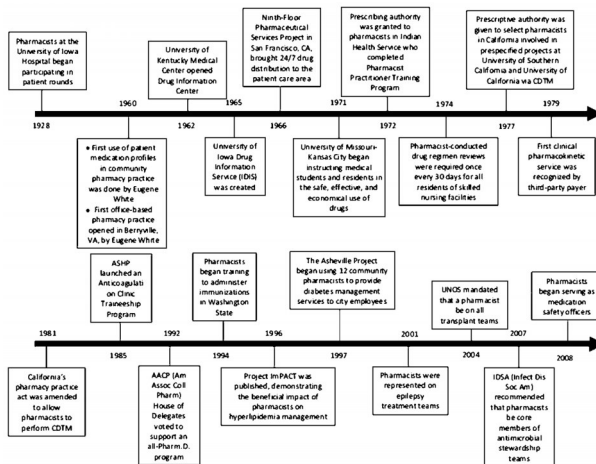
## 1 美国临床药学的发展

如今在美国,临床药学提供的以患者为中心的监护已拓展至所有的医疗机构,包括医院、诊所,以及近来的社区药房<sup>[2,4]</sup>。与之相反,在20世纪中叶仅不到40%医院聘用了药师,因此,药师更多地是在社区药房工作<sup>[4]</sup>。社区药房当时的主要工作是销售处方药和非处方药。在此背景下,公众认为药学是药品交易的行当,而不是提供医疗服务的职业<sup>[4]</sup>。那时药学教育体系尚未很好地建立,药师也未扮演临床监护的角色。

20世纪早期已有药学院成立,但成为一名执业药师并不需要毕业于药学院。这一时期不仅罕有从药学院毕业的学生,药学院的入学资历要求也极其混乱。1913年仅有50%的药学院要求学生在入校前至少完成1年高中学习<sup>[4]</sup>。目前,药师要成为一名有执照的从业者,必须要满足一定要求。进入药学院前,学生必须完成大学水平的特定预备科目,并通过药学院入学考试(the Pharmacy College Admission Test, PCAT),这是一个测试受试者学术能力的测验,以甄选有资格完成药学教育的申请者。一旦申请人被药学院录取,必须在3年的时间内学习包括药理学、药物化学、药物治疗学、药动学等各个方面的药学知识。3年学习后,学生需完成最后1年的体验式药学培训(Experiential pharmacy training),包括在各种药学机构的实践,如医院、社区药房、药品咨询处和门诊。这些课程和实践教育为学生建立了药物的科学和临床应用的基础。完成4年的学习计划后,学生就能被授予临床药学博士学位(Pharm. D.),再经过国家考试即成为一名执业药师(Licensed pharmacist)。更详细的有关美国药师教育的介绍可参考由Olsen教授等人所著的《美国临床药学教育与培训》一文(待发表于《中国药房》杂志)。

1928年,药师最早开始通过参与多学科查房,在住院部门作为临床人员工作<sup>[4]</sup>。早期的临床药学工作重点是普及药师在住院患者中的作用,20世纪后期,临床药学进入了更专业化的时代,如1979年以抗菌药物为主的药动学给药服务,以帮助医师优化药物剂量并首次被第三方保险商认可。药师早期参与的另一个领域是抗凝监测和法林给药服务,多家医院建立了药师运行抗凝服务的模式。20世纪80年代,美国卫生系统药师协会(the American Society of Health-System Pharmacists, ASHP)针对抗凝服务制定了正式的临床培训项目。本世纪初,人们对药师专业服务的重要作用有了更多认识,例如美国器官共享网络(the United Network for Organ Sharing, UNOS)和美国传染病协会(the Infectious Diseases Society of America, IDSA)规定,药师应当是所有移植小组和抗菌药物管理项目的活跃成员。图1展现了20世纪在临床药学发展过程中所发生的里程碑事件<sup>[4]</sup>。

如今,临床药师凭借药物知识上的专业广度和经过培训的独特技能,在医疗机构得到了广泛认可。临床药师除了提供客观、循证的治疗信息以取得针对性的个体化治疗效果外,也要保障药物使用安全、适当和具有成本效益。ACCP声明,临床药师有责任和义务达成上述这些治疗目标;为了实现这一要求,临床药师不应仅仅被当作医疗团队的顾问<sup>[2]</sup>。因此,临床药师目前已是医疗团队与患者直接互动的一部分,与多



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图1 临床药学发展时间线<sup>[4]</sup>

### Fig 1 The Clinical Pharmacy innovation timeline

AACP=美国药学院协会(American Association of Colleges of Pharmacy); CDTM=合作药物治疗管理(Collaborative Drug Therapy Management)

学科临床团队的整合使其能直接地去防止药物治疗中的错误。医疗护理决策者也期望临床药师能够引导药物的合理、适当使用。

## 2 临床药师在住院部的角色

临床药师与医师、患者和其他医疗服务提供者共同合作,保证最合理用药。完成临床药学博士学位学习后,很多医院药师还会完成毕业后1年(Postgraduate year one, PGY1)或毕业后2年(Postgraduate year two, PGY2)住院培训项目。涉及的专业领域包括门诊监护、心脏病、重症监护、药物信息、急诊医学、老年医学、人类免疫缺陷病毒(HIV)、传染病、内科学、护理管理、肾脏、神经内科、儿科、营养、肿瘤、药物基因组学、实体器官移植以及其他专业<sup>[5]</sup>。

临床药师的职责主要包括4个部分:判定和评估药物治疗、制定和应用监护方案、持续评价和用药监测<sup>[6]</sup>。无论实践机构如何,所有的患者监护工作都至少包含这些职责中的一个。通常,药师与一个多学科的团队共同参与患者的监护查房,保证每天为患者提供药物治疗的应用管理<sup>[7]</sup>。在查房前和查房期间,临床药师需要评价包括患者的病史、诊断、过敏反应、肾功能以及其他所有的实验室检查结果,评估所有药物治疗的合适剂量、频率、持续时间和不必要使用等情况。此外,要监测药物有效性、药物相互作用、药物与食物相互作用和不良反应/事件,以及负责不良事件的预防和管理<sup>[7]</sup>。当处方中有治疗窗狭窄的药物时,开展治疗药物监测工作也是药师的职责。治疗药物监测需要药动学和药效学知识,来达到药物治疗个体化<sup>[8]</sup>。这些工作都应在药物治疗之前或同时进行,从而使药师能在查房或开药的时候提供干预或者临床建议。鉴于药师在药学领域的专长,医师会接受药师提出的很多干预措施,但不是所有的建议都会被接受,采纳与否基于团队讨论和临床医师的判断<sup>[9]</sup>。药师也会与临床营养师一同工作,根据患者的体质量、实验室检查以及医疗条件,评估全静脉营养的医嘱,优化营养方案。此外,经过高级生命支持(Advanced cardiac life support, ACLS)认证的药师也能够对心脏骤停的情况做出应对<sup>[10]</sup>。

目前,急救机构药师承担了大量用药重整(Medication reconciliation)工作,即药师在患者入院或出院护理过渡时,确认用药历史和当前药物清单的准确性。这一责任之所以转移到药师,是因为研究发现,入院、转院、出院以及再次入院的药品清单差异,会产生不完整、过时或不准确的用药史,从而导致大量错误用药<sup>[10]</sup>。用药重整目前已有固定程序:药师或药学技术人员获得患者的药物清单,记录入院前的药物并审查患者信息;随后,药师询问患者或家属以获取患者的药物过敏清单,除了当前的处方药,还包括草药制品和非处方药;询问患者在门诊药房取药的情况,核实患者了解的药物信息;最后,药师比较所有的清单,进行用药重整,注明所有差异和已证实的药物相关问题,在医疗记录中记录最终的药物清单<sup>[10]</sup>。

教育责任是临床药师工作的另一个重要方面。药师需要应对来自医疗、护理和药学人员的药物信息问题,提供最新的基本参考信息或基于这些问题的临床课题的批判性分析。药师也会指导医师最佳用药以改善患者监护。此外,还有对药理学学生的培训,包括入门或高级药理学实践轮转(Introductory or advanced pharmacy practice experience rotations),以及临床药师住院培训(PGY1或PGY2)。学员在临床药师的指导下,观摩临床查房,进行专题讨论、案例展示,临床药师也鼓励其尽可能地独立工作,以使其在完成训练时能成为独立的从业者。药师的教育对象不仅仅局限于卫生专业人员,某些专业领域的药师会在患者出院前为患者和家属提供教育,以改善其对药物和自身健康状况的认识。

临床药师必须履行部门职责,除了参与质量保证项目加强药理学监护服务外,还包括制定、实施、维护部门政策和药物安全有效使用的相关程序。临床药师也积极参与如药物与治疗学委员会(the Pharmacy and Therapeutics Committee, PTC)等医院委员会,制定医院药物处方,或通过适当用药减少药物花费<sup>[10]</sup>。许多机构还要求临床药师在其专业领域开展及发表相应研究。临床药师的几个常见研究领域包括药动学和药效学、患者预后和实践科学(Implementation science)。

住院部门工作能让临床药师受益匪浅。在这些地方,临床药师往往处于一个丰富直接的实践环境,包括患者监护、教学、部门任职和研究。临床药师能够与所有类型的医疗服务提供者互动,发展长期关系和建立跨专业的信任,使其不论在医院还是患者出院后都能积极地服务患者。

### 3 临床药师的角色拓展至门诊

预计在未来,美国的门诊处方药数量将会上升,相应的需要药师干预的治疗相关问题的发生频率也会增高<sup>[11]</sup>。2012年,公共卫生信息学研究所指出因用药不当和不必要而浪费的费用达2 000亿美元<sup>[12]</sup>。不必要的医疗费用支出的来源有6个:药物治疗依从性不足、不及时开展循证治疗实践、抗生素滥用、用药错误、仿制药应用欠佳、多药治疗管理不当。这些问题的改善,本质上应该通过长期的患者监护实现,而不仅是在住院期间。门诊是一个提供持续健康监护的地方,包括预防性治疗和慢性疾病的长期治疗。在门诊机构加强临床监护能减少住院机会,全面改善社区健康。

门诊临床药师在初级护理机构和专科诊所都能开展工作。疾病治疗领域包括慢性疾病,如心脏衰竭、慢性肾脏病、哮喘、慢性阻塞性肺疾病(COPD)、疼痛、抑郁症、酒精戒断、抗凝和传染性疾病(包括HIV、丙型肝炎病毒和肺结核)。此外,门诊临床药师治疗管理的急性情况包括复杂的尿路和流感感

染、疼痛管理和癫痫发作,以及慢性疾病如COPD、加重哮喘、心脏衰竭。2008年,ACCP、美国药师协会(American Pharmacists Association, APA)和ASHP的领导者强调了药师在门诊机构为患者提供慢性健康状况监护的重要性,因为这些疾病的医疗费用占到美国每年医疗保健支出的75%<sup>[3]</sup>。

### 4 临床药师在门诊的角色

门诊临床药师通常在一个门诊办公室里工作,直接监护患者,与医疗人员共同工作和管理用药。药师也可在公共机构或社区诊所工作,但工作内容通常不包含配药。这种实践地点使药师能够与所有医疗服务提供者合作,与患者发展长期关系,更易与患者接触。与住院部相似,临床药师在门诊的作用也分为4个主要组成部分:判定和评估药物治疗、制定和应用监护方案、随访评价和药物监测<sup>[6]</sup>。

门诊临床药师的一个重要职责是提供预防性医疗服务<sup>[3]</sup>。其中一个例子是提高美国民众的免疫率以降低可预防传染病的感染率<sup>[13]</sup>。在大多数的临床机构中,门诊临床药师常常要加强相关筛选及管理疫苗接种的专业知识和培训,因为药师目前管理了超过50%美国公众的流感疫苗接种。门诊临床药师的另一项临床预防干预是戒烟计划,目前有约5 000万的美国成年人吸烟,这导致了急性和慢性疾病的发生<sup>[3]</sup>。

门诊临床药师另一方面的职责是提供药物治疗管理(Medication therapy management, MTM)<sup>[3]</sup>。MTM系指药师提供的医疗服务,旨在优化药物治疗和提高患者的治疗效果。MTM涵盖广泛的药师临床服务,包括患者评估、综合用药审查、药物治疗安全性和效果的监测,以及通过教育提高用药依从性。药师和医疗人员之间MTM服务的记录与沟通对确保患者护理的连续性至关重要。研究表明,门诊临床药师提供的MTM能提高医疗服务协调性,减少药物相关问题并降低发病率和死亡率。在一项研究中,研究者对比了接受药师MTM服务的患者和那些类似的但未接受MTM服务的患者,发现接受MTM的患者的胆固醇水平和血压有大幅改善。此外,接受MTM的患者的医疗费用有显著降低<sup>[14]</sup>。

下面用一个例子来说明门诊临床药师如何在门诊机构中提供MTM服务。每天,药师会整理每个预约当天就诊患者的用药史。药师会审查用药史中的依从性、药物相互作用或其他药物治疗问题。患者到达诊所后,药师会在医师接待患者前负责完成用药史或用药重整。对于新就诊患者,药师会完成一份用药史以确定当前所有药物以及患者对这些药物的依从性、用药行为和过敏情况<sup>[6]</sup>。对复诊患者,药师会评估药物的有效性、安全性、适用性和依从性。若患者最近住过院,药师会比较出院用药清单与门诊用药清单的差异。此外,药师也会为了监测药物疗效或副作用而安排实验室检查。如果确定了药物治疗问题,药师会为医师提供建议,以在患者就诊期间解决问题。药师会在患者就诊后,呈现给患者一份关于其当前药物、药物剂量和给药频率的准确清单。

就诊后,患者往往需要拜访临床药师。其目的是解决门诊过程中发现的药物治疗问题,进行用药或疾病状况的教育,提供治疗和监测服务等。在此期间,临床药师会对患者进行有关药物治疗选择、新疗法的治疗目的、药物的管理、依从性的重要性以及可能的副作用的教育。此外,为评估药物的疗效和安全性,药师可以安排或实施其他实验室检查。患者与药师交流的时间为10~90 min不等,所有的交流和建议必须在拜访完药师后,记载到患者的医疗记录中。许多诊所由药

师进行电话随访,这是提供持续的依从性支持、药物治疗监测或提供实验室检查结果的手段。

群组管理(Group visits)是门诊开始采用的一种新颖的患者护理方式。群组管理的目标是确保在相同的就诊中能解决患者治疗的所有问题。群组管理由一个医疗团队,带领一组有相同慢性病状态的患者,在其共享的预约医疗时间完成。会面通常包括一名医疗助理、护士、药师、临床治疗师(Clinical therapists)和医师。在看病期间,患者会与各个医疗服务提供者见面讨论自己护理的方方面面。群组管理通常以集体教育会议结束,以更好地帮助患者了解其目前的疾病状况和如何更恰当地管理治疗<sup>[10]</sup>。

临床药师的另一个新兴作用是应用药物基因检测进行个体化药物治疗<sup>[15]</sup>。每4个处方药中就有1个的代谢途径受遗传药理学多态性的影响,这些多态性会增加或减少药物暴露,可能会影响药物的疗效或安全。此外,一些遗传药理学试验可预测药品不良反应发生的可能性。例如,1种阿巴卡韦过敏反应的发生与HLA \* B-5701 等位基因的表达密切相关<sup>[16]</sup>。目前,很少有基层保健医师会根据药品包装中说明书的遗传药理学信息开具处方<sup>[17]</sup>。因此,遗传药理学评估可以看作是药师MTM服务的延伸,如基于遗传药理学的检验结果建议剂量调整,或当有指征时推荐进行遗传药理学检测<sup>[17]</sup>。

门诊临床药师的职责除了接待患者就诊外,还包括药物治疗的选择、回答医疗人员的问题和治疗方案的制定,类似于住院药师的作用。临床药师针对单个患者的特点建议医师哪些药物合用效果最好或最适合,门诊医师依靠这些建议评估和管理药物间和药物与食物的相互作用,以及管理肾功能变化患者的药物剂量。此外,门诊临床药师为药学学生和住院培训药师提供教学。最后,临床药师回答来自医疗护理人员的药物相关问题,除了解决个别的患者问题,还需要实现提高患者用药依从性和医患相互理解的目标。

对于一名临床药师而言,在门诊工作有很多益处。药师有着多元化的实践内容,能与患者建立持续的信任关系,使其能在慢性疾病的长期管理中优化治疗结果<sup>[18]</sup>。研究表明,包括一名药师在内的多学科的团队,能提高患者的治疗效果和患者满意度,并降低整体医疗费用<sup>[19]</sup>。一项Meta分析发现,临床药师的干预比护理干预对血压的影响更大,并能够提高实现血压控制的几率<sup>[20]</sup>。另一项系统评价显示,当临床药师直接参与心力衰竭的监护治疗时,患者的住院风险显著下降<sup>[21]</sup>。这些研究以及其他相似的研究促进了临床药师在门诊中角色的拓展。

## 5 结语

随着临床药学在美国朝着多个方向拓展与演化,许多药学领导者认为获得医疗服务提供者地位(Provider status)是药师整合到医疗团队的重要一步。医疗服务提供者地位体现了药师提供各种药学服务而获得保险公司经济补偿的能力。没有提供者地位,患者可能会由于服务成本限制其获得临床药师服务<sup>[18]</sup>。有一种观点认为,提供者地位可以通过促进药师提供直接监护的资格认证和专业认证,扩大药师在门诊的临床药学实践,并且拓展临床药学的认知范围,最后促进官方认可的临床药学博士教育项目和毕业后住院培训项目的标准的发展<sup>[3]</sup>。

经过富有创新精神的临床药学带头人不懈的努力,使临床药师的角色在美国卫生保健系统已经很好地树立起来,但

这种认识并非没有挑战。改变实践标准和对这一职业长期持有的观点,需要时间、毅力和意愿去完成并不断超越。一旦临床药学在医院系统建立起来,下一步就是将临床药学服务拓展到门诊。这些进展将进一步帮助患者从训练有素的药师处获得一系列药学服务。临床药师的作用尽管在不断拓展,科研工作仍然是药师职业的一个重要组成部分。值得注意的是,证明用药错误减少、改善患者预后和医疗资源的有效利用将巩固临床药师未来的地位。

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附 Kimberly K.Scarsi 博士原文

## Development and Practice of Clinical Pharmacy in the United States

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**ABSTRACT** OBJECTIVE: To introduce the development of clinical pharmacy in the United States, and to describe the typical practice mode of clinical pharmacist in the inpatient and outpatient department. METHODS: Some highlights of the history of clinical pharmacy practice over the past century were summarized briefly, and clinical pharmacy practice expanded from inpatient department to outpatient department; some typical responsibilities of clinical pharmacists in the United States were described. RESULTS&CONCLUSIONS: The practice of clinical pharmacy has evolved from a focus on medication and product delivery to “a patient centered”, with the goal of improving the safe and effective use of medications. Beginning in the early 1900s, during a time when most hospitals did not employ a pharmacist, forward-thinking pharmacists first participated in patient care rounds. This was followed by the other innovative clinical practice models, which demonstrated the potential of the pharmacy profession. These changes led to the development of the Doctor of Pharmacy degree program to better train pharmacists to be clinicians, using their expertise of pharmacy to optimize patient care. This evolution did not occur quickly or without challenge, but through the effort of pharmacists and professional organizations to change the direction of pharmacy practice, pharmacists are now recognized as an essential component of a multidisciplinary care team.

**KEYWORDS** USA; Clinical pharmacy; Hospital pharmacy; Outpatient care

In the 1900s, pharmacy practice in the United States (U.S.) was a “product-centric profession”, meaning the primary focus was the provision of a medication product for a fee. However,

the practice of pharmacy has evolved into a profession that is increasingly more “patient centric”, meaning that the patient is at the center of the pharmacist's activities through contribution to

clinical care decisions<sup>[1]</sup>. This shift in focus emphasizes the changing role of the pharmacist on the healthcare team, resulting in clinical pharmacists increasingly being recognized for their expertise and role on the clinical care team. The American College of Clinical Pharmacy (ACCP) defines clinical pharmacy as an area of pharmacy concerned with the science and practice of rational medication use<sup>[2]</sup>. Expanding this definition, the role of the clinical pharmacist is a licensed pharmacist who provides patient care to enhance medication therapy and to support health, wellness, and disease prevention.

Clinical pharmacists were first utilized in an inpatient, hospital setting. Over time, the clinical services of pharmacists were demonstrated to reduce medication prescribing errors and ultimately improve patient care in the hospital setting<sup>[1]</sup>. The growing respect for the clinical pharmacist in this setting inspired pharmacy leaders to expand the role of clinical pharmacy and ensure pharmacists were integrated into an evolving healthcare delivery system in the U.S. To this end, a shift in focus by the U.S. healthcare system has occurred in order to enhance patient care on an outpatient basis. The goals of this emphasis on enhanced outpatient care are to utilize preventive care and improved management of chronic medical conditions to improve the health status of Americans, and ultimately reduce healthcare costs by preventing both initial and recurrent hospital admissions cost<sup>[3]</sup>. Given this shift in focus, ambulatory care clinical pharmacists, or pharmacists who provide clinical services in outpatient clinics, has emerged as a new area of clinical practice for pharmacists.

The objectives of this manuscript are to describe the evolution of clinical pharmacy in the U.S., first in a hospital setting and then moving into an ambulatory setting, and to describe typical clinical pharmacist practice models in both an inpatient and outpatient clinical settings.

## 1 Clinical Pharmacy evolution in the United States

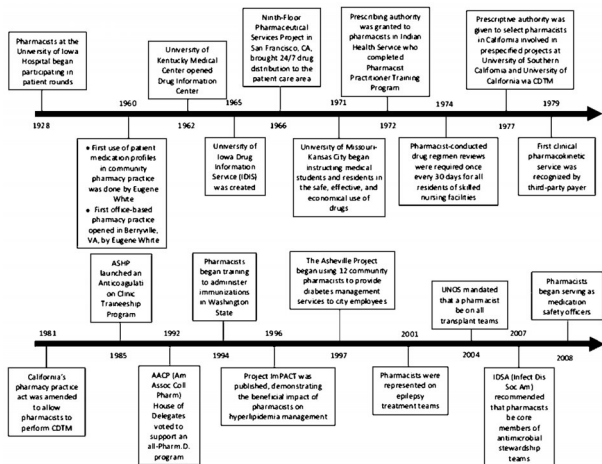
Today in the U.S., clinical pharmacy has expanded to provide patient centered care in all health care settings, including hospitals, physician's clinics, and more recently into community pharmacies<sup>[2,4]</sup>. Conversely, through the mid-1900s, less than 40% of hospitals employed pharmacists, therefore, pharmacists primarily worked in community pharmacies.<sup>4</sup> At that time, community pharmacy was centered on the sale of prescription and non-prescription products. Given that setting, the public perceived the pharmacy to be a place for commercial trade, rather than a profession that provided health care<sup>[1]</sup>. During this era, the pharmacy education system was not yet well formed and pharmacists' role in clinical care was not yet established.

In the early 20th century, colleges of pharmacy had been created, but it was not required to have attended or to have graduated from a college of pharmacy to become a licensed pharmacist. Not only was graduation from a college of pharmacy rare, the qualifications required to attend a college of pharmacy were highly variable. In 1913, only 50% of colleges of pharmacy required students to have completed at least one year of high

school prior to enrollment<sup>[1]</sup>. Today, for a pharmacist to become a licensed practitioner, there are a number of requirements that must be met. Before entering a college of pharmacy, a student must complete specific pre-requisite classes at the collegiate level, and complete the Pharmacy College Admission Test (PCAT), which is a test that measures academic ability to help identify applicants that are qualified to complete a pharmaceutical education. Once an applicant has been accepted into a college of pharmacy program, students must study various aspects of pharmacy including pharmacology, medicinal chemistry, pharmacotherapy, and pharmacokinetics over a three-year period. After the three years of study have been completed, students are required to finish one final year in experiential pharmacy training. This consists of hands on experience in a variety of pharmacy settings, including hospitals, community pharmacies, drug information, and outpatient clinics. This coursework and experiential education provides a foundation for both the science and clinical application of medicines. Once this four-year program has been completed, the student receiving their doctor of pharmacy degree (Pharm.D.) and after passing a national exam becomes a licensed pharmacist. More detailed information about pharmacist education in the U.S. can be found in the companion article in this journal "Pharmacy and Clinical Education and Training Programs in the USA" by Olsen *et al.*

Pharmacist initially began practicing as clinicians in inpatient, hospital settings by participating in multidisciplinary patient rounds for the first time in 1928<sup>[4]</sup>. While early clinical pharmacy activities focused on expanding the pharmacist's role in hospitalized patients, the late 1900s represented an era of more specialization in the practice of clinical pharmacy. Pharmacokinetic dosing services, commonly for antimicrobial dosing, were implemented to aid physicians in optimizing drug dosing, and were first recognized by third-party insurance providers in 1979. Anticoagulation monitoring and warfarin dosing services were another early area of pharmacist involvement, and many hospitals established pharmacist run anticoagulation services. In the 1980s, the American Society of Health-System Pharmacists developed formal clinical training programs for anticoagulation services. The early 2000s brought even more recognition of the vital role pharmacists play in specialized services, for example the United Network for Organ Sharing (UNOS) and the Infectious Diseases Society of America mandated that pharmacists be active members of all transplant teams and antimicrobial stewardship programs, respectively. Fig 1 describes significant milestones occurring through 20th century that shape the practice of clinical pharmacy<sup>[4]</sup>.

Today, clinical pharmacists are utilized in healthcare settings for their specific breadth of expert medication knowledge and unique skill set for which they have been trained. Clinical pharmacists provide the primary source of safe, appropriate, and cost-effective medication use, in addition to serving as a source of objective, evidence-based therapeutic information to reach targeted, patient specific therapeutic outcomes. The ACCP



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**Fig 1 The clinical pharmacy innovation timeline<sup>[4]</sup>**

AACP=American Association of Colleges of Pharmacy; ASHP=American Society of Health-System Pharmacists; CDTM=Collaborative Drug Therapy Management; IDSA=Infectious Diseases Society of America; UNOS=United Network for Organ Sharing.

states that clinical pharmacists assume both responsibility and accountability for achieving these therapeutic goals; therefore, to accomplish this, clinical pharmacists are expected to be more than consultants to a medical team<sup>[2]</sup>. Thus, clinical pharmacists are now a part of direct interaction with the patients and their integration into multidisciplinary clinical teams allow the clinical pharmacist to directly safeguard against drug therapy errors. Clinical pharmacists are expected to lead the way in rational and proper drug usage among health care providers<sup>[2]</sup>.

## 2 Roles of the clinical pharmacist in the inpatient setting

Clinical pharmacists work in collaboration with physicians, patients, and other health care providers in order to ensure that medication usage contributes to the best standard of care. After completing the Pharm.D. degree, many hospital based pharmacists complete additional training through postgraduate year one (PGY1) and postgraduate year two (PGY2) residency programs. Specialty areas include but are not limited to ambulatory care, cardiology, critical care, drug information, emergency medicine, geriatrics, human immunodeficiency virus (HIV), infectious disease, internal medicine, managed care, nephrology, neurology, nutrition, oncology, pediatric, pharmacogenomics, and solid organ transplant<sup>[5]</sup>.

The four main components encompassing the duties of clinical pharmacists include assessment, evaluation of medication therapy, development and implantation of a plan of care, and ongoing evaluation and medication monitoring<sup>[6]</sup>. All patient care duties, regardless of the practice setting, fall into at least one of these components. Typically the pharmacist will participate in patient care rounds with an interdisciplinary team in order to provide pharmacotherapeutic management for patients on a daily basis<sup>[7]</sup>. Before and during rounds it is necessary to evaluate patient data including history, diagnosis, allergies, renal function, and

all other laboratory results. The pharmacist will evaluate all drug therapies for appropriate dosage, frequency, duration, and unnecessary use. In addition, they monitor for effectiveness, drug-drug interactions, drug-food interactions, and adverse events, as well as adverse event prevention and management as necessary<sup>[7]</sup>. Therapeutic drug monitoring for medications with narrow therapeutic ranges, is another responsibility of the clinical pharmacist when a targeted drug is prescribed. Therapeutic drug monitoring requires pharmacokinetic and pharmacodynamic knowledge of the drug to individualize the medication therapy<sup>[8]</sup>. All of these activities occur prospectively and concurrently which allow the pharmacist to make interventions and clinical recommendations in at the time of patient rounds or medication prescribing. Physicians accept many of these interventions because they know the expertise that pharmacists have in pharmacology, others are not accepted based upon team discussion and clinicians' judgment<sup>[9]</sup>. A pharmacist will also work with clinical dietitians to evaluate total parenteral nutrition orders to optimize the nutritional regimen based on the patient's current weight, labs, and medical condition. Additionally pharmacists certified in advanced cardiac life support (ACLS) will respond to cardiac arrest codes<sup>[10]</sup>.

Currently, pharmacists in acute care settings hold much of the responsibility for medication reconciliation and for the accuracy of the medication history and current medication list during transitions of care at admission or discharge. This responsibility has shifted to the pharmacist after research identified that incomplete, outdated, or inaccurate medication histories contributed to a significant number of medication errors arising from discrepancies in admission, transfer, discharge, and hospital readmission medication lists<sup>[10]</sup>. The process is now a structured procedure where the pharmacist or pharmacy technician access the patient's medication list, documents pre-admission medications, and reviews patient information. Subsequently, the pharmacist will interview the patient or family to obtain a list of the patient's medication allergies, in addition to current prescription medication, herbal products, and over the counter medications. Information about the outpatient pharmacy where the patient fills prescriptions is also obtained during the interview, allowing the pharmacist to verify the medication information obtained from the patient. Finally, all of the lists are compared and the pharmacist conducting the medication reconciliation will address any discrepancies or medication related problems that are identified and document the final medication list in the medical record<sup>[10]</sup>.

Education responsibilities are another important aspect of a clinical pharmacist's job. The pharmacist will respond to drug information questions from medical, nursing, and pharmacy staff, providing up to date primary references or critical analysis of clinical topics based on the questions received. Pharmacists will also educate physicians about optimal medication use in order to improve patient care. Training is also provided for pharmacy students, through introductory or advanced pharmacy practice experience rotations, and pharmacy practice residents

(PGY1 or PGY2). Trainees are guided by the clinical pharmacist, through modeling practice behaviors on clinical rounds, topic discussions, and case presentations, but are also encouraged to work as independently as possible in order to prepare them for becoming independent pharmacist practitioners upon completion of their training. Health professionals are not the only people educated by pharmacists, depending on the specialty in which they are working, pharmacists may provide patient and family education daily or prior to discharge to improve the patient's understanding of their medications and health.

The clinical pharmacist must also fulfill institutional responsibilities, which may include developing, implementing, and maintaining departmental policies and procedures related to effective and save drug use, in addition to participating in quality assurance programs to enhance pharmaceutical care. Clinical pharmacists are also active on institutional committees, such as the Pharmacy and Therapeutics Committee, to develop the institutional medication formulation and to minimize drug costs through appropriate use of medications<sup>[10]</sup>. Many institutions also require the clinical pharmacist to conduct, present, and publish research in their area of expertise. A few areas of research common for clinical pharmacists include pharmacokinetics and pharmacodynamics, patient outcomes, and implementation science.

There are many benefits to working in an inpatient setting as a clinical pharmacist. Pharmacists in these settings often have a practice mix of direct patient care, teaching, institutional responsibilities, and research. They are able to interact with all types of health care providers developing long-term relationships and inter-professional trust, enabling pharmacists to positively influence patient care in the hospital setting and upon discharge.

### 3 Expanding the role of clinical pharmacists into ambulatory settings

As the number of outpatient prescription drugs being prescribed in the U.S. is anticipated to rise in the coming years, this too will increase the frequency of medication-related problems that require the intervention of a pharmacist<sup>[11]</sup>. In 2012, the Institute for Healthcare Informatics projected that more than \$200 billion U.S. dollars were spent as a result of the improper and unnecessary use of medications<sup>[12]</sup>. Six areas were identified as contributory to this unnecessary health care expense: medication non-adherence, delayed evidence-based treatment practice, antibiotic misuse, medication errors, suboptimal use of generic products, mismanaged poly-pharmacy. The nature of many of these areas for improvement, such as medication non-adherence, evidence-based practice, and mismanaged poly-pharmacy, are most effectively managed over the long-term care of the patient, rather than only during hospitalization. An ambulatory care setting is a place where health care treatment is provided on a continual basis and includes preventative therapy and long-term management of chronic conditions. Enhanced clinical care in ambulatory settings is expected to result in fewer hospital admissions, and overall improved health of the community.

Ambulatory care clinical pharmacists practice in both prima-

ry care settings and in specialty clinics. The diseases managed include chronic diseases such as heart failure, chronic kidney disease, asthma, chronic obstructive pulmonary disease (COPD), pain management, depression, alcohol abstinence, anticoagulation, and infectious diseases including HIV, hepatitis C virus, and tuberculosis. Additionally, ambulatory care pharmacists manage acute conditions including complicated urinary tract and influenza infections, pain management, and seizures, as well as management for exacerbations of chronic diseases such as in COPD, asthma, and heart failure. In 2008, leaders of ACCP, American Pharmacists Association (APhA), and American Society of Health-System Pharmacists stressed the importance of pharmacists in the ambulatory care setting to provide care for patients with chronic health conditions because the expenses of these conditions represent 75% of the annual health expenditures in the U.S.<sup>[3]</sup>.

### 4 Role of the Clinical Pharmacist in an ambulatory setting

The ambulatory care clinical pharmacist is generally located in an outpatient office, allowing for direct patient care, provider interaction, and medication management. The practice site may be an institutional or community based clinic but medication dispensing is usually not part of the pharmacist's role in these settings. This practice location allows the pharmacist to coordinate with all health care providers while also developing long-term patient relationships in a setting that is more accessible to patients. Similar to the inpatient setting, the clinical pharmacist's role in an outpatient clinic all fall into one of the four main components: assessment, evaluation of medication therapy, development and implantation of a plan of care, and follow up evaluation and medication monitoring<sup>[6]</sup>.

An important role for ambulatory care pharmacy is the provision of preventative care services<sup>[3]</sup>. One example of preventative care is the goal to increase the immunization rate in order to reduce the rate of preventable infectious diseases in Americans<sup>[13]</sup>. In most clinical settings, it has become routine for ambulatory care pharmacists to develop the specialized knowledge and training to screen for and administer vaccinations when clinically indicated and pharmacists currently administer over 50% of the influenza vaccines given to the U.S. public. Another preventive clinical intervention for ambulatory care pharmacists is tobacco-smoking cessation programs, given that about 50 million American adults smoke cigarettes, leading to both acute and chronic illness<sup>[3]</sup>.

Another aspect of ambulatory care pharmacy is the provision of medication therapy management (MTM)<sup>[3]</sup>. MTM is defined as medical care provided by pharmacists whose aim is to optimize drug therapy and improve therapeutic outcomes for patients. MTM is a broad category of clinical services by pharmacists, which include patient assessment, comprehensive medication review, monitoring the safety and efficacy of medication therapy, and enhanced medication adherence through education. Finally, documentation and communication of MTM services between the pharmacist and provider are essential to ensure conti-



nunity of care. Studies demonstrate that MTM provided by ambulatory care pharmacists improve the coordination of care, reduce medication-associated problems, and improve morbidity and mortality. In one example, researchers compared patients who received MTM services by a pharmacist to those that were similar but did not receive MTM services. In subjects who received MTM, the researchers observed substantial improvement in both cholesterol levels and blood pressure. Furthermore, those who received MTM had significantly lower total healthcare costs<sup>[14]</sup>.

An example of how an ambulatory clinical pharmacist may provide MTM services in an outpatient setting is as follows. Each day, the pharmacist will compile a patient medication refill history for each patient scheduled to see the physician for that day. The pharmacist will review the refill history for adherence, drug-drug interactions, or other medication therapy problems. When the patient arrives in the clinic, the pharmacist may be responsible for completing the medication history or medication reconciliation before the physician sees the patient. When seeing a new patient, the pharmacist complete a medication history in order to identify all current medications, adherence to those medication, medication taking behaviors, and allergies<sup>[6]</sup>. If the patient is returning to the clinic, a pharmacist will assess the patient's medications for appropriateness, effectiveness, safety, and adherence. If the patient has been recently hospitalized, the hospital discharge medication list is compared with the outpatient medication list and discrepancies are investigated. Additionally, the pharmacist may order laboratory tests to monitor medications effectiveness or side effects. If a medication therapy problem is identified, a recommendation is given to the physician in order to resolve the problem during the patient's visit. At the conclusion of the visit, the accurate list of the patient's current medication, dose, and frequency is given to the patient.

After seeing the physician, the patient will often have see the clinical pharmacist. The purpose of these visits could be to resolve medication therapy problems that were identified during the visit, to provide medication or disease state education, management or monitoring. The activities during these visits include education about medication therapy options, goals of the new therapy, administration of the medication, importance of adherence, and possible side effects. Additionally, the pharmacist may order or perform additional laboratory tests to assess medication efficacy and safety. Patient visits with the pharmacist can range from 10 to 90 minutes and all interactions and recommendations must be documented in the patient's medical record when the visit is completed. Many clinics use follow up phone calls to patients, which are performed by the pharmacist to provide ongoing adherence support, to monitor drug therapy, or to provide laboratory results.

A unique patient care strategy that ambulatory clinics are starting to use is group visits. The goal of a group visit is to ensure that the entire spectrum of care for the patient is addressed during the same visit. The visit involves a team of medical providers that lead a shared medical appointment with a group of pa-

tients with the same chronic disease state. The meetings often include a medical assistant, nurse, pharmacist, clinical therapists, physicians. During the visit, the patient will see each health care provider and discuss various aspects of their care. The visits will usually end with a group education session in order to better help the patients understand their current disease state and how to manage it more appropriately<sup>[10]</sup>.

Another emerging role of clinical pharmacists is individualized pharmacotherapy through the application of pharmacogenetic testing<sup>[15]</sup>. One in four prescription drugs are metabolized by metabolic pathways that can be affected by pharmacogenetic polymorphisms. These polymorphisms may increase or decrease drug exposure, which may influence drug efficacy or safety. Additionally, some pharmacogenetic tests can indicate the likelihood of an adverse drug reaction; for example, occurrence of an abacavir hypersensitivity reaction is closely associated with the expression of HLA\*B-5701 allele<sup>[16]</sup>. Currently, few primary care practitioners utilize the pharmacogenetic information that is contained in package inserts to guide prescribing<sup>[17]</sup>. Therefore, pharmacogenetic assessment may be an extension of MTM services by pharmacists, such as recommending dose adjustments based on pharmacogenetic results, or making a recommendation to perform the test when indicated<sup>[17]</sup>.

Ambulatory clinical pharmacist duties extend beyond patient visits and include drug therapy selection, questions from providers, and treatment protocol development, similar to the inpatient pharmacist's role. Outpatient physicians rely on the pharmacists to advise them on which medications work best together or are most appropriate for the individual patient's characteristics, to assess and manage drug-drug and drug-food interactions, and to manage drug dosing in patients with changing renal function. In addition, pharmacists in ambulatory settings provide education to pharmacy students and pharmacy practice residents. Finally, the pharmacist answers drug related questions from medical and nursing staff, in addition to individual patient questions, with the goal of improving medication adherence and comprehension.

There are many benefits to working in an ambulatory setting as a clinical pharmacist. Pharmacists have a diverse practice that builds an ongoing, trusting relationship with patients, allowing pharmacists to optimize outcomes over the long-term management of chronic illnesses<sup>[18]</sup>. Studies have shown that a multidisciplinary team that includes a pharmacist improves patient outcomes, increases rates of patient satisfaction, and reduces overall health care costs<sup>[19]</sup>. One meta-analysis found that clinical pharmacist intervention had a greater impact than nursing intervention on blood pressure and improves the chances of achieving blood pressure control<sup>[20]</sup>. Another systematic review showed a significant reduction in the risk of hospitalization when a clinical pharmacist was part of a patient's direct care heart failure treatment<sup>[21]</sup>. These and similar studies have led to the expanded role of clinical pharmacists in the ambulatory setting.

## 5 Conclusion

With the multiple directions that clinical pharmacy is expanding and evolving in the U.S., many pharmacy leaders feel that provider status is a vital step for pharmacists to be integrated into the patient care team. Provider status is a term that describes the ability for pharmacists to be monetarily compensated by insurance companies for providing various pharmacy services. Without provider status, patients may be limited in the access to the care they may receive from clinical pharmacists due to cost of services<sup>[18]</sup>. It's argued that provider status will expand the practice of clinical pharmacy in ambulatory care settings by advancing the credentialing and certifications for pharmacists providing direct care to patients, expand the recognized scope of pharmacy practice, and lastly make advances within the standards for accredited Pharm.D. educational programs and post-graduate residency training programs<sup>[9]</sup>.

Through the work of innovative pharmacy practice leaders, the role of clinical pharmacists is now well established in the U.S. healthcare system, but this recognition was not without challenges. Changing practice standards and long held views of the profession required time, persistence and a willingness to go above and beyond the normal expectations. Once clinical pharmacy was well established in the hospital system, the next step was the expansion of clinical pharmacy services into ambulatory care settings. These advances will serve to further increase patients' access to a range of pharmacy services from highly trained pharmacists. As the role of clinical pharmacists expand, research remains an essential component of the profession. In particular, demonstration of reduced medication errors, improve patient outcomes, and efficient use of healthcare resources will ensure the role of clinical pharmacists in the years to come.

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# 《全球疫苗安全蓝图》解读及思考<sup>△</sup>

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**摘要** 目的: 提高我国疫苗上市后安全监测的能力, 明确我国疫苗上市后监测未来发展的方向。方法: 介绍世界卫生组织《全球疫苗安全蓝图》出台的背景、战略目标与执行目标, 分析我国疫苗上市后安全监测现状。结果与结论: 近年来, 我国疫苗上市后安全性监测发展迅速, 取得的成绩也得到了国际的认可。但与《全球疫苗安全蓝图》提出的目标相比, 我们在主动监测、信号分析、数据规范等方面仍存在不足。可以借助世界卫生组织和其他国际组织的力量, 推动我国疫苗上市后监测迈上新的台阶。

**关键词** 全球疫苗安全蓝图; 疫苗; 上市后安全性监测

## Interpretation and Thinking about *Global Vaccine Safety Blueprint*

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**ABSTRACT** OBJECTIVE: To improve the ability of vaccine post-marketing surveillance, and clearly define the development direction of it in China. METHODS: Though introducing the background, strategic objective and operation objective of *Global Vaccine Safety Blueprint*, the situation of vaccine post-marketing surveillance in China was analyzed. RESULTS&CONCLUSIONS: Vaccine post-marketing surveillance have developed fast in China recent years and get generally confirmation. However, compared with the goals in the blueprint, there are some activities should be strengthened, such as active surveillance, signal analysis and data standardization, etc. We should take use of the opportunity offered by WHO and other international organizations to shrink the gap between our country and the advanced countries. Drawing support from WHO and other international institutions, vaccine post-marketing surveillance can step on the new level in China.

**KEYWORDS** *Global Vaccine Safety Blueprint*; Vaccine; Post-marketing surveillance

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