



第5版

Vaccines

疫苗学

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Orenstein, Paul A. Offit

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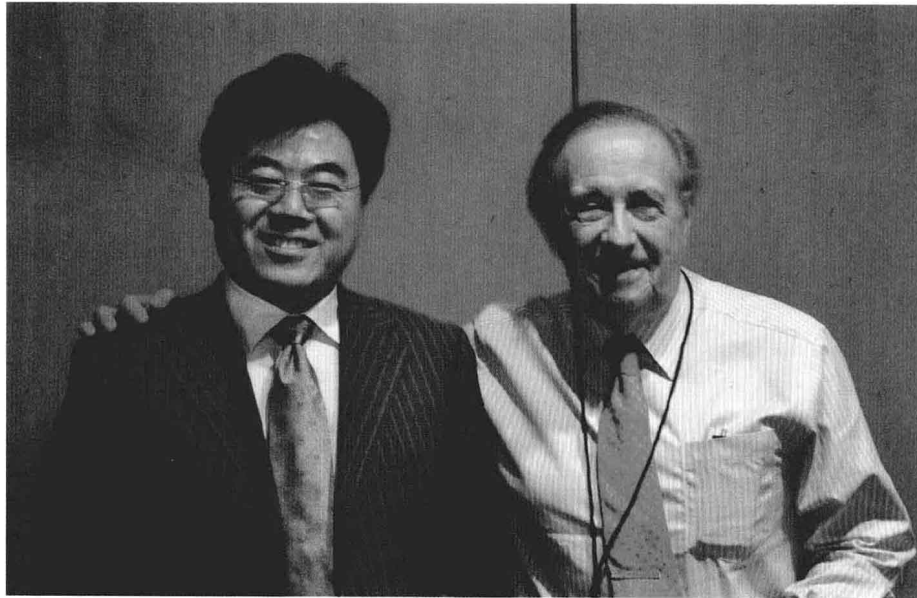
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Preface to the Chinese version of the fifth edition



The fifth edition of *Vaccines on vaccines and their use* is directed at the physicians who use them, emphasizing products licensed in the United States, but also including chapters on vaccines still in development. Our hope is that this book will serve as a reference source for all those interested in vaccines and disease prevention. We also hope that the Chinese edition will be helpful to Chinese audiences.

During the new century, China has made considerable achievements in the field of the Expanded Program of Immunization (EPI). Since 2007, the central government increased its financial support to cover vaccines that now supports fifteen vaccine-preventable diseases.

Dr. Liang Xiaofeng, as a senior expert in immunization and a member of WHO's Strategic Advisory Group of Experts on immunization made great efforts to improve the cooperation between China and the rest of the world in matters of vaccination. He coordinated the input of vaccine experts to translate the book. I now hope Chinese readers can benefit from this Chinese version so that the book contributes to the prevention of vaccine-preventable diseases in China.

第5版中译本序言

《疫苗学》第5版的主要内容为疫苗及其使用,服务对象是使用疫苗的医务人员。书中主要介绍了美国上市的疫苗,同时也包括了研发中的疫苗。希望本书能为对疫苗和相关疾病预防的同行提供参考,更希望对中国同行提供帮助。

中国近年来在免疫规划领域取得了巨大的进步,2007年扩大国家免疫规划范围,将甲型肝炎、流行性脑脊髓膜炎等15种可以通过接种疫苗有效预防的传染病纳入国家免疫规划。

梁晓峰从事免疫规划工作十余年,同时也是世界卫生组织免疫规划策略顾问组成员,一直不遗余力地推动中国与其他国家在免疫规划领域的交流与合作。此次,他组织了我国疫苗科研、生产和疾病预防控制领域的资深专家团队,对《疫苗学》第5版进行了翻译。祝愿《疫苗学》中文版本能够使广大读者受益。



Stanley A. Plotkin

序言一

疫苗在保护人类健康方面的影响是巨大的,疫苗使人类在面对传染病的威胁时,首次化被动为主动,在降低死亡率和提高人均预期寿命方面发挥了不可替代的作用。通过疫苗接种,人类已经消灭了天花,有效控制了脊髓灰质炎、麻疹等十余种主要传染病。

新中国成立后,我国人民健康水平得到显著提升,人均期望寿命已从 35 岁提高到 73.5 岁。但是,传染病仍然是我国人民的主要健康威胁之一。经过几代卫生工作者的努力,我国在疫苗的研发、生产和使用方面均取得了长足进步,自 1978 年开始实施计划免疫以来,目前多数疫苗可预防传染病的发病已降至历史最低水平。特别是 2009 年 4 月深化医药卫生体制改革启动以来,卫生部门将 15 岁以下人群补种乙肝疫苗列为六项重大公共卫生服务项目之一,乙肝控制工作取得了重大进展,我国有望在不远的将来摘掉“肝炎大国”的帽子。2009 年,面对甲型 H1N1 流感蔓延的严峻形势,我国政府组织多部门、多机构通力合作,用最短的时间研制、生产出了甲型 H1N1 流感疫苗,并成功进行了大规模接种,相关重要研究成果先后在《柳叶刀》、《新英格兰医学》等国际著名学术刊物上发表,显著提升了我国在疫苗领域的国际学术地位。

近年来,随着生命科学和生物技术的快速发展,国际疫苗研发工作不断取得新进展,有关专门论著也在不断推陈出新。1988 年,为满足美国临床医生对疫苗实际应用的需求,Plotkin 教授编写了 *Vaccines* 一书,成为这一领域的经典著作之一。该书第 1 版的内容主要是当时美国已批准上市的疫苗,同时也包含了一些正处于研发过程中的疫苗。1994 年的第 2 版增加了 b 型流感嗜血杆菌蛋白结合疫苗、甲肝疫苗、新型伤寒疫苗,以及 DNA 重组疫苗等研发的新技术方面的内容。1999 年的第 3 版对脊髓灰质炎、麻疹等疫苗的内容进行了更新。2004 年的第 4 版增加了多糖肺炎疫苗的新内容。2008 年的第 5 版则增加了人乳头瘤病毒疫苗、轮状病毒疫苗、水痘-麻疹-风疹-流行性腮腺炎四价蛋白结合疫苗、四价的蛋白结合多糖疫苗、带状疱疹疫苗,以及分子技术 HIV、疟疾、肺结核三大疾病的实验性进步等内容,此外,还包括全球各大区的免疫规划策略等方面的最新进展。

本书是 *Vaccines* 第 5 版的中译本,也是中国学者首次将该书译成中文。我希望这本书的中译本成为我国有关科研工作者、公共卫生人员、卫生行政人员、乃至疫苗产业从业者的工作参考书,为我国的疫苗研发和免疫规划事业起到推动作用,并对我国正在进行的新药创制和传染病防治两个重大科技专项的实施发挥积极作用。

卫生部部长

2011 年 8 月 22 日

序言二

1988年,Stanley A. Plotkin等编撰了专著 *Vaccines*,“疫苗学”一词开始被医学书刊广泛引用。2007年,Stanley A. Plotkin等再次修订了 *Vaccines*(第5版),本书共5篇76章,由160多位从事疫苗研发、生成、鉴定、流行病学、临床等专家结合各自积累的丰富知识、实际经验以及最新研究结果编撰,较全面、系统地总结了疫苗发展、生产、制造等概括,介绍了天花、霍乱、甲肝等批准上市疫苗,腺病毒、疟疾、人类免疫缺陷病毒(HIV)等新疫苗研发和应用策略,特殊人群免疫预防,以及疫苗经济学、安全性、法律等相关的公共卫生问题,是一部理论和应用相结合、以应用为主的大型专业参考书。

疫苗学涵盖了微生物、流行病、免疫、生物化学、遗传、分子生物、生物工程等众多学科,现在已形成了一门独立的学科。从1796年琴纳用牛痘疱浆接种儿童试验至20世纪中期,新疫苗不断研制成功并投入免疫预防,这一时期,疫苗基本由灭活或减毒病原体制成,品种少、质量差。20世纪后期,随着分子生物学、生物技术、合成化学、分析化学、基因组学等科学的迅速发展和在疫苗研发过程的广泛应用,极大地推动了新疫苗的研发,相继出现了亚单位疫苗、重组活载体疫苗、毒力基因缺失疫苗以及核酸疫苗,许多疫苗已不再是完整的病原体,疫苗针对的疾病也不再局限于传染性疾病,人乳头瘤病毒感染、动脉粥样硬化、自身免疫性疾病、避孕等也可以用疫苗来预防和治疗,埃博拉出血热、严重急性呼吸系统综合征(SARS)、甲型H1N1流感等新发传染病的疫苗研发有所进展,本书均作了专题介绍,而这些疫苗的研发及出版物在国内少有涉及。

新中国成立后,我国疫苗研发人员本着对人民健康负责的奉献精神和对疫苗事业的敬业精神,实现了疫苗研发从无到有,目前我国已具备生产WHO多数免疫规划疫苗。俞永新院士利用乙脑SA14-14-2株研发了乙脑减毒活疫苗,该疫苗具有副作用小,注射针次少,免疫效果高特点,在东南亚乙脑流行区被广泛应用。该疫苗生产用毒种SA14-14-2株和生产工艺已被纳入由WHO制定的《乙脑减毒活疫苗生产和质量控制指南》。毛江森院士成功地培育出安全、有效的甲型肝炎减毒活疫苗毒种,并研制出甲型肝炎疫苗,为我国甲肝防控工作作出了杰出贡献。2009年,我国仅用3个月时间研制并应用了甲型H1N1流感疫苗,陈竺部长倾注了大量心血,并成为我国乃至全球接种甲型H1N1流感疫苗志愿者第一人。我国甲型H1N1流感疫苗临床试验数据、免疫效果观察等及时发表在《柳叶刀》、《新英格兰》等著名杂志上,为全世界的流感应对提供了非常珍贵的资料,提升了中国在疫苗研发、生产和使用方面的国际地位。

我国免疫规划工作也迅猛发展,在全世界享有盛誉。我国根除了天花,消灭了脊髓灰质炎,白喉和百日咳等发病罕见,5岁以下儿童乙肝表面抗原携带率已降至1%以下,麻疹、新生儿破伤风等疾病发病率显著下降。2007年,我国实施扩大免疫规划,预防疾病增加了风疹、流行性乙型脑炎、流行性脑脊髓膜炎、甲型病毒性肝炎等疾病,由5苗防7病扩大到11苗防12病,人民群众健康得到了更好的保障。

进入21世纪以来,SARS、猪链球菌病、甲型H1N1流感、结核等新发和再燃传染病对人类健康构成了新的威胁,炭疽、天花等可能被恐怖组织用来发动生物袭击,疫苗安全事件和人民健康需求对发展新疫苗和改进现有疫苗提出了新的要求。生物新技术、免疫学新进展等为研发和改进疫苗奠定了基础、创造了条件。我国进入疫苗研发和免疫规划工作黄金期,同时也面临挑战。免疫规划人员需要不断更新疫苗新知识、为新疫苗制定免疫预防新策略等,迫切需要了解国外疫苗及应用新进展。

经 *Vaccines* 主编 Stanley A. Plotkin 和 Elsevier 出版公司许可,中国疾病预防控制中心负责牵头,在中国生物技术集团公司和北京市朝阳区疾病预防控制中心的支持下,组织国内疾病预防控制中心、疫苗生产和科研部门具有很高理论水平和丰富实践经验的资深专家翻译和审译了本书。内容涵盖了疫苗的生产工艺、上市疫苗的相关疾病流行背景和生产应用、展望新型疫苗的发展、全球各大区的免疫规划策略等内容。中文版本将为各级疾病控制、科研、生产和高校院所等部门提供有价值的参考资料。

感谢 Stanley A. Plotkin 等原著者的热心帮助,Stanley A. Plotkin 还专门为中译本作了热情洋溢的序言。

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本书难免有不尽如人意的地方和错误之处,诚恳希望读者提出宝贵意见,以便在今后版本中更正。

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第 1 版前言

首次感染可以增强宿主抵抗力,而且以后也能产生一种有效的防护。因此可以考虑在伤害很小的前提下,给宿主一定的感染,让其保持免疫力。主动免疫或接种的目标就是使宿主达到类似于主动感染某特定疾病并治愈的状态。

Jules Bordet
Traite de l'Immunité dans les
Maladies Infectieuses, 1920

一百多年前,实验室研制出了首剂疫苗。在那一时期,疫苗的成功可以用“效果非凡”来形容。在人类的几次主要灾难中,疟疾和蠕虫病仍无有效的疫苗,虽然现在又加上了人类免疫缺陷病毒感染。目前仍有很多地方性疾病(主要是呼吸道传染病)急需疫苗,这也正是数百家实验室致力于免疫预防研究的动力。

实际上,从 Pasteur 时代开始,医学界和整个世界在一定程度上认识到,疫苗接种预防才是预防传染病的理想措施。

但很奇怪,尽管大家都认识到了这一点,却很少有关于疫苗实际应用的专著,它不同于疫苗的基础免疫学,也不同于疫苗的发展过程。而且我们还发现,医生和医学生对疫苗的了解远不如对抗生素和其他治疗药物了解得多。尽管疫苗的有效性已被证实,但只有美国和其他发达国家才有基于人群的疫苗接种,这些国家的成功可归功于教育的发展以及由此产生的儿科医生的带动。而在儿科以外的医学领域仍很少应用或考虑疫苗。

另外,疫苗还一直遭受抨击,如自由主义者宣称生病是人类的权利,宗教狂热者认为上帝的旨意包含疾病和死亡,法律系统则获益于多数人不了解风险/利益比或公共卫生问题,而健忘也使得人们容易忘记疫苗接种前的疾病状态。

对这些问题还需要加一点,那就是医生和患者都对治疗更加感兴趣。人们更多关注于心脏移植、连体婴儿分割、重症监护的技术发展,为什么不呢?这些更具有戏剧性的色彩。迄今为止,没有一名医生在他(她)的职业生涯中保存哪怕一丁点儿的由疫苗拯救生命的片断。

因此,我们决定编写一本关于疫苗及其应用的教材,希望对使用疫苗的医生有一定的指导作用。内容重点是美国已批准上市的产品,但同时也包含了一些正在研发疫苗的章节。在一些案例中,如果我们认为某些主题非常重要,即使疫苗处于早期阶段,我们也将书中保留其内容。我们希望本书可以供所有对疫苗预防疾病感兴趣的人们参考。

古希腊有两个健康之神,医神和卫生之神,分别负责治疗和预防。20 世纪的医学仍是这两个概念,而疫苗是最有效的预防方式。疫苗和公共卫生共同造就了现代社会,如果明智地应用,仍可继续赠予人类预防的礼物,这比治疗更加宝贵。

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