

Evolution of Medical Services for HIV/AIDS in Thailand

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Abstract

Background: Thailand started the anti-retroviral supply program in 1992 primarily for low income groups. The budget has increased but coverage has decreased due to the large number of cases requesting supply. Rapid advancement of HIV therapy has resulted in higher drug cost which is not affordable to people in developing countries. The cost effectiveness review in 1995, conducted by staff of the World Bank, World Health Organization, and Ministry of Public Health (MOPH), demonstrated high cost with limited benefit. It encouraged program evolution, from "*supply for services*" to "*supply for research*". Faced with an expanding AIDS epidemic and economic set back, Thailand has to adapt its program to fit scientific, ethic, and economic situations.

Activities: The program now extends to (a) adapting current therapeutic regimens, (b) developing new treatment and (c) natural history study of people with HIV/AIDS who receive anti-retrovirals (ARV), anti-opportunistic infections (anti OIs), or alternative care. Laboratory issues, and prevention activities are also included. To allocate an approximately 300 million baht budget each year, participating hospitals were invited to submit proposals for consideration. Proposals were ranked and supported according to scores and research priority. A clinical research network was set up in 1996 and supply was shipped out in 1997 on double combination for 1,200 cases, with triple combination for 40 cases, all in 58 sites. Investigators were trained for *Good Clinical Practices* (GCP) to reassure data handling quality. Psychological and social support were encouraged through the health system research network. Until 15 Jan 98, 49 proposals were submitted (42 ARV, 1 herbal medicine, 6 pediatrics/perinatals). A working group consisting of local experts from medical schools, and the MOPH together ranked these proposals. Those with high scores received medical supplies while the low scores received technological advice in order to increase their capability to participate in research in the near future.

Conclusions: Central supply encouraged physicians to treat more cases but discouraged their hospitals to set up their own budget. The clinical research network allowed team and infrastructure building up which can be adapted for drug, vaccine trials and observational databases. More training is needed. For other developing countries, Thailand's experiences should be perceived as an example not a model.

Key word: HIV, AIDS, Clinical Trial, Medical Supply, Thailand

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Background

Thailand has been severely hit by the HIV epidemic. Infection rates among the low risk population, such as pregnant women and blood donors, have been around 1 per cent while infection rates among high risk populations, such as female commercial sex workers and males attending sexually-transmitted disease clinics, have ranged from 5 per cent to 30 per cent⁽¹⁻⁹⁾. In 1995, the *National Economic and Social Development Board* (NESDB) estimated that there were 800,000 prevalent HIV infections in Thailand. Forecasting models projected approximately 30,000 new AIDS cases with 500 pediatric AIDS cases annually during the years 1996-2000⁽¹⁰⁾.

Progression rate was estimated to be 6.8 per cent⁽¹¹⁾. Survival rate was estimated in an infectious hospital to be 7 months⁽¹²⁾ which was believed to be shorter than in general because of lead time bias. Treatment and prophylaxis for opportunistic infections especially *Pneumocystis carinii* pneumonia could significantly increase survival⁽¹³⁻¹⁶⁾. However, access to drugs and care is not universal in Thailand and only a small proportion of the Thai population can afford to modern regimens^(17,18).

Globally, HIV/AIDS related medicines including anti-retrovirals (ARV) have been developed rapidly. In the United States, the number of drugs approved by the US Food and Drug Administration (US FDA) has increased from 1 in 1987 to 11 in 1990 and to 42 in 1996 (Fig. 1).

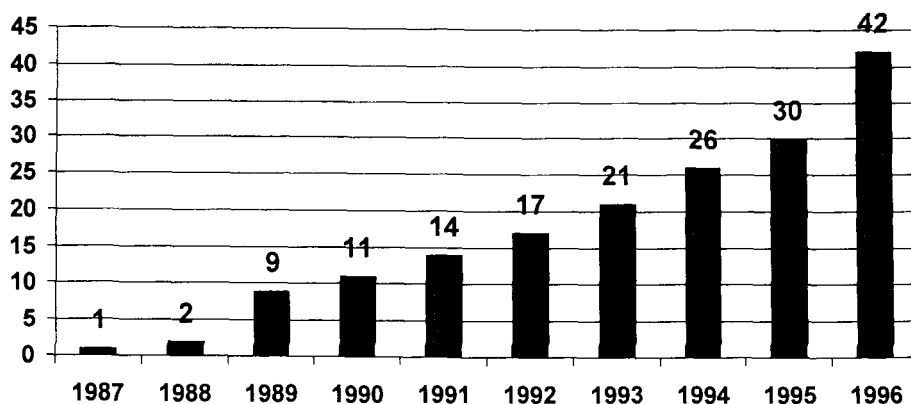
As an overview, Thailand started its anti-retroviral supply for low income groups in 1992 but after the program review by the World Bank, World Health Organization, and the Thai Ministry of Public Health (MOPH) in 1995, the program was shifted to more research agenda. With careful consideration, medical services for HIV/AIDS in this budget sector have been expanded to a broader perspective of 3 aspects in 7 areas. Details are described later in this paper.

This paper aims to give understanding on medical services for HIV/AIDS in Thailand, constraints, and possible solutions especially with clinical research networking. Opinions are personal and do not imply the policy or standpoints of affiliated institutions of the authors. However, they might reflect trend for development of clinical research network in Thailand in the next few years.

Evolution of medical services for HIV/AIDS in Thailand

(1) Supply of ARV for the low income groups

The Ministry of Public Health, under the decision of the National AIDS Committee (NAC) in 1992, decided to supply anti-retroviral drugs for low income HIV infected patients in order to provide equal opportunity for people with HIV/AIDS to get access to care. The budget increased from 35 million baht in 1992 to about 300 million baht in 1996 and 1997. AZT price decreased dramatically from 45 to 8 baht per 100 mg capsule due to both a greater amount of government purchase



Source PhRMA Annual Survey "New Medicines in Development for AIDS"

Fig. 1. United States Approved AIDS and AIDS related medicines.

(stronger negotiating power) and expanded competition among manufacturers. The Thai Government Pharmaceutical (GPO) started manufacturing and providing AZT to the MOPH at about 9 baht a capsule.

With the exponential increase of cases and also the rapid advancement of combined ARV therapy, benefits from the program were suspected. The Ministry of Public Health in 1994 consulted the World Health Organization, and the World Bank and requested experts to investigate cost-effectiveness of the program. The team reviewed epidemiological projections, clinical efficacy, policy alternatives, and economic models to recommend rational use of ARV in Thailand.

(2) Review for rational use of ARV

A total of 8 policy alternatives were included in the review. The baseline was treatment of opportunistic infections only. Three other alternatives included using monotherapy (AZT) for AIDS, double nucleosides (AZT/ddI or AZT/ddC) switched or concurrent therapy for AIDS. The other three were mono or double nucleosides for symptomatics. The last alternative was AZT monotherapy for the asymptomatics. At the time of the review, protease inhibitors were not available in Thailand and information on highly active anti-retroviral therapy

(HAART) is not widely distributed so they is not included in the models.

Cost effective analysis started with epidemiological projections to estimate case loads of AIDS, symptomatic, and asymptomatic HIV infected persons in Thailand from 1994 to 2005. Cost for therapy was estimated according to 8 policy alternatives assuming complete coverage of treatment following the standard guidelines developed by the Ministry of Public Health⁽¹⁹⁾. Benefits from various treatment regimens were survival years gained derived from clinical trial results and were transformed in to *Quality-adjusted Life Years*¹ (QALY's). Benefits and cost were compared for economic analysis by different alternatives.

Effectiveness to cost ratio ranged from 4 (AZT for asymptomatics) to 20 (AZT then ddI or ddC switch therapy for AIDS) QALY's per one million baht spent. Even monotherapy for the asymptomatics, on this assumption of complete coverage (treat every case), would cost more than 3 times the governmental AIDS prevention and control budget. For private affordability, about 70 per cent of the population would not be able to purchase this regimen from their nonfood expenditure. Combination therapy is much less affordable. Economic analysis demonstrated high cost and low benefit with limited affordability^(17,18).

¹ QALY's were calculated using 0.95 and 0.70 weighted scores for symptomatic HIV and AIDS respectively.

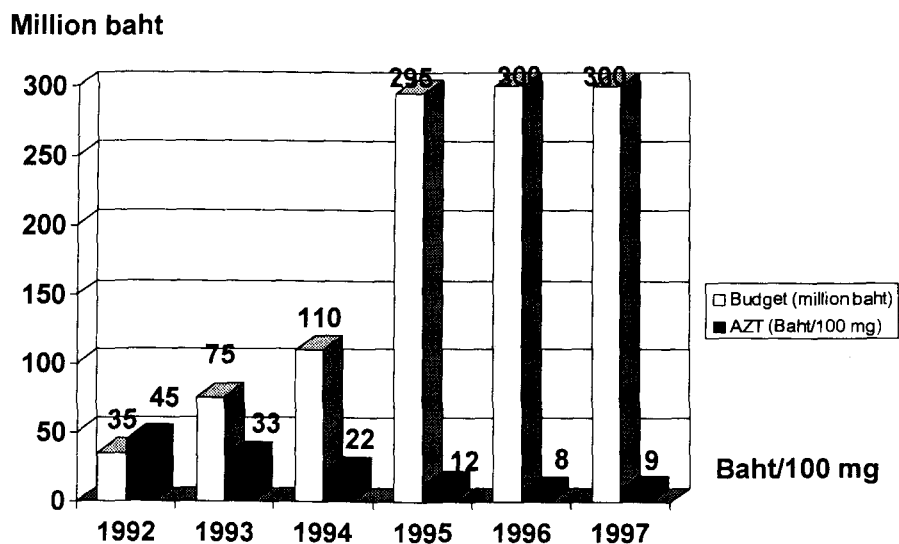


Fig. 2. Budget for anti-retrovirals and price of AZT (per 100 mg).

(3) Thailand's response

Recorded data on ARV supply was reviewed carefully. Coverage and compliance were analysed. Most cases were non-compliant and the program could cover less than 30 per cent of (AIDS and symptomatic) cases entering health care systems. Low effectiveness of the program was obviously due to low coverage and low physician/patient compliance.

From the review and the fact that patient as well as physician compliance was quite low, the Ministry of Public Health had to decide either to terminate ARV supply or to transform it to a more rational program. Low compliance could be due to unawareness of both patients and physicians, or due to lack of team work for care continuum. The health care system in Thailand has been minimally developed for chronic disease management. To solve the problem at its root, awareness and team-work have to be properly developed.

Also, increasing symptomatic HIV and AIDS cases have been perceived as a burden to the country but from another point of view, they could be an opportunity for the country to coordinate for clinical research. The MOPH decided to solve this problem by setting up a network for ARV supply.

(4) Clinical trial network of the MOPH

Carefully selected hospitals/institutions were included to ensure good participation. Unselected hospitals received ARV supplies by quota in order to relieve social pressure. Care providers in selected hospitals were invited to join the GCP (*Good Clinical Practices*)(20) training and ARV was supplied for an agreed number of cases.

The network, in the first phase, included 45 hospitals in 20 provinces throughout the country. The first protocol was a randomized open label study among 2,000 ARV naive adults comparing AZT+ddI to AZT+ddC. Endpoints would be clinical, and laboratory markers. Compliance was determined from follow-up. Results from ACTG 175(21) and Delta(22) studies have just become available. The MOPH decided to carry out this protocol and planned to compare the results with those 2 well known studies.

Preliminary analysis of protocol 1 in December 1997, 6 months after all study sites started their enrollment, revealed a total of 1,095 subjects enrolled in the study. Among them, 538 were randomized for AZT/ddI and 557 for AZT/ddC. There were 5 deaths (3 vs 2), 1 disease progression (0 vs 1), 7 dropouts (6 vs 1), 15 losses to

MOPH clinical trial network (ARVPROT1) study sites (20 provinces, 45 hospitals/institutions)

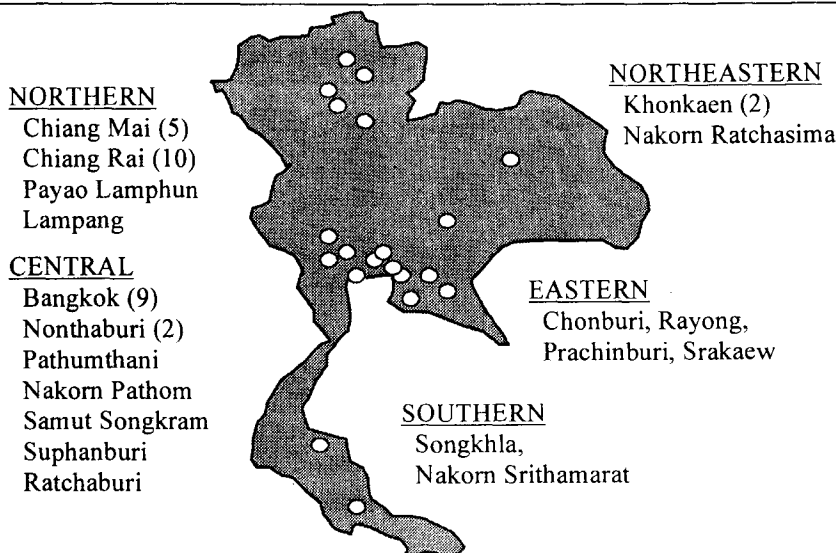


Fig. 3.

follow-up (7 vs 8), 31 Adverse reactions (9 vs 22), 10 CD₄ dropouts (4 vs 6), and 78 changes of regimen (61 vs 17). Subjects would be followed for at least 1 more year then rolled over to another protocol.

In order to coordinate the triple combination regimen and investigate how possible to include viral load monitoring for subjects in the hospitals without viral load equipment, protocol 2 was initiated in Chiang Rai, Bangkok, and Rayong hos-

pitals. The study was an open label observational study of AZT/ddI/Saquinavir among 40 HIV infected subjects (20 in each site) with CD4 more than 200 cells/mm². Viral load assay was highly recommended for every case. The MOPH supplied free medications and advised that either hospitals or subjects should contribute for laboratory investigations. This protocol aimed to induce multi-party contributions to increase partnerships and interdependency actions. Since triple combination therapy is

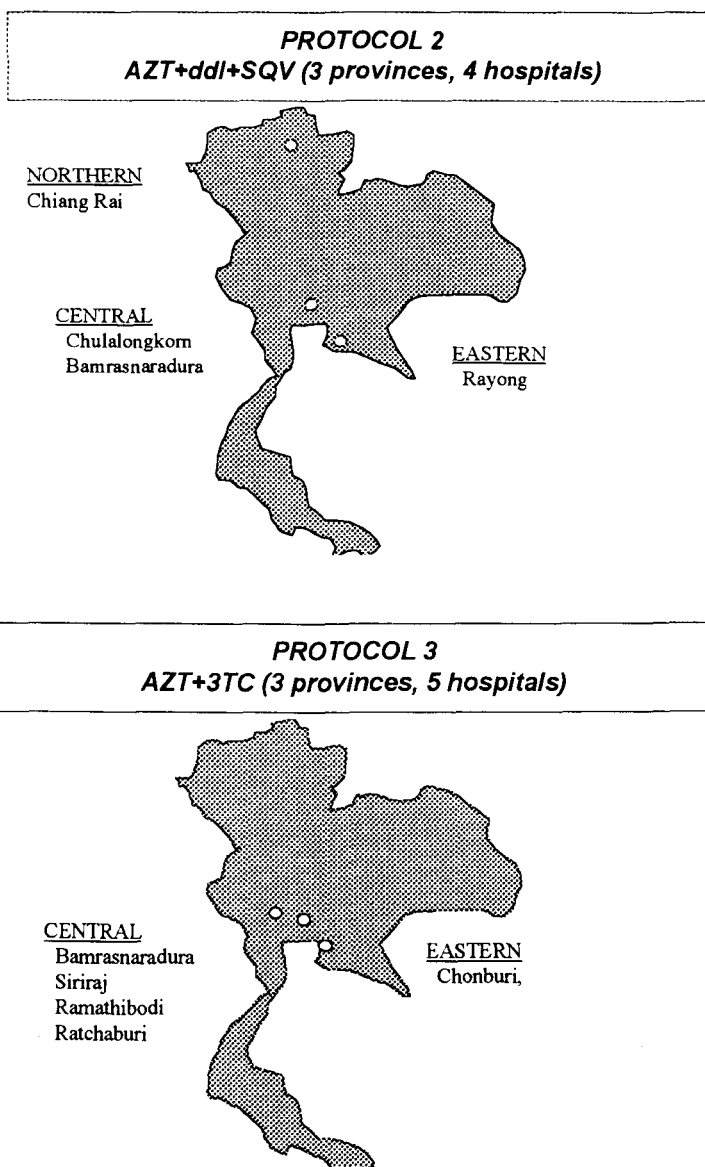


Fig. 4. MOPH study Protocol 2 and Protocol 3.

Table 1. Proposals submitted to the AIDS Division, up to January 1998.

	Anti-retrovirals	Anti-opportunistics	Immune modulators	Lab Dx and monitoring	Perinatal prevention and child care	Post exposure prevention	Alternative care
1. Adapting international technology for Thailand	41	0	0	0	6	0	0
2. Developing new technology for Thailand	0	0	1	0	0	0	1
Natural history of HIV infection	0	0	0	0	0	0	0

Note: Categorization was made according to major supply requested in the proposals with a hierarchical classification from right to left in the table. The proposal for alternative medicine requested ARV supply only for baseline therapy. Perinatal and pediatric interventions were classified in the same group because they were under consideration of the same proposal review team. The immune modulator proposal was the joint collaboration for US-NIH, the *HIVNAT*, and Thailand MOPH phase II, Interleukin-2 study.

generally complicated for both physicians and patients, it was agreed to enroll only the best compliant subjects. Enrollment was reasonably slow. Up to January 1998, 10 subjects were included in each study site.

Protocol 3 was also an open label observational study of AZT/3TC among 100 subjects in 5 hospitals; Ramathibodi, Siriraj, Bamrasnaradura, Chonburi, and Ratchaburi to investigate short term benefits and short term adverse effects. Up to January 1998, cases were completely enrolled. Data are being analysed.

(5) Expansion of the clinical research perspectives

With respect to scientific advancement and policy modifications, the AIDS Division proposed an expansion of clinical research perspectives for Thailand from only anti-retrovirals to anti-opportunistic infections, laboratory technique, prevention, development of health care settings, and alternative care to serve 3 major aspects of (1) adapting international technology to fit Thailand's environment (2) developing new technology for Thailand, and (3) studying the natural history of people with HIV/AIDS who received different treatment regimens. Proposals submitted in those possible research areas are demonstrated in 2 dimensional matrix in Table 1.

An advisory group was appointed, consisting of experts in HIV/AIDS care from university hospitals and hospitals under the Ministry of Public Health. Investigators in participating hospitals and

other hospitals were invited to submit proposals for consideration. Up to 15 January 1998, the AIDS Division received 49 proposals, 42 ARV for adults (1 ARV supply for the phase II Interleukin-2 study), 4 ARV for children, 1 herbal medicine, 2 perinatal interventions. Because of a limited budget, among adult ARV proposals considered according to scoring criteria in Table 2, only 9 proposals received full support and 1 received half support. Investigators were informed about weaknesses of the proposals and were invited to re-submit if they were not supported. The process aimed to strengthen every participating hospital, so there was no pass or fail. The goal was to make every hospital capable of conducting clinical trials.

Table 2. Scoring criteria for proposal consideration.

Considerations	Total
1. Applicability for Thailand	10
2. Scientific validity	10
3. Feasibility (design, size, complication)	10
4. Standard publishability	10
5. Best beneficial and negotiative considerations (free study medication, technology transfer)	10
6. Infrastructure development, multi-center approach	10
Total	60

Source: originated by Kiat Ruxruntham on behalf of the advisory group.

DISCUSSIONS AND CONCLUSIONS

Thailand is one of the few countries where government supply of anti-retrovirals has been institutionalized. The program generates both positive and negative impacts to HIV/AIDS care. Rapid response by the government allows more HIV/AIDS cases to get access to care which, subsequently, causes more workload to the health care system. Careful evaluation identifies the need to develop comprehensive and continuum of care for HIV/AIDS. Central supply of anti-retrovirals is then, now, a tool to bind participating hospitals together in the clinical trial network.

Evolution of anti-retroviral supply in Thailand results from coincidences of the rapid epidemic, economic growth, immediate responses, and demand for drug trial platforms. The explosive epidemic calls for public and private concerns. Economic growth allows the government to be capable of supplying anti-retrovirals continuously. Scientific advancement facilitates new anti-retroviral development and increases demand for clinical trial sites/subjects.

In the first years of full subsidized ARV supply, physicians and hospital administrators were more interested in HIV/AIDS care. One of the reasons was they received anti-retrovirals without any need to negotiate for more budget. Spill over was minimal because medications were supplied directly to target hospitals. However, the process induced dependency and most administrators did not see any need to set up their budget on this. Since 1994, the AIDS Division reached its full capacity of supply because of overwhelming requests.

While technology progressed, new anti-retrovirals were developed and monotherapy become obsolete. With a limited budget, subsidy for combination therapy would yield less coverage. Program adjustment had to be rational on justifications. The turning point was in 1995 when program evaluation started. Thailand responded to this quite well by dissociating supply for services to supply for research. The AIDS Division was assigned to do supply for research while supply for services was incorporated into regular systems.

Thai MOPH adjusted subsidized the ARV supply program to clinical research network in

1996. Case enrollment started in 1997. More than 45 hospitals/institutions participated in the first protocol. The network expanded its perspective from only anti-retroviral study to broader areas of HIV/AIDS care including immune modulators, opportunistic infections treatment or prophylaxis, laboratory supports, and alternative care.

The immediate aim of program adjustment was to develop the system to be capable of providing care for chronic diseases including HIV/AIDS. The increasing number of AIDS patients has been perceived as a burden to the country but is now being transformed into clinical research opportunities because three essential elements of (1) participating hospitals, (2) team training, and (3) strong coordinating bodies were identified. Participating hospitals with good health teams were at the frontiers. The AIDS Division supported their training and medical supplies.

Another possible outcome of infrastructure building was an observational database for Thailand. Piece by piece, information from following-up HIV/AIDS cases, either with or without treatment, could eventually be put together to make observational databases for a clear picture of natural and modified courses of HIV/AIDS in Thailand. Similar databases have been established in Europe, North America, and Australia⁽²³⁻³⁰⁾. The AIDS Division serves as the central data processing and analysis unit.

More training is obviously needed in this network. Care providers in participating hospitals need more HIV/AIDS care knowledge and skills. They should also be trained for good data collection, data handling, laboratory facilities, and on site data analysis. Basic and refresher courses on these issues must be regularly organized to reassure integrity of the network and to allow more participating personnel to circulate in and out of the network.

With the evolution, participating hospitals will be strengthened for future *multicenter-same-protocol*. This would facilitate a collaboration for HIV drug and vaccine development. Thailand's experiences should be perceived as an evolving model in a developing country with explosive HIV infection and could be treated as a lesson learned for other countries.

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วิวัฒนาการบริการทางแพทย์สำหรับผู้ติดเชื้อผู้ป่วยเอดส์ในประเทศไทย

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วิพุธ พูลเจริญ, พ.บ. M.P.H.*, ยุทธ โพธารามิก, พ.บ.*

เบื้องหลัง: ประเทศไทยเริ่มการสนับสนุนยาต้านไวรัสให้ผู้ป่วยเอดส์ที่มีรายได้น้อย ตั้งแต่ปี พ.ศ. 2535 งบประมาณสำหรับการนี้เพิ่มขึ้นอย่างต่อเนื่อง แต่ก็ไม่เพียงพอกับความต้องการที่เพิ่มมากกว่าเป็นผลทำให้ความครอบคลุมในการสนับสนุนยาลดลง นอกจากนี้วิทยาการด้านการรักษาที่เปลี่ยนไปอย่างรวดเร็ว ทำให้ต้องใช้ยาที่มีราคาสูงขึ้น ยิ่งทำให้ความสามารถในการหาหาเพื่อการรักษาในประเทศกำลังพัฒนาน้อยลงไปอีก ในปี พ.ศ. 2538 กระทรวงสาธารณสุขด้วยความร่วมมือขององค์การอนามัยโลกและธนาคารโลก ได้ทำการทบทวนโครงการ พบว่าค่าใช้จ่ายยาต้านไวรัสไม่ก่อให้เกิดผลได้ที่คุ้มค่า จึงทำให้มีการปรับเปลี่ยนนโยบายการสนับสนุนยาต้านไวรัส จาก "การสนับสนุนให้ตามหืขอ" เป็น "การสนับสนุนเพื่อการวิจัย" และด้วยเหตุที่การระบาดของเอดส์ในประเทศไทย ยังคงขยายตัวอยู่เรื่อย ๆ ประกอบกับภาวะเศรษฐกิจถดถอยในช่วงที่ผ่านมา ทำให้ประเทศไทยต้องปรับนโยบายต่อไปอีก เพื่อให้เกิดความเหมาะสมทั้งทางด้านวิทยาศาสตร์ จริยธรรมและภาวะเศรษฐกิจ

กิจกรรม การสนับสนุนยาต้านไวรัสจึงขยายออกไปเป็นการสนับสนุนเวชภัณฑ์ เพื่อศึกษาวิจัยด้าน (ก) ปรับสูตรการรักษาที่ใช้ในต่างประเทศเพื่อให้เหมาะกับคนไทย (ข) พัฒนาสูตรการรักษาใหม่ที่เหมาะสมกับคนไทย (ค) ธรรมชาติวิทยาของการติดเชื้อ ไม่ว่าจะเป็นการรับยาต้านไวรัส ยารักษา หรือ ป้องกันโรคติดเชื้อฉวยโอกาส และการรักษาในทางเลือกอื่น นอกจากนั้นการตรวจทางห้องปฏิบัติการและการป้องกัน ก็เป็นแขนงที่ต้องพัฒนาควบคู่กันไป เพื่อที่จะให้สามารถใช้งบประมาณด้านนี้ที่มีประมาณปีละ 300 ล้านบาทให้คุ้มค่าที่สุด ในการนี้สถานพยาบาลที่สนใจ จะได้รับเชิญให้ร่วมเครือข่ายวิจัยการให้บริการทางการแพทย์ที่จัดตั้งขึ้นมา ตั้งแต่ พ.ศ. 2539 โดยส่งโครงร่างการวิจัยเพื่อรับการพิจารณาและรับการสนับสนุนทรัพยากร โครงร่างการวิจัยเหล่านี้ จะได้รับการให้คะแนนตามเกณฑ์ ทั้งด้านเนื้อหาและความสอดคล้องกับสภาพการณ์ โครงการแรกที่ได้เริ่มดำเนินการตั้งแต่ พ.ศ. 2540 เป็นการศึกษาแบบเปิด เพื่อเปรียบเทียบผลการรักษาระหว่างการใช้ยา AZT+ddC กับ AZT+ddI ในติดเชื้อ/ผู้ป่วย 1,200 ราย โครงการที่สองศึกษาผลการรักษาด้วยยาสามชนิดพร้อมกัน ในผู้ติดเชื้อ/ผู้ป่วย 40 ราย ทั้งหมด ในสถานพยาบาล 58 แห่งทั่วประเทศไทย และเพื่อให้ได้มาตรฐานที่ดี ในการศึกษาวิจัยผู้ร่วมเครือข่ายยังได้รับการอบรม Good clinical practice (GCP) ด้วย นอกจากนี้เครือข่ายยังดำเนินการผ่านโครงการพัฒนาระบบ การดูแลรักษาผู้ติดเชื้อ ผู้ป่วยเอดส์ เพื่อสนับสนุนให้สถานพยาบาลเหล่านี้ มีบริการให้คำปรึกษาและบริการทางสังคมไปพร้อมกัน

จนกระทั่งถึงวันที่ 15 มกราคม พ.ศ. 2541 มีโครงการที่ขอรับการสนับสนุนเวชภัณฑ์ส่งให้พิจารณาจำนวน 49 โครงการ (ยาต้านไวรัส 42 สมุนไพร 1 และ การป้องกันการติดเชื้อจากแม่สู่ลูก กับการรักษาในเด็ก 6 โครงการ) คณะผู้เชี่ยวชาญซึ่งประกอบด้วยอาจารย์และนักวิชาการจากมหาวิทยาลัยและโรงพยาบาลของกระทรวงสาธารณสุขร่วมกันพิจารณาและให้คะแนนโครงการเหล่านี้ โครงการที่ได้คะแนนสูงได้รับการสนับสนุนเวชภัณฑ์ ส่วนโครงการที่ได้คะแนนต่ำได้รับคำแนะนำเพื่อปรับปรุงโครงการต่อไป

สรุป การสนับสนุนยาต้านไวรัสจากส่วนกลางที่ผ่านมากระตุ้นให้แพทย์ทำการรักษาผู้ป่วยมากขึ้น แต่ในขณะเดียวกันก็ทำให้เกิดการชะลอตัว ในการจัดทำค่าของงบประมาณของหน่วยงานเหล่านั้น เครือข่ายวิจัยการให้บริการทางการแพทย์ได้ก่อให้เกิดการสร้างทีมงานและพัฒนาโครงสร้างพื้นฐาน อันจะนำไปสู่ความพร้อม เพื่อทำการวิจัยทั้งการรักษาและการพัฒนาวัคซีน ตลอดจนการพัฒนาระบบฐานข้อมูล อย่างไรก็ตามบุคลากรในเครือข่ายก็ยังต้องการการพัฒนาอย่างต่อเนื่อง บทเรียนที่สำคัญคือพัฒนาการในด้านนี้ของประเทศไทยเป็นได้เพียงตัวอย่างสำหรับประเทศกำลังพัฒนาอื่นๆ มิใช่เป็นต้นแบบที่สามารถจะนำไปใช้ได้ทันที

คำสำคัญ : โรคเอดส์, บริการทางการแพทย์, วิจัยทางคลินิก, เครือข่าย, ประเทศไทย

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