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投稿規定

〔Review Article〕

# The Roles of Volunteers in Promoting Community-based Care for People with HIV/AIDS in Developing Countries

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**Abstract**

HIV infection continues to spread in populations particularly in many developing countries. Home-based care from volunteers is one potentially viable and sustainable form of care in that traditional family structures are already stressed and increased burdens of care are reaching breaking point. Community-based care is needed to promote widely in order to sustain care and reduce their burden. The use of volunteers for dealing with the social consequences of AIDS could be one of the ways to promote and support community-based care. Four examples of existing programmes are evaluated in this paper. These are the AIDS Support Organization in Uganda, the Shanti Project in the US, Terrence Higgins Trust in UK and Family AIDS Caring Trust in Zimbabwe. From the review of literature, the following main lessons become clear. Volunteers play an important role in dealing with the social consequences of AIDS and help to reduce the budget of HBC in developing countries. When selected elements of programmes are introduced from developed countries to developing countries, a number of issues need to be considered, such as : cultural and technological appropriateness, availability of local resources, acceptability in the local context and cost-effectiveness. In order to promote the success of community-based AIDS volunteer programmes, there are a number of points that should be taken into account. For example, incentives and confidentiality, limited service coverage, quality control of activities and support systems. In terms of sustainability of programmes, points to be considered include : donor dependency, community initiatives and flexibility.

**Key words:** HIV/AIDS, volunteers, commuinty-based care, developing countries

## 1. Introduction

Despite considerable prevention efforts, Human Immunodeficiency Virus (HIV) infection continues to spread in populations, particularly in many developing countries. By 2005 the population of the most severely affected countries in Africa will be 13—59 million less than it would have been without Acquired immune deficiency syndrome[1] (AIDS). While sub-Saharan Africa remains the region thus far hardest hit by the HIV/AIDS pandemic, recent epidemics have been identified in Southeast Asia[2]. Public health systems in poor countries, already heavily burdened with demand for health care before the AIDS pandemic, are finding it difficult to cope with AIDS[3].

Home-based care (HBC) is one potentially viable and sustainable way of method providing quality of care while avoiding overwhelming hospitals with AIDS patients. However, traditional family structures, already stressed by poverty, poor health, and increased burdens of care, are in many instances reaching the breaking point[4]. Therefore, there is an argument for investing in community-based care (CBC) for persons/people with AIDS (PWA) and their families in order to sustain care and reduce their burden. Making optimum use of community solidarity and social capital for dealing with the social consequences of AIDS could be one of the ways to promote community-based approaches to supporting PWA. Volunteers can diminish the social isolation of PWA and their families, while helping them with practical tasks of daily life[5]. This paper examines the characteristics and roles of community-based

volunteer programmes which have been established to support the growing number of PWA, and their families in developing countries. It attempts to assess the impact on health of such programmes.

## 2. Current strategies for care and support in developing countries

### 2.1. Home-based care

*2.1.1. Definition and types of HBC*

HBC has assumed various meanings in different situations and countries. WHO/GPA defines[6] HBC as "a programme that, through regular visits, offers health care services to support the care process in the home environment of the person with HIV infection. Home visits may be the only service provided, or they may be part of an integrated programme which offers the patient and his family services in the home, hospital or community". One goal of HBC is to provide comfort and support. It is part of the continuum of care from the household to the national level. However, HBC often only focuses on the patient and the family and on how they can be helped to look after the patient. According to Osbome-CM et al[7], it is divided into five models: (1) hospital outreach, (2) NGO-based, (3) church-based, (4) community-rooted and (5) PWA network. Cameron-C et al[8] identifies two models: health service initiated HBC and community initiated HBC.

*2.1.2. Current situation of HBC in developing countries*

In sub-Saharan Africa and parts of Asia, the initiative to set up home-care services has often come from an NGO and has been reliant on external aid support[9]. Donor dependency may develop and sustainability is increasingly becoming an issue to consider at the inception or renewal phase of projects[9].

*2.1.3. Advantages of HBC*

There are a number of advantages of HBC. These include:

1) HBC is often cost effective compared to hospital care

2) The patient is not excluded from the community

3) Family support for the PWA is strengthened

4) Very sick or dying people often prefer to stay at home

*2.1.4. Disadvantages of HBC*

The main disadvantages of HBC are:

1) Family support and care for PWA are not always available

2) There is a risk of overburdening the individual carer or household

3) Levels of coverage are often low

4) Many patients at some phase of their disease need more than their home can provide

5) Lack of access to referral and to support when needed

### 2.2. Community-based care

*2.2.1. The meaning of community*

The term community is one of the most complex and imprecise in the vocabularies. In 1992 for the World AIDS Day, the Director General of the WHO defined 'community' in very narrow and apolitical ways: 'The community—be it neighborhood, the school or the college community, a professional groups or the smaller support network composed of family and friends—is a uniquely powerful force in societies everywhere'[10]. Nevertheless, often place is the crucial variable, and community is defined in geographical terms, and many of the central works in community studies assume a geographical base to community[10]. In this paper, the meaning of community is used rather in geographical terms, and CBC is used instead of using other words, such as community-based approach, community-based action, community-based strategy and community-based progamme.

*2.2.2. The importance of CBC*

One of the main objectives of CBC could be to compensate for the deficiencies of HBC. A Rwanda home care model[11] showed that the CBC has proved to be sustainable, capable of reaching target audiences over wide geographic areas, and reduces community fears and prejudices about AIDS. According to the report of the WHO[12], the HBC project will only continue to be beneficial if an emphasis is placed on community involvement in support of AIDS patients, if voluntary service is encouraged, and if AIDS programmes are integrated into existing primary health care (PHC) activities. CBC as part of a continuum of care may reduce the cost of institutional health care and improve the quality of life of PWA and their fami-

lies[7].

## 3. Use of volunteers for dealing with the social consequences of AIDS

### 3.1. Motivation of general volunteers

In general, volunteers' motives may extend further than the simple desire to help their neighbor. For example, given the tough job market, some individuals are volunteering as a possible bridge to employment, and are eager to learn to skills and gain experience that they might transfer to a new work setting[13]. However, a study of Marx-JD[14] showed that those who volunteer in health and human services, in comparison to those who do not, were more likely to be motivated by an opportunity to gain a new perspective on things. In addition, human service volunteers were also more apt to be motivated by altruistic reasons.

### 3.2. Motivation of AIDS volunteers

One of the findings of a study which was conducted in a HIV social care centre in South London showed that common motivations for volunteering were to learn more about HIV, to give something back to affected communities, and to gain job-relevant experience[15]. The case of volunteers who worked in an AIDS hospice in Toronto showed that volunteers were motivated by a general desire to contribute, as well as a desire for interaction and personal growth, and to experience hospice models of care[16].

### 3.3. Typical problems of AIDS volunteers

There are a number of limitations in the use of volunteers: for example, the problems of volunteers' limited time, uncertain motives, and a high degree of individual independence can result in debilitating levels of uncertainty for organizational volunteers[17]. Concerning AIDS volunteers, typical problems include such as stigma and work-related psychological distress (i.e. burnout).

### 3.4. Stigma

AIDS stigma affects the well-being of PWA and influences their personal choices about disclosing their serostatus to others. It also affects PWAs' loved ones and their caregivers, both volunteers and professionals[18]. Volunteers and non-volunteers experience AIDS volunteerism as more stigmatizing than other forms of volunteerism, and potential stigmatization prevented non-volunteers from helping an AIDS organization[19].

### 3.5. Burnout

Maslanka-H[20] has pointed out that care providers working with people with HIV have shown high levels of burnout as staff were required to deal with a multi-faceted disease, while creating new ways of working with clients. At the same time high burnout levels were also being seen among volunteers who were supplementing the work of paid staff. Claxton-RPR et al[21] reported that burnout is a probable cause of dropout among emotional support volunteers who work with PWA and burnout has a significant cost implications for voluntary organizations in terms of training and recruitment. This study also indicated that although burnout is an important psychological factor in retaining volunteers, it was not possible to identify individuals at risk of burning out either from their self-reported motivations or from demographic factors.

Nesbitt-WH et al[22] compared volunteers and health care professionals in terms of burnout. They found that burnout in volunteers may be different from that in health care professionals for the following reasons: 1) volunteers choose to work in the HIV/AIDS areas, 2) they have control over the time they spend volunteering, 3) volunteers are internally motivated to work in the HIV/AIDS area and 4) if the volunteers do not enjoy the work, they can terminate their involvement with minimal cost.

## 4. Review of existing community-based AIDS volunteer programmes

### 4.1. The AIDS Support Organization (TASO): Uganda

*4.1.1. History*

TASO was the first organized community response to the AIDS epidemic in Uganda[23]. It was founded by Noreine Kaleeba in 1987 after her husband died from AIDS and brought together people who were themselves infected, or who were living with people who were infected[10]. In the book of Hampton-J[24], Mrs. Kaleeba explained that the idea of TASO originated from the example of the doctors and nurses who looked after her hus-

band in Britain in particular the buddy system of counselling of the Terrence Higgins Trust. TASO came into existence in order to address the needs of PWA and their families through provision of counselling, medical and nursing care and material assistance, first in Kampala and, with time and experience, it responded to requests from other towns to set up centres[25].

*4.1.2. Main programmes and finances*

AIDS support programmes have four main aspects: 1) counselling, to improve quality of life and prevent spread of disease; 2) provision of medical services, including home care; 3) social welfare, and 4) community initiatives[26]. For example, the community initiatives began in 1990 when TASO recognized the urgent need to empower people at the local level so that they could tackle AIDS-related problems themselves. Since its establishment in 1987, there are a number of partners and agencies[25]. Some of the main external funding agencies are Action Aid, the Overseas Development Administration (UK), and the United States Agency for International Development[25].

*4.1.3. Training and the roles of volunteers*

Coghlan-A et al[27] explained that TASO launched the community initiatives programmes in 1990 in order to empower people within their own communities to prevent the further spread of HIV and to better support PWA. Under this programme, TASO trainers help community leaders from a village AIDS committee and identify community needs and objectives. Local leaders then select community volunteers, who receive training from TASO in AIDS prevention, education, counselling, and care. They conduct formal and informal educational sessions with groups and individuals, visit homes to provide counselling and assistance with care.

### 4.2. The Shanti Project: the US

*4.2.1. History*

The Shanti Project was founded in 1974 by Dr. Charles Garfield, a research psychologist, and began as a nonprofit community-based organization to deal with the problems of death and dying in San Francisco[28]. In 1981, its focus shifted to the AIDS epidemic, and in 1982, Shanti contracted with the San Francisco Department of Public Health to provide counselling services and a housing programme for PWA[28].

*4.2.2. Main programmes and finances*

The Shanti project provides 4 main services: emotional support and counselling, information and referral services, practical support and housing services. Local government provides the bulk of support (60% of total revenue) to the project, with private donations (40%) the second largest source of funding. In its volunteer programmes, the project relies heavily on donated labor. Arno-Ps[28] pointed out that a fundamental reason for the survival of these groups is their extensive use of volunteer labor.

*4.2.3. Training and the roles of volunteers*

Emotional support and counselling services are provided by the Shanti Project whose trained professional and non-professional community volunteers offer free long-term counselling to PWA, their sexual partners, and their families[28]. Practical support programmes provide volunteers to help with normal day-to-day activities such as cooking, cleaning, doing the laundry, shopping, and getting from one place to another. At the Shanti project, volunteers provide the bulk of services themselves, once they are adequately trained. The training of the emotional support programmes includes overviews of the medical and psychological aspects of AIDS, substance abuse modification techniques, grief counselling specific to AIDS, alternative therapies and information on the services of other AIDS provider organizations. The training of the practical support volunteers includes an AIDS medical overview, basic training on lifting and physically assisting debilitated persons, group dynamics, assessing suicide risks and evidence of substance abuse that requires referrals, and use of role-playing to develop the necessary skills for helping clients.

### 4.3. Terrence Higgins Trust (THT): UK

*4.3.1. History*

According to a leaflet (An introduction to the HIV and AIDS charity for life) of THT, it was formed in 1982, when Terry Higgins became one of the first people in the UK to die of AIDS. A group of his friends set up THT to fight discrimination against PWA, after witnessing his treatment while in hospital. After the organization received its first grant from the Department of

Health, THT's charitable status was confirmed and private donations began to come in[29]. The THT claims that they are now the largest HIV charity in Europe and have five offices across England, serving 70 percent of people diagnosed with HIV.

*4.3.2. Main programmes and finances*

The THT provides practical support, help, counseling and advice for anyone with or concerned about AIDS and HIV infection[30]. It provides three support services; 1) community support services such as counselling, buddies (one-to-one befriending service), helper cell (practical support to people with HIV who would otherwise be unable to do certain tasks by themselves) and hardship fund (financial help), 2) information services (helpline, information centre, websites, treatment support service) and 3) advice services (housing, welfare rights and legal advice). According to the annual report of 1997—1998[29], most of its annual revenue in 1998 came from grants and contracts (50.0%), voluntary income (42.9%). Overall, resources mainly spent on health promotion (40.1%), advice centre (17.5 %), marketing (17.1%), and care and support services (15.2%).

*4.3.3. Training and the roles of volunteers*

Some of the services (e.g. buddy service and helper cell) are mainly carried out by volunteers. The THT's volunteers are unpaid and they are only provided lunch and transportation expenses. The buddy service was created in 1984. Buddies are trained volunteers who befriend and support PWA and symptomatic HIV positive on a one-to one basis, according to individual needs[31]. The buddy service is provided by just under 600 trained volunteers and managed by a staff term of five[31]. Buddies are required to attend an initial training weekend, monthly support meeting and are offered regular ongoing training sessions. The helper cell service provides practical support to PWA living in London who would otherwise be unable to do certain tasks by themselves[32]. Services include driving, interpreting, plumbing, electrical and do it yourself jobs, light removals, gardening, domestic help, pet-care and hairdressing. The work is carried out by selected, trained volunteers, who have the necessary skills, but they are not usually professionally qualified (except for car drivers and electricians)[32].

**4.4. Family AIDS Caring Trust (FACT): Zimbabwe**

*4.4.1. History*

FACT was formed in Mutare, Zimbabwe's third largest city in 1987[33]. It is a volunteer organization with most of its manpower initially coming from Christian religious organizations[34]. At the beginning, participants planned the development of FACT's counselling, education, administration and information activities. After several months, a complementary method of providing support for PWA was established. FACT's home care programme started in 1992[33]. Moreover, FACT has initiated a programme called Families, orphans and children under stress that makes links with, and trains and supervises women of local church groups to support orphaned children[7].

*4.4.2. Main programmes and finances*

The main programmes of FACT are community-based AIDS education, counselling, information service, home care service and support of orphaned children.

In terms of home care, the programme operates in the urban area of Mutare, which contains three townships with a population of 131,367. The area employs a trained nurse as a coordinator and four assistants, each assigned a zone within the city, who carry out the bulk of the visits. Although members on a voluntary basis undertook initial FACT's activities, after 3 months, sufficient funds had been raised within the community to employ a secretary to coordinate the work of volunteers. Most of the first year's budget was received as donations from members and local businesses[34].

*4.4.3. Training and the roles of volunteers*

Though some of the programmes (such as home-care service) do not involve lay volunteers, volunteers contribute to many of FACT's activities. FACT's approach has been to involve as many people as possible in each aspect of its work. The principle of volunteer participation is incorporated into the training of volunteers; each is encouraged to initiate their own educational programme; and financial assistance and resources such as information leaflets and teaching aids are provided[34].

## 5. Discussion

### 5.1. Application to different social contexts

The question is raised as to whether these community-based care cases can be applied to different groups in different social contexts and cultures. For example, whether cases from developed countries replicable in developing countries or not. Asthana-S and Oostvogels-R[35] explained that good examples of communal action to prevent HIV and to support people with AIDS come from within the gay community. These include THT in the UK, the Gay Men's Health Crisis and the San Francisco AIDS Foundation in the US. As well as focusing on the gay community, which is a generally well organized section of society in developed countries, most of them are middle-class phenomena. Whereas HIV if now spreading fastest among the poor in all countries[36], who may not have the resources to support on the power to utilize such cases. However, Martin-AL[37] asserted that the San Francisco model (the Shanti Project) is applicable to other settings if certain conditions are met. For example, a safe environment; the presence of a lay caregiver, whether family member, partner, friend, or volunteers; and accessibility to a range of health care and social services. However, there is no need to replicate everything. For example, as the founder of TASO, Mrs. Kaleeba was influenced by the buddy system of counselling in THT, it is a good idea to introduce selective elements of programmes, which are feasible, suitable and appropriate to the new settings. In particular, when a selected elements of programmes are transferred from developed countries to developing countries, attention should be given to a number of points. These include such as cultural and technological appropriateness, availability of local resources (personnel, equipment and finances), acceptability in the local context and cost-effectiveness. It is also important to consider the capacity of local social and health services, forging links between there and volunteer programmes, and statutory services to support such programmes. Particularly, cultural appropriateness is one of the most important points for adapting a new programme from different cultural setting. It should be analyzed carefully beforehand whether local people can trust and support the use of volunteers, and understand issues around stigma and social vulnerability.

### 5.2. Advantages of use of AIDS volunteers for promoting community-based care

As the four cases of community-based AIDS volunteer programmes reviewed here have demonstrated, volunteers play an important role in dealing with the social consequences of AIDS. For example, volunteers act as "supportive friends" and allow subjects the opportunity to express their feelings[38]. AIDS volunteers can help PWA with practical tasks, increase community awareness, reduce the burden on caregivers, promote a spirit of cooperation within their community, and help to reduce the budget of HBC in developing countries.

### 5.3. Main issues in considering the use of AIDS volunteers

A number of points should be taken into account in order to ensure the success of community-based AIDS volunteer programmes. These include the need for incentives for volunteers, confidentiality for both volunteers and PWA, funding, expansion of service coverage, quality control of activities and care for volunteers. In terms of incentives, Wyant-S and Brooks-P[13] believe that although volunteers may appreciate the traditional certificate pin or letter of thanks, volunteer administrators should explore other means of recognition that are tied in to the individual volunteer's motives for volunteering in the first place. Wellington-F et al[39] reported that in both Zambia and Jamaica, the provision of non-monetary incentives such as badges, t-shirts, and training materials enhanced voluntary participation in the effort. Regarding the four cases from the US, UK, Zimbabwe and Zambia, apart from THT, it was not explained in detail whether these organizations provide any monetary or non-monetary incentives to their volunteers. However, it is important to recognize the minimum needs of volunteers in order to enhance voluntary participation.

Confidentiality is one important ethical issue in using CBC. For example, the Director of TASO will not greet new clients and counselors in public places, and there is no sign outside the TASO of-

fice[24]. As many professionals and lay volunteers are involved, education and careful selection of volunteers is important.

Limited service coverage is another concern. The CBC needs to be extended more widely in order to cover for all PWA who require CBC. For example, the FACT programme has a coverage of 2.5—23% [40]. In contrast, the THT claims to serve 70% of people diagnosed with HIV in England. Although it may be difficult to achieve wide coverage on small budgets and limited number of volunteers in many developing countries, it is desirable that equitable distribution of services for many PWA and their families.

Quality control of activities are probably indispensable to the success of programmes. As shown by all our cases, effective training and supervision of volunteers is essential. In order to do their work to the best of their ability, they need to be given the best training possible.

In addition to the training, daily support systems are also important. Nesbitt-WH et al[22] pointed out that in order to deal with their emotional needs special attention should be paid to allowing volunteers freely to express problems associated with emotional overload and high workload; and providing clear emotional support was essential. Barbour-RS[41] also reported that lack of role clarity was a salient factor with regard to psychological distress amongst volunteers. Moreover, younger, more inexperienced volunteers appeared to be at great risk of psychological distress. Many people who act as community-based AIDS volunteers are frequently seropositive themselves. As a consequence, if clients, staff or volunteers have any illnesses such as tuberculosis or shingles, these illnesses will easily transmit among them. Therefore, special consideration is needed in the selection of AIDS volunteers. Without any support for volunteers, they may be become demoralized, over burdened resulting in high turnover.

### 5.4. Sustainability

As the HIV/AIDS pandemic progresses, funders are increasingly supporting established organizations[42]. Many community-based AIDS programmes in developing countries depend upon external assistance, and it has serious implications for programme continuity and sustainability. For example, as the scale and the coverage of TASO rise, most of the budget relies upon international organizations' fund. However, it is not only programmes in developing countries but also many programmes in developed countries which have serious problems around sustainability. For instance, the Shanti Project and the THT rely heavily on donated labor. Their financial status also depends mostly on local government, private donations and grants. In developing countries, one can not count on governments for financial support. However, the Family Health Trust in Zambia has deliberately sought to reduce dependence on foreign donors by seeking local funds from business operating in the country[10]. Furthermore, as the first year's budget of FACT was received as donations from members and local businesses, particularly in developing countries, it is necessary to reduce too much reliance on external funders and find sustainable methods of fund-raising. Asthana-S and Oostvogels-R[35] suggest that community fundraising and the use of volunteers in education, counselling and care is often necessary in the absence of official support or funding. Therefore, consideration should be given to measures such as community fundraising and consideration of how to use the limited financial resources in the most cost-effective way, in order to increase income and control expenses in resource poor settings.

Another concern is if the programmes are led by NGOs or the government, and not by the community itself. O'Malley-J[42] noted that communities need to take control themselves, communicate messages among themselves which are understood and respected, follow their own leaders, and take actions that are appropriate and effective. Clement-M et al[43] also pointed out that this is the surest way to begin an initiative at community level which will result in sustained behavior change. From these points, it can be said that even if a community-based programme is initially led by NGOs or the government, the community should take control, and rearrange programmes appropriate to their community's needs. Moreover, as the THT's clients have been extended to general people such as women and immigrants, and the Shanti Project shifted its focus from the

problems of death and dying to the AIDS epidemic, their flexibility to meet the demands of the time should be a good example of how to sustain and develop programmes.

## 6. Conclusion and recommendation

To sum up, from the review of literature, some of the main lessons become clear. Firstly, volunteers play an important role in dealing with the social consequences of AIDS and promote community-based care. Together with the activities of volunteers, this has enabled individuals to remain in the community and help to reduce the budget of HBC in developing countries. At least following five points should be taken into account in order to promote the success of community-based AIDS volunteer programmes.

- Incentives for volunteers
- Confidentiality for both volunteers and PWA
- Limited service coverage
- Quality control of activities
- Support systems for volunteers

Secondly, in terms of sustainability of programmes, the following three points need to be consider.

- Donor dependency
- Community initiatives
- Flexibility

Thirdly, as four examples of community-based AIDS volunteer programmes have been demonstrated, these cases can be replicated to different groups in different social contexts, if certain conditions are met. These conditions include cultural and technological appropriateness, availability of local resources, acceptability in the local context and cost-effectiveness.

Finally, what is probably most important is motivation of local people to support. Without people's cooperation it is very difficult to start and sustain such programmes. Therefore, it should be analyzed carefully beforehand whether such programmes meet the needs of local people and whether many people express their willingness to support programmes for their community. However there are no enough resources in many developing countries, and there may be limitation of their own efforts to promote such programmes. Therefore, forging link between local social and health services and volunteer programmes and statutory services to support such programmes are important.

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# 途上国におけるHIV感染者/AIDS患者のためのコミュニティベースドケア推進に果たすボランティアの役割

大友　優子

国立公衆衛生院　公衆衛生看護学部

途上国におけるHIV感染者/AIDS患者のための在宅ケアは，ひとつの実行・持続可能な選択方法であるが，伝統的な家族構成は，増え続けるAIDS患者のために責務と重圧で既に崩壊寸前にある．本稿は途上国において，地域に根ざしたエイズプログラムを推進するために果たすボランティアの役割について明らかにすることを目的とした．ボランティア活動の重要性と役割を評価するために，4つのHIV感染者/AIDS患者の支援プログラムについて文献レビューを行った．主な結果として，ボランティアは患者の在宅ケア経費を削減し，偏見や差別等の社会的影響を軽減する等の重要な役割を担っていること，また，先進国のエイズプログラムを途上国に適用する場合は，文化や技術の適性，地域資源活用の可能性，地域の受け入れ状況や費用効果等の問題があること等が明らかになった．

**キーワード：**HIV/AIDS，ボランティア，コミュニティ・ベースド・ケア，発展途上国

〔Original Article〕

# Analysis of Medical Charge by Length of Stay in Korea
## —The Case of Treatment for Herniated Lumber Disc—

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**Abstract**

The purpose of this study is to analyze the effect of hospital revenue increase by shortening length of stay after examining of medical charge by details of treatment. In doing so, herniated lumber disc is chosen and the aspect of medical charge for it by length of stay is first examined. 169 patients who were discharged from an university hospital of 1,000 beds scale from January 1, 1997 to December 31, 1997 after treatment for herniated lumber disc were made the subject of this study. Medical charges by details of treatment and length of stay ware investigated according to operated cases or unoperated cases. Medical charge for herniated lumbar disc in case of operation was low on the first day of admission However, it was high on the second and the third day of admission, while it rapidly decreased on the forth day of admission. It gradually decreased after the fourth day and finally displayed constant level. According to the results of the effect of annual revenue per bed by shortening the average length of stay by one day, increase of the annual revenue was 1,674,588 won in case of operated patients, while it was 809,763 won in case of unoperated patients.

**Key words :** length of stay, hospital bed utilization, medical charge, hospital revenue

## I. Introduction

Many general hospitals in Korea experience the adverse balance between revenue and expenditure although they face beds shortage due to increase of the demand of admission after introduction of national health insurance[1]. This situation happens because length of stay (LOS) by increase of a chronic degenerative disease increases.[2] Also, medical cost under management of International Monetary Fund (IMF) which brought increase of wages and materials cost influenced the situation[3]. To solve the problem of bed shortage under this situation, the government and private sector are planning to increase large-scale hospitals, However, they need make first of all attempts to improve the balance in hospital.

To adopt the method which can improve the balance in hospital, this study attempts to device the method of effecive bed management. The effect of hospital revenue increase by shortening length of stay after examining of medical charge by details of treatment is analyzed in this study. In doing so, herniated lumber disc is chosen and the aspect of medical charge for it by length of stay is first examined.

In this study, cost means the monetary value of goods and services. Profit is the excess of total revenue over total cost during a specific period of time. Therefore, total revenue is the sum of total cost and total profit. In the hospital, the revenue is the income obtained as the results of medical services. Thus it can be noted that the medical charge refers to the revenue of the hospital.

## II. Research Methodology

### 1. Research Model

Medical charge is affected by various factors such as kinds and state of diseases, length of stay, characteristics of hospitals, and demographic characteristics of patients. Especially, it is influenced greatly by length of stay in case of the same

disease, and length of stay is affected by health condition and characteristics of patients, accessibility, characteristics of hospitals, type of treatment, degree of service, etc.[4] Also, medical charge shows different aspects by length of stay. Medical charge is high at the first stage of admission, while medical charge decreases gradually as length of stay goes by. Finally, medical charge at a certain point keeps constant level.[5]

This happens because most diseases need intensive medical services in the early stage of admission, and the demand on medical service decreases as the length of stay lapses. Thus, simple medical treatment for recovery is given at a certain point.

The bed turn over rate[6] increases and medical charge can be increased by shortening the length of stay. As shown in <Figure 1>, if length of stay of an inpatient is 15 days, one bed can be turned monthly two times, but a bed turn over rate increases monthly three times if length of stay is shortened by 10 days. At this time, while a medical revenue of part B decreases by shortening the length of stay, medical revenue of part A and part C increases. Therefore, the effect of an increased hospital revenue by shortening length of stay is as much as A+C-B monthly.

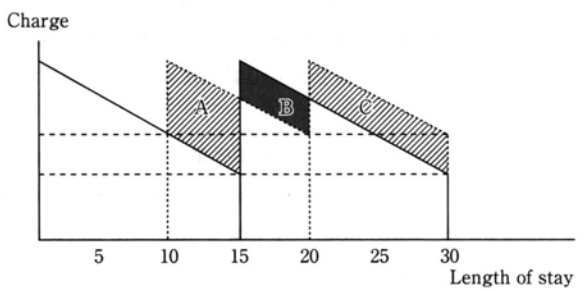


**Figure 1.** A model increase of medical revenue by shortening length of stay

## 2. Research Data

169 patients who were discharged from an University Hospital of 1,000 beds scale from January 1, 1997 to December 31, 1997 after treatment for herniated lumber disc (ICD Code No. M 51.0~M 51.9) were selected as the subjects of this study.

Medical charges for operated patients and unoperated patients by details of treatment and length of stay were investigated. Medical charges by length of stay were divided into basic charge, operation and procedure charge, medication and injection charge, examination charge, material charge and other charge[4].

Basic charges include doctor's charge, sickroom charge and food charge. Medication and injection charges include medicine charge, prescription charge, and injection charge. Operation and procedure charges include an anesthesia charge, operation charge, procedure charge, blood transfusion charge, and chemical therapeutic charge. Examination charges include clinical examination charge, pathological examination charge, special examination charge, radiation photographing charge, and dicipherment charge. Material and other charges include medical expendable charge and other treatment charge.

## 3. Methodology of Data Handling and Analysis

Medical charges by length of stay were analyzed according to details of treatment, and Statistical Analysis System (SAS) was used for data handling.[7] To estimate medical charge by length of stay an estimated model of medical charge by length of stay was developed, using median as a representative value. The effects of the increase of hospital revenue and reduction of medical charge by shortening length of stay are analyzed, calculating integral values by a regression equation estimated according to the first, second, third and an exponential function respectively.

To calculate the income amount increased per bed by shortening length of stay, the regression equation is used. The income per bed is acquired by multiplying a bed turnover rate by accumulated charge by shortened days when length of stay is shortened, and the income amount increased per bed is calculated by subtracting the value which a bed turnover rate is multiplied in accumulated charge up to average length of stay. If the bed turnover rate is multiplied by this, the annual income amount increased per bed by shortening length of stay is calculated.

If average length of stay is shortened by one day (n-1) and two days (n-2) when the average length of stay is n, the effect of annual income increase per bed by shortening average length of stay is as follows.

1) The annual medical income per bed when average length of stay is n (Yn)

$Yn = \int_0^n f(x)\,dx \times (365/n)$ (f(x) : medical charge per case n : length of stay)

2) The annual medical income per bed when average length of stay is shortened by one day ($Yn_{-1}$)

$Yn_{-1} = \int_0^{n-1} f(x)\,dx \times (365/n_{-1})$

3) The annual medical income per bed when average length of stay is shortened by two days ($Yn_{-2}$)

$Yn_{-2} = \int_0^{n-2} f(x)\,dx \times (365/n_{-2})$

Therefore, the effect of the annual income increase per bed by shortening by one day of average length of stay is ($Yn_{-1}$-Yn) , and is ($Yn_{-2}$-Yn) by shortening by two days.

## III. Results

### 1. Analysis of Medical Charge by Length of stay

Among 169 herniated lumbar disc patients, there were 87 operated patients (51.5%) and 82 unoperated patients (48.5%). Average length of stay for operation (21.1 days) was longer than that for non-operation (14.4 days). Total charge for an operated patient (3,530,655 won) exceeds that for an unoperated patient (1,343,117 won) by far more two times, and, in case of charge per day, charge for operation (167,210 won) was higher than that for non-operation (92,943 won).

#### 1) Operation

In case of operation, charge per day by treatments was 167,210 won. Among them, operation and procedure charge was highest (54,931 won, 32.9%). Basic charge was 21.5 percentage, and materials and other charge was 20.5 perccentage. Medication and injection charge and examination charge were 16.2 percentage and 8.9 percentage respectively.

In case of charge by length of stay, examination charge for the first day of admission was 113,844 won (46%), and examination charge for the second day was 246,689 won (36.3%). Thus it appeared that the portion of examination charge on the first and second day of admission was great.

Medical charge for the third day reached its peak (863,518 won) , and, among them, operation and procedure charge (47.3%) and materials charge (38.0%) were 737,815 won (total 85.3 %).

Medical charge for the fourth day (483,657 won) was lower than that for the third day, but lots of charge was produced. Operation and procedure charge (34.2%) and materials charge (38.6%) were 72.8 percentage of total charge, so it appears operations are perfomed intensively on the third and fourth day of admission. Also, medical charge from the fifth day decreases considerably, and medical charge per day from the nineteenth day was lowest among subjects. Thus it is clear that long-term inpatients received simple admission treatment for recovery<Table 1>.

#### 2) Non-operation

Of the medical charge per day (92,943 won), basic charge was highest (47.3%). Examination charge was 28.3 percentage, while medication and injection charge was 15.2 percentage.

In case of the charge by length of stay, examination charges for the first day and second day of admission were 59.9 percentage and 61.4 percentage respectively. However, it decreased somewhat from the third day. Finally, medical charge per day from the twentieth day was lowest among subjects.

Except basic charges for the early stage of admission, basic charges exceeded 50 percentage of total charge. Thus, among total charge, fixed cost such as bed cost covered most of medical charges <Table 2>.

### 2. Hospital Revenue Increase by Shortening Length of Stay

According to the result of the analysis of medical charge for discharged herniated lumbar disc patients, operation and procedure charge (32.9 %) was highest for operated patients, while basic charge (47.3%) was highest for unoperated patients. Specially, medical charge per day on the third day of admission was highest for operated patients, while medical charge around the fifteenth day of admission was lowest among charges for diseases of subjects. Thus it appears that simple treatment for inpatients were performed after a certain period.

The equation of regression estimation of medical charge is shown in table 3 and presumed medi-

**Table 1.** Charge for herniated lumbar disc by length of stay (operation)

| LOS | No.of patients | charge per day/case (%) | basic (%) | med. & inject. (%) | op. & pro. (%) | examination (%) | material & etc. (%) |
|---|---|---|---|---|---|---|---|
| 1 | 87 | 113,844 (100.0) | 30,322 (26.6) | 2,414 ( 2.1) | 26,570 (23.3) | 52,440 (46.0) | 2,096 ( 1.8) |
| 2 | 87 | 246,689 (100.0) | 36,039 (14.6) | 21,502 ( 8.7) | 84,910 (34.4) | 89,690 (36.3) | 14,545 ( 5.8) |
| 3 | 87 | 863,518 (100.0) | 33,384 ( 3.8) | 39,357 ( 4.5) | 408,969 (47.3) | 52,960 ( 6.1) | 328,846 (38.0) |
| 4 | 87 | 483,657 (100.0) | 33,754 ( 6.9) | 49,310 (10.1) | 165,829 (34.2) | 48,030 ( 9.9) | 186,732 (38.6) |
| 5 | 87 | 144,629 (100.0) | 36,188 (25.0) | 38,976 (26.9) | 43,083 (29.7) | 12,172 ( 8.4) | 14,208 ( 9.8) |
| 6 | 87 | 134,757 (100.0) | 37,508 (27.8) | 30,280 (22.4) | 34,688 (25.7) | 11,723 ( 8.6) | 20,557 (15.2) |
| 7 | 87 | 165,046 (100.0) | 39,485 (23.9) | 30,830 (18.6) | 40,713 (24.6) | 15,994 ( 9.6) | 38,021 (23.0) |
| 8 | 87 | 93,087 (100.0) | 38,397 (41.0) | 27,530 (29.5) | 11,145 (11.9) | 13,800 (14.8) | 2,213 ( 2.3) |
| 9 | 87 | 92,664 (100.0) | 38,440 (41.4) | 27,062 (29.2) | 19,889 (21.4) | 5,066 ( 5.4) | 2,204 ( 2.3) |
| 10 | 87 | 103,963 (100.0) | 37,181 (35.8) | 29,751 (28.6) | 22,662 (21.8) | 6,207 ( 6.0) | 8,161 ( 7.8) |
| 11 | 83 | 87,003 (100.0) | 35,844 (41.1) | 30,204 (34.7) | 11,314 (13.0) | 8,302 ( 9.5) | 1,337 ( 1.5) |
| 12 | 73 | 85,608 (100.0) | 38,167 (44.5) | 23,182 (27.0) | 14,563 (17.0) | 7,227 ( 8.4) | 2,467 ( 2.8) |
| 13 | 68 | 75,574 (100.0) | 36,868 (48.7) | 19,164 (25.3) | 9,325 (12.3) | 7,829 (10.3) | 2,386 ( 3.1) |
| 14 | 65 | 80,891 (100.0) | 38,951 (48.1) | 19,911 (24.6) | 13,801 (17.0) | 6,710 ( 8.2) | 1,606 ( 1.9) |
| 15 | 64 | 80,930 (100.0) | 36,564 (45.1) | 26,214 (32.3) | 9,644 (11.9) | 7,295 ( 9.0) | 1,211 ( 1.4) |
| 16 | 55 | 80,322 (100.0) | 35,480 (44.2) | 22,650 (28.2) | 8,382 (10.4) | 5,118 ( 6.3) | 8,802 (11.0) |
| 17 | 55 | 63,059 (100.0) | 30,299 (48.0) | 26,685 (42.3) | 2,110 ( 3.3) | 3,441 ( 5.4) | 522 ( 0.8) |
| 18 | 49 | 73,275 (100.0) | 38,560 (52.6) | 29,175 (39.8) | 2,366 ( 3.2) | 1,907 ( 2.6) | 1,266 ( 1.7) |
| 19 | 34 | 61,732 (100.0) | 31,855 (51.6) | 24,850 (40.2) | 3,556 ( 5.7) | 1,208 ( 1.9) | 260 ( 0.4) |
| 20 | 29 | 60,794 (100.0) | 30,158 (49.6) | 23,292 (38.3) | 2,240 ( 3.6) | 5,089 ( 8.3) | 14 ( 0.0) |
| 21 | 26 | 60,206 (100.0) | 30,855 (48.3) | 23,754 (37.5) | 5,573 ( 8.8) | 3,015 ( 4.7) | 7 ( 0.0) |
| 22 | 24 | 67,111 (100.0) | 29,144 (43.4) | 30,461 (45.3) | 2,876 ( 4.2) | 4,162 ( 6.2) | 467 ( 0.6) |
| 23 | 21 | 60,021 (100.0) | 30,764 (51.2) | 23,680 (39.4) | 3,153 ( 5.2) | 2,374 ( 3.9) | 48 ( 0.7) |
| 24 | 19 | 50,976 (100.0) | 29,819 (58.4) | 18,175 (35.7) | 1,745 ( 3.4) | 1,194 ( 2.3) | 42 ( 0.1) |
| 25 | 17 | 50,232 (100.0) | 32,320 (64.3) | 14,309 (28.4) | 1,300 ( 2.5) | 2,295 ( 4.5) | 6 ( 0.0) |
| 26 | 16 | 57,543 (100.0) | 31,366 (54.5) | 21,392 (37.1) | 2,604 ( 4.5) | 2,112 ( 3.6) | 67 ( 0.1) |
| 27 | 16 | 60,094 (100.0) | 29,111 (48.4) | 21,323 (35.5) | 1,740 ( 2.9) | 7,669 (12.8) | 250 ( 0.4) |
| 28 | 13 | 63,463 (100.0) | 26,968 (42.5) | 19,993 (31.5) | 6,518 (10.3) | 7,977 (12.6) | 2,004 ( 3.2) |
| 29 | 13 | 62,215 (100.0) | 28,772 (46.2) | 16,681 (26.8) | 8,554 (13.7) | 7,333 (11.7) | 873 ( 1.4) |
| 30 | 10 | 73,368 (100.0) | 32,378 (44.1) | 30,309 (41.3) | 4,661 ( 6.3) | 6,006 ( 8.1) | 12 ( 0.0) |
| * | 1,620 | 167,368 (100.0) | 35,980 (21.5) | 27,114 (16.2) | 54,931 (32.9) | 14,845 ( 8.9) | 34,340 (20.5) |

*1,620 : total number of patient days

cal charge is displayed in figure 2. Medical charge for herniated lumbar disc in case of operation was low on the first day of admission. However, it was high on the second and the third day of admission, while it rapidly decreased on the fourth displayed finally constant level.

Especially, it was highest of the third day of admission because operation and procedure were performed at this time. It appeared that medical charges for operation, procedure, and materials were produced intensively.

Also, most medical charges were claimed for basic treatment, medication, and injection after the averate length of stay. Contrary to this, medical charge for the unoperated patients was highest on the second day which was regarded as the early time of admission <Figure 3>. It happened because various examinations were conduced in the early time of admission. It can be pointed out that the patients received simple treatment which mostly covered basic treatment.

The analysis of the data implies that simple exams could be done by outpatient care before a patient is admitted. Furthermore, simple care for recovery could be provided by outpatient care after early discharge. It could improve efficiency of bed utilization. This could also increase the medical revenue per bed and decrease national medical expenditure as well as reduction of out-of-pocket payment of patients.

The results of the analysis of the effect of reduction of average length of stay on the increase of annual medical revenue per bed is as follows <Table 4>.

According to the effect of the annual revenue increase per bed by shortening length of stay by one day, 1,674,588 won increased in case of the operated patient, while 809,763 won increased in

**Table 2.** Charge for herniated lumbar disc by length of stay (non-operation)

| LOS | No.of patients | charge per day/case (%) | basic (%) | med. & inject. (%) | op. & pro. (%) | examination (%) | material & etc. (%) |
|---|---|---|---|---|---|---|---|
| 1 | 82 | 122,462 (100.0) | 39,268 (32.1) | 5,818 ( 4.8) | 2,686 ( 2.2) | 73,334 (59.9) | 1,354 ( 1.1) |
| 2 | 82 | 215,375 (100.0) | 47,346 (22.0) | 18,284 ( 8.5) | 13,210 ( 6.1) | 132,314 (61.4) | 4,219 ( 2.0) |
| 3 | 80 | 123,831 (100.0) | 45,064 (36.4) | 11,795 ( 9.5) | 9,978 ( 8.1) | 54,286 (43.8) | 2,707 ( 2.2) |
| 4 | 72 | 104,015 (100.0) | 46,734 (44.9) | 19,219 (18.5) | 11,444 (11.0) | 26,154 (25.1) | 462 ( 0.4) |
| 5 | 64 | 120,067 (100.0) | 47,137 (39.3) | 16,836 (14.0) | 7,461 ( 6.2) | 48,190 (40.1) | 441 ( 0.4) |
| 6 | 62 | 95,436 (100.0) | 47,008 (49.3) | 14,454 (15.1) | 5,697 ( 6.0) | 26,720 (28.0) | 1,582 ( 1.7) |
| 7 | 59 | 81,614 (100.0) | 43,759 (23.9) | 12,567 (15.4) | 6,074 ( 7.4) | 17,037 (20.9) | 2,175 ( 2.7) |
| 8 | 56 | 106,105 (100.0) | 46,881 (44.2) | 15,666 (14.8) | 8,328 ( 7.8) | 32,053 (30.2) | 3,175 ( 3.0) |
| 9 | 52 | 84,604 (100.0) | 42,611 (50.4) | 17,129 (20.2) | 9,769 (11.5) | 14,397 (17.0) | 695 ( 0.8) |
| 10 | 49 | 82,481 (100.0) | 43,121 (52.3) | 20,294 (24.6) | 7,670 ( 9.3) | 11,223 (13.6) | 171 ( 0.2) |
| 11 | 45 | 83,729 (100.0) | 40,192 (12.2) | 17,129 (20.5) | 7,705 ( 9.2) | 16,539 (19.8) | 2,044 ( 2.4) |
| 12 | 42 | 62,689 (100.0) | 42,233 (67.4) | 12,931 (20.6) | 5,490 ( 8.8) | 1,775 ( 2.8) | 257 ( 0.4) |
| 13 | 38 | 62,798 (100.0) | 38,248 (60.9) | 12,213 (19.4) | 6,195 ( 9.9) | 5,869 ( 9.3) | 271 ( 0.4) |
| 14 | 36 | 72,418 (100.0) | 42,339 (58.5) | 12,717 (17.6) | 9,374 (12.9) | 7,346 (10.1) | 640 ( 0.9) |
| 15 | 34 | 61,363 (100.0) | 39,960 (65.1) | 11,494 (18.7) | 7,805 (12.7) | 1,461 ( 2.4) | 641 ( 1.0) |
| 16 | 32 | 38,311 (100.0) | 40,712 (59.6) | 19,297 (28.2) | 7,001 (10.2) | 1,086 ( 1.6) | 213 ( 0.3) |
| 17 | 30 | 60,524 (100.0) | 37,880 (62.6) | 13,777 (22.8) | 6,769 (11.2) | 1,641 ( 2.7) | 454 ( 0.8) |
| 18 | 23 | 63,286 (100.0) | 38,914 (61.5) | 14,654 (23.2) | 7,933 (12.5) | 1,692 ( 2.7) | 91 ( 0.1) |
| 19 | 20 | 62,757 (100.0) | 42,896 (68.4) | 10,416 (16.6) | 7,443 (11.9) | 0 ( 0.0) | 0 ( 0.0) |
| 20 | 19 | 51,492 (100.0) | 35,668 (69.3) | 8,064 (15.7) | 7,251 (14.1) | 0 ( 0.0) | 507 ( 1.0) |
| 21 | 16 | 63,242 (100.0) | 40,716 (64.4) | 13,027 (20.6) | 7,499 (11.9) | 1,998 ( 3.2) | 0 ( 0.0) |
| 22 | 13 | 68,015 (100.0) | 38,573 (56.7) | 12,868 (18.9) | 9,267 (13.6) | 7,302 (10.7) | 0 ( 0.0) |
| 23 | 13 | 57,767 (100.0) | 38,119 (66.0) | 9,514 (16.5) | 9,556 (16.5) | 0 ( 0.0) | 576 ( 1.0) |
| 24 | 11 | 67,071 (100.0) | 38,469 (57.4) | 8,838 (13.2) | 4,941 ( 7.4) | 14,822 (22.1) | 0 ( 0.0) |
| 25 | 11 | 57,809 (100.0) | 37,645 (65.1) | 4,359 ( 7.5) | 4,489 ( 7.8) | 11,296 (19.5) | 18 ( 0.0) |
| 26 | 10 | 58,768 (100.0) | 40,330 (68.6) | 5,107 ( 8.7) | 5,571 ( 9.5) | 6,889 (11.7) | 869 ( 1.5) |
| 27 | 10 | 65,189 (100.0) | 38,768 (59.5) | 9,130 (14.0) | 5,306 ( 8.1) | 11,982 (18.4) | 0 ( 0.0) |
| 28 | 9 | 67,310 (100.0) | 41,412 (61.5) | 15,523 (18.6) | 3,892 ( 5.3) | 9,482 (14.1) | 0 ( 0.0) |
| 29 | 8 | 60,580 (100.0) | 40,590 (67.0) | 3,334 ( 5.5) | 8,842 (14.6) | 6,934 (11.4) | 880 ( 1.5) |
| 30 | 8 | 60,958 (100.0) | 39,349 (64.6) | 15,096 (24.8) | 6,512 (10.7) | 0 ( 0.0) | 0 ( 0.0) |
| * | 1,086 | 92,943 (100.0) | 43,998 (47.3) | 14,152 (15.2) | 7,539 ( 8.1) | 26,273 (28.3) | 981 ( 1.1) |

*1,086 : total number of patient days

case of the unoperated patient. It appeared the amount of the operated case marked two times of that of the unoperated case.

On the other hand, the annual revenue increase per bed by shortening length of stay by three days was 5,660,755 won in case of the operated patient, while it was 3,513,011 won in case of the unoperated patient. Therefore, the effect was much higher in case of the operated patient.

As seen in the result, the first day of admission was not necessarily required in case of the operated patient. Also, from the eighteenth day of admission the charge for basic treatment and the charge for medication and injection covered 92 percentage of total charge. Thus, by shortening the first day of admission and final three days before discharge, the annual revenue increase per bed will be greater.

If a hospital could shift the first day of admission to ambulatory examination and treatment, revenue per bed from outpatient and inpatient care could be increased.

The point of reduction depends on decision of a doctor considering the condition of the patient, age, health status and the manager of the hospitals. Increase of the bed turnover rate by discharging patient earlier than usual could increase the inpatient revenue and outpatient revenue.

## IV. Discussion

Cutting of excessive length of stay is a good method to improve the turnover rate of hospital beds and to increase of income of the hospitals. It was reported that a little cut of length of stay did not make significant influence on the recovery of the patients in the cases of some medical services. According to the study on shortening length of

**Table 3.** Presumed equation of daily medical charge

| | | regression model | $R^2$ |
|---|---|---|---|
| operation | | | |
| charge per day | $\chi \leq 3$ | $y=70012\ \chi^2+55027\ \chi+8043$ | 0.7105 |
| | $\chi > 3$ | $y=1247193\frac{1}{\chi}-4473$ | 0.7848 |
| basic charge | | $y=-21.581\ \chi^2+404.98\ \chi+34356$ | 0.7423 |
| medication/injection | $\chi \leq 4$ | $y=15854\ \chi-11490$ | 0.9819 |
| | $\chi > 4$ | $y=84978\frac{1}{\chi}+18746$ | 0.8532 |
| operation/procedure | $\chi \leq 3$ | $y=191199\ \chi-188916$ | 0.8613 |
| | $\chi > 3$ | $y=491988\frac{1}{\chi}-15573$ | 0.7089 |
| examination | $\chi \leq 2$ | $y=37250\ \chi+15190$ | 0.8725 |
| | $\chi > 2$ | $y=151978\frac{1}{\chi}-4106$ | 0.8034 |
| material/others | $\chi \leq 3$ | $y=163375\ \chi-161588$ | 0.7785 |
| | $\chi > 3$ | $y=481615\frac{1}{\chi}-15605$ | 0.6339 |
| non-operation | | | |
| charge per day | $\chi \leq 2$ | $y=92913\ \chi+29549$ | 0.8144 |
| | $\chi > 2$ | $y=10742\frac{1}{\chi}+20345$ | 0.9161 |
| basic charge | | $y=11.667\ \chi^2-611.09\ \chi+47193$ | 0.7096 |
| medication/injection | | $y=-15.546\ \chi^2+225.31\ \chi+14026$ | 0.6095 |
| operation/procedure | | $y=-1.6579\ \chi^2-29.26\ \chi+8348$ | 0.5028 |
| examination | $\chi \leq 2$ | $y=58980\ \chi+14354$ | 0.8631 |
| | $\chi > 2$ | $y=168206\frac{1}{\chi}-2910$ | 0.8407 |

*$\chi$ =length of stay

stay, despite the cutting of four days of length of stay the patients who had taken herniotomy, appendectomy, cholesystostomy, their recovery rate did not change significantly.[8)9)] It is also reported that despite of the decrease of length of stay from 13 days to 5.5 days during ten years after adapting of the compensation system of medical expenses for Diagnostic Related Groups (DRG) the quality of medical services had rarely changed[10)]. These results suggest that the average length of stay should be cut unless it has impact on the quality of medical services.[11)12)]

The results of this study, which analyzed the charge by length of stay of parents who suffered from herniated lumbar disc are as follows. The charge for the first day of admission is relatively low and the charge for the second day of admission of unoperated patients and for the third day of admission of operation patients, however, are highest. After the days the charge for admission decreaes gradually and eventually becomes rather constant.

Above results are a little different from other researcher's. According to their results,[13)~17)] the charge for admission of internal diaeases peaks on the first day and the charge for admission of surgical diseases peaks on the second day.[18)~20)] The charge for other diseases such as an acute appendicitis, Caesarian section, and an acute pneumonia peaks on the first day fo admission.[4)] Despite of a little differeces between these results and others', they have a point of sameness: length of stay should be cut.

The medical revenue per hospitalized day can be analyzed because the patients pay the medical expenses according to the medical services. However, it is difficult to examine the medical charge per hospitalized day because most of the medical charges are fixed charges which are charecterized as indirect charge. Although the material charge per patient which is recognized as variable charge can be examined to some extent, it is almost impossible to analyze it exactly because of various kinds and frequent movement of the materials.

It is clear that hospital profitability will be improved if medical revenue increasaes by shortening the length of stay. Generally speaking, the more the ratio of fixed charge increases, the more

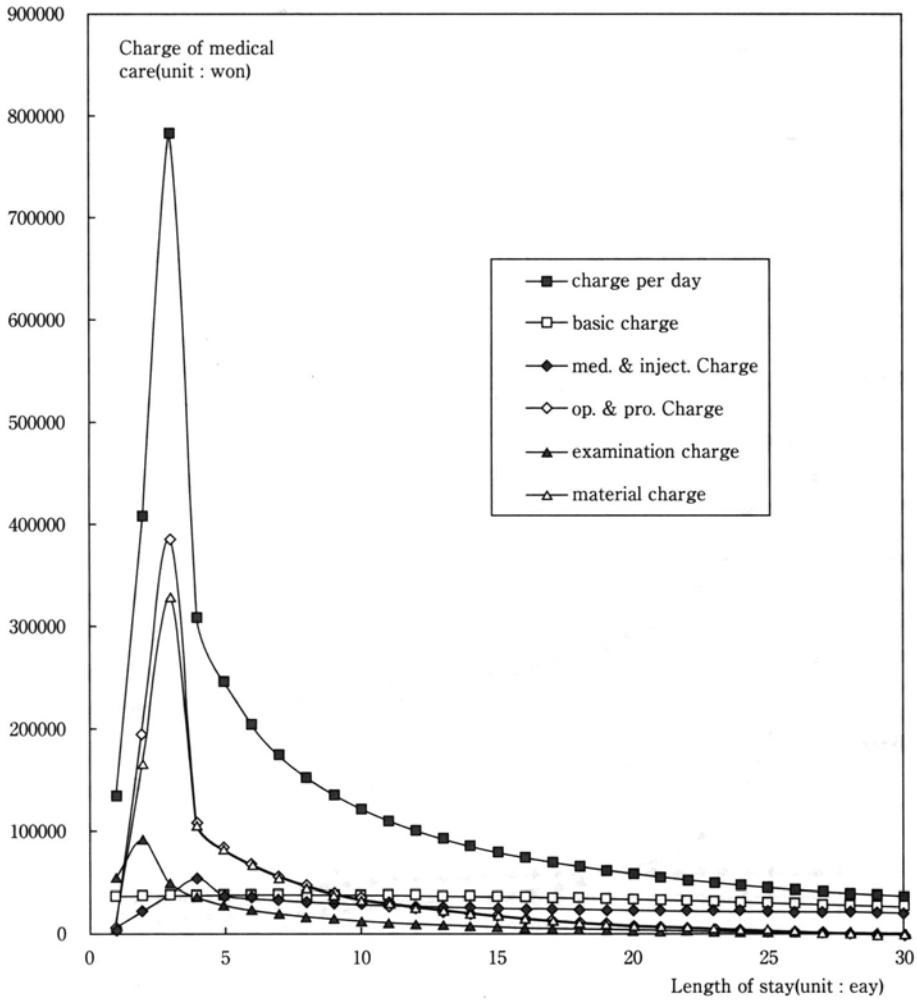


**Figure 2.** The presumed cost for herniated lumbar disc by length of stay (operation)

the improvement of hospital revenue by shortening the length of stay is effective.[21] Especially, if fixed charge covers above 50 percentage of medical charge like university hospitals in Korea, it can be estimated that the effectiveness of hospital profitability by shortening the length of stay will be great.

## V. Conclusion

The sharp increase of medical demand caused the shortage of beds in some large general hospitals in Korea. In order to cope with this situation, some hospitals have been expanding the number of beds or many new hospitals have been building. Subsequently, these approaches accelerated the increase of national health expenditure in Korea under management of International Monetary Fund. In this aspect, maximization of utility through efficient use of limited resources of hospital is emerging as one of important issues in health care field.

Therefore, this study explored the aspect of medical charge per hospitalized day of patients who suffered from herniated lumbar disc and derived the model of presumed charge. It also analysed the effect of shortening length of stay. The major findings of this study are as follows:

1. Average length of stay was 21.1 days in case of operated patients, while it was 14.5 days in case of unoperated patients. The medical charge per operated patient, who was hospitalized for long time, was 3,530,655 won. It marked above 2.7 times of the medical charge per unoperated patient (1,343,117 won). The daily average charge was 167,210 won in case of the operated patient, while it was 92,943 won in case of the un-

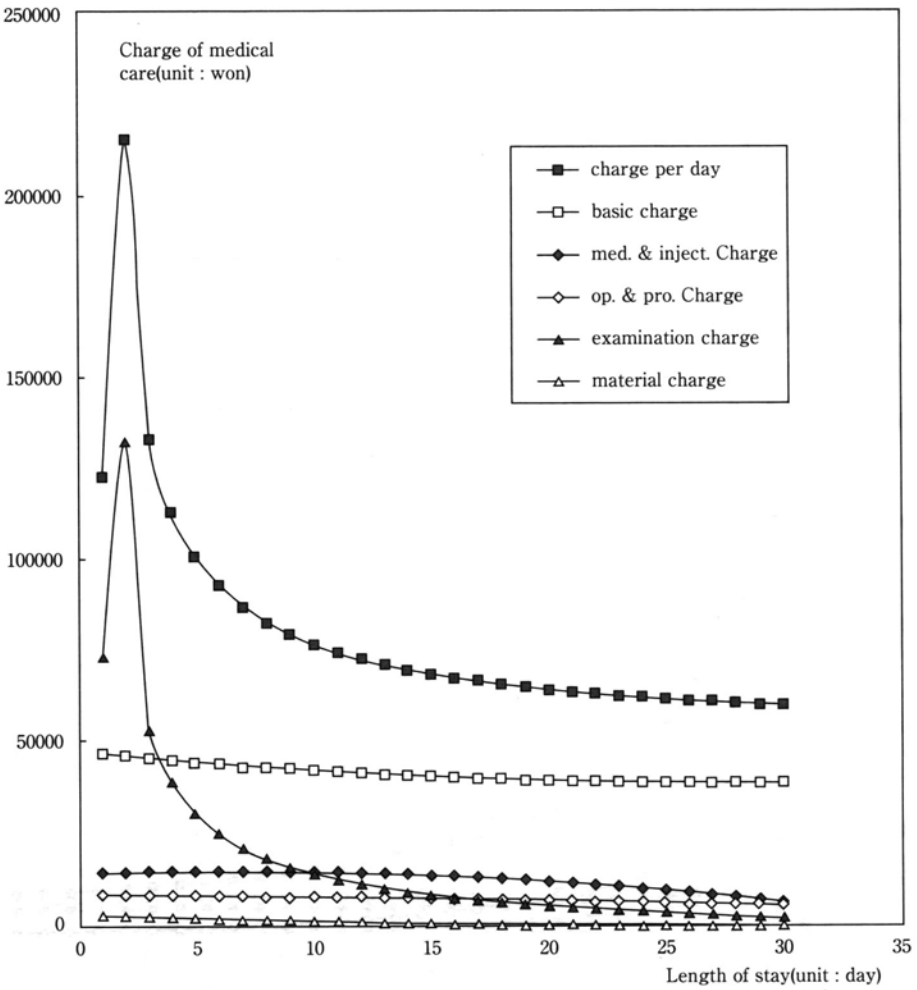


**Figure 3.** The presumed charge for herniated lumbar disc by length of stay (non-operation)

**Table 4.** Increase of annual hospital income per bed by shortening length of stay

(unit : won)

| | length of stay | shortening length of stay | | | | |
|---|---|---|---|---|---|---|
| | | 1 days | 2 days | 3 days | 4 days | 5 days |
| operation | 21.1 | 1,674,588* | 3,571,782 | 5,660,755 | 7,747,657 | 10,328,473 |
| non-operation | 14.4 | 809,763 | 2,047,093 | 3,513,011 | 4,504,153 | 5,766,160 |

*The increase of hospital income is 1,674,588 won when average length of stay is shortening by one day. The amount is calculated by using regression estimation eguation $y=70012\ \chi^2+55027\ \chi+8043\ (\chi\leq 3)$ and $y=1247193\ \frac{1}{\chi}-4473\ (\chi>3)$.

① Medical charge for admission per case when average length of stay is 21 days :

$y=\{\int_1^3 (70012\ \chi^2+55027\ \chi+8043)\,dx+\int_4^{21}(1247193\ \frac{1}{\chi}-4473)\,dx\}=3254248$

② Medical charge for admission per case when average length of stay is 20 days :

$y=\{\int_1^3 (70012\ \chi^2+55027\ \chi+8043)\,dx+\int_4^{21}(1247193\ \frac{1}{\chi}-4473)\,dx\}=3191042$

Therefore, annual income increase per bed when average length of stay is shortered by one day (②−①) :

$3,191,042\times\frac{365}{20}-3,254,248\times\frac{365}{21}=1,674,588$

operated patient.

2. According to medical charges by hospitalized day, the medical charge for operated patients was low on the first day of admission. It increased on the second and the third day. However, it gradually decreased after the third day of admis-

sion because the patients received mostly basic treatments.

3. According to the results of the analysis of daily medical charge by details of treatment, operation and procedure charge for operated patients was hightest (32.9 percentage), while materials or other charge, basic charge, medication and injection charge, and examination charge were 20.5 percentage, 21.5 percentage, 16.2 percentage, and 8.9 percentage respectively.

On the other hand, in case of unoperated patients the basic charge was highest (47.3 percentage), while examination charge, medication and injection charge, operation and procedure charge, and materials and other charge were 28.3 percentage, 15.2 percentage, 8.1 percentage, and 1.1 percentage respectively.

The results show that basic simple examination for diagnosis mainly tended to be provided on the first day of admission, and that more complex examination and operation tended to be previded on the second or third day after admission.

4. It appears that shortening the length of stay uniformly may not be proper measure as only the doctor could judge whether the patients can be discharged according to the condition of patients. However, the effect of annual revenue increase per bed by shortening the average length of stay by one day can be estimated. According to the results, the annual revenue increase per bed was 1,674,588 won in case of operated patients, while it was 809,763 won in case of unoperated patients.

In conclusion, this study shows that the university hospitals and large-sized general hospitals, which reached already the peak of bed occupancy rate, can improve the hospital revenue through the efficient use of beds by shortening length of stay. It is expected that shortening length of stay can make patients to alleviate the economic burden and contribute to making use of limited health care resources efficiently. Thus, it can be also useful to both patients and hospitals and contribute to reduction of national health care expenditure. In the context, the verious and positive measures to encourage hospitals to shorten length of stay should be explored.

**Notes**


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〔報　告〕

# カンボジア国立母子保健センターにおけるクリティカル・パス手法の試験的使用経験

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キーワード：クリティカル・パス，カンボジア，質管理，患者サービス，病院管理

## はじめに

いわゆるクリティカル・パスの考え方は，クリニカル・パスやケア・マップなどと名前を変えて，アメリカやオーストラリア，イギリスなどで医療の世界に導入されつつあるが，「わが国はもとより，アメリカにおいてもクリティカル・パス導入による成果や問題点に関する論文はまだ少なく，クリティカル・パスそのものの概念や目標，意義，手法なども統一化されたものにはいたっていない」[1)]という事情であり，開発途上国での使用経験も散発的で，非常に限られている[2)]．今回，カンボジア国立母子保健センターで患者待ち時間のサンプル調査を行い，その結果を“古典的”クリティカル・パスの手法に準じて試験的に解析し，問題点を検討，改善することを通して Total Quality Management（TQM：全組織的な質管理）に役立てた経験を述べる．

## 背　景

カンボジア母子保健プロジェクトは 1995 年 4 月から 5 年間の予定で日本とカンボジアの合意の下，日本国際協力事業団（JICA）のプロジェクトとして開始された．プロジェクトサイトはカンボジア国立母子保健センター（NMCHC）で，同センターは 1997 年に日本の無償資金協力で新しく建てかえられ，150 床の病院と宿泊施設を含む研修施設，それに予防部門の事務所を含んでいる．プロジェクトでは新センター開院後，TQM の考え方を導入し，徐々にその適応を広げている過程にある．その活動と相まって患者数は増加の一途にあり，分娩数は旧母子保健センターでは月間約 350 例であったが 2000 年 3 月現在では 600 例を越え，また外来患者数も月 2,300 人ほどであったが 7,000 人（一日平均 230 人）を越えるまでになった．しかしながらそれに伴い，患者の待ち時間増加が問題になってきた．このため，1999 年 4 月 21 日に患者待ち時間調査を行うことになった．

なお調査はプロジェクトの性格上，はじめ日本側の発案で，今後のカンボジア側の主体性を促すため試験的に行われ，これを基にカンボジア側が本格的調査を行うことを期待していたが，考察で述べるような理由によりそれも行われないまま試験的調査結果をマネージメントに生かすことになった．

NMCHC の外来サービスの流れを簡単に解説する（図 1）．すなわち，患者は入口で番号札を貰い，順次総合受付カウンターで受付登録する（図中番号，1）．そのまま会計カウンターに行き，前払い方式で診療費を支払う（2）．この後，外来に進み（3），それぞれの診療部門の受付カウンターで受付登録後（4），外待合室，次いで中待合室で待ったのち診療を受ける（5）ことになる．また診察時点で検査などが必要であれば，再度会計カウンターで追加料金を支払った後，検査などを受けて結果を貰い外来診察室に戻る．妊産婦検診（ANC）については，初回患者は採血による貧血や感染症のチェックと採尿による尿蛋白の検査を受けるが，2 回目以降の受診患者については異常がないかぎり臨床検査は受けない．また病院の啓蒙教育活動の一環として，すべての妊産婦検診受診者に対して母親学級（6）を受講することを勧めている．なお，総合受付カウンターは妊産婦検診，産婦人科と新生児検診（予防接種を含む），臨床生理検査（Para-clinic：臨床検査，超音波，レントゲン，心電図の各検査を含む），入院の 4 つの窓口に分かれて，別々に受付している．

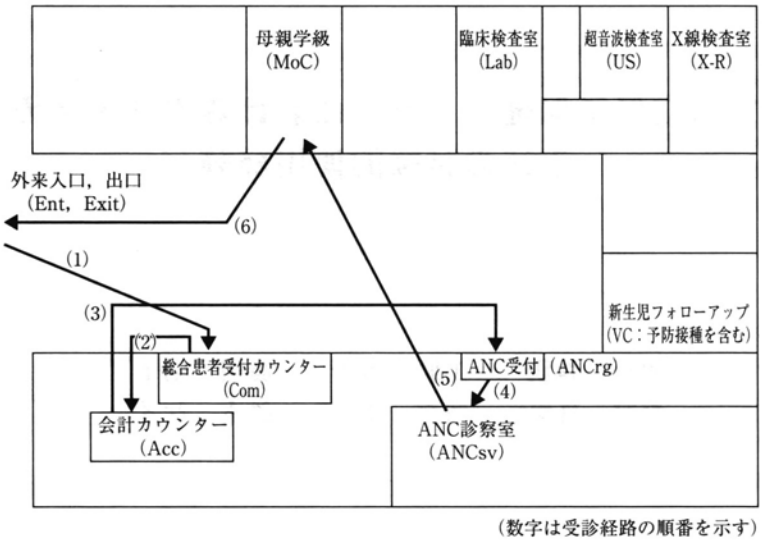



**図 1.** 代表的外来患者の流れ（例：妊産婦検診 2 回目以降）

## 方　法

調査は，外来部門の柱である，妊産婦検診（初回），妊産婦検診（2 回目以降），新生児検診，臨床生理検査の 4 つのサービスについて，それぞれ 3 人ずつ受診時刻による待ち時間の違いを知るために，来院した患者に約 15 分間隔で調査票を渡し，外来来院，総合患者受付，支払い，各診療部門での受付，診察，検査，退出まで，各部署での受け付け時刻を記入する形で行われた．それを，カンボジア側カウンターパートへのわかりやすさを考慮して，図 2 の如く図示，解析して病院運営会議での検討材料とした．なお調査票は黄色の目立つ色とし，なるべく調査のスーパーバイザー（日本人）が見落としのないように心がけた．しかしながら，うち妊産婦検診（2 回目以降）の 1 例と，外来検査 1 例では，途中見失い，検討から外した．

## 結　果

患者待ち時間調査の結果の図表（図 2）から，以下のことが判明した．すなわち，問題点としては，

①妊産婦検診について，患者により受診する際の経路が異なる

②患者により来院から総合受付までの時間が様々であり，患者によってはかなり長く，受付を忘れられている可能性がある．

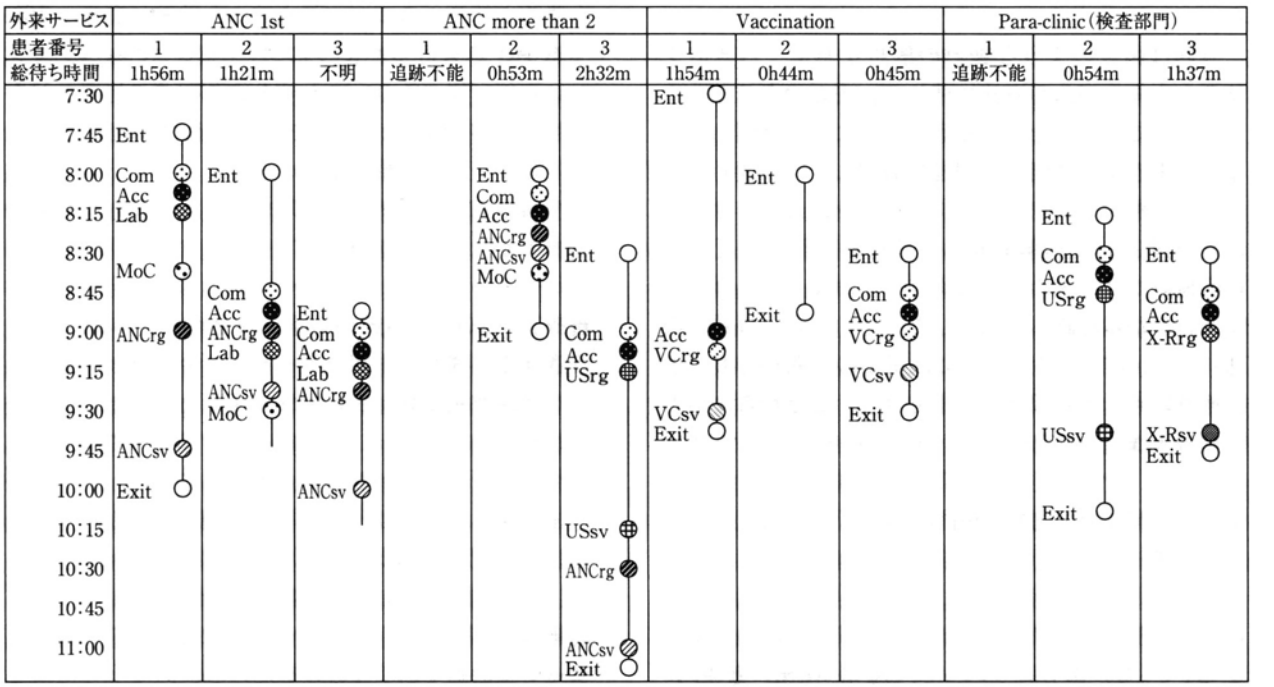
③診療部門の受付から実際の診察を受けるまでに，妊産婦初回検診では平均 30 分掛かり，待ち時間が長い．

④妊産婦検診の診察に費やされる時間が短かった．(平均約 5 分)

⑤新生児検診の 1 例では，来院と帰宅しか確認されず，外来総合受付を通っていない患者がいる可能性がある．

その他，⑥総合受付，会計，各診療部門での受付までは一連の流れとして滞りない，ということも確認された．

この解析結果を踏まえ，問題解決を試みた．まず，問題①については，各部署を移動する順番を明らかにするなど，患者の流れを再度検討の上，統一し，診療者やガイドナースと呼ばれる誘導係による順路指示の徹底を図った．②については，患者によって来院順と受付順が異なったり，またサービス毎の受診人数の違いにより窓口別の受付順が異なることがあるなど，患者によるバラツキがあることから，総合受付カウンターで患者受付番号の呼び出し放送を開始した．また，受付の待ち時間については受付職員の応援体制を決めたほか，受付スペースの拡張などの解決法についても検討された．問題③については，診察ブースの数や診察時間，あるいは対象患者の問題にも関連するため手付かずのままである．問題④については，なおざりな診療行為も認められたことから，さらに診療における各手技を的確に行うように指導を行った．問題⑤については，患者観察から同様の事態が示されており，患者を個人的に診療して金銭を授受するという職員による不正診療も疑われることから，現在改善方法を検討中である．




(Ent:入口, Com:患者受付, Acc:会計, Exit:出口, ANC:妊産婦検診, MoC:母親学級, VC:予防接種, Lab:臨床検査, US:超音波, X-R:レントゲン, rg:登録, sv:受診)

**図 2.** 患者待ち時間調査結果

## 考　察

クリティカル・パスの基本的形態は，近年では「疾病や診療群別に，容態の経過や種々の介入を同一のフォーマットで時系列に並べ，関連職種が把握しやすくしたもの」[3]と長谷川が指摘しているように，“疾病治療に直接関わるもの”で，しかも「医療チームが共同で作りあげた，患者の最良の管理だと信じるところを示した仮設」[4]で，「横軸に時間を取り，縦軸に患者へのケアなどの介入項目をあげたマトリックスで描かれる」[5]というように，“マトリックス”状で，“共同で作り上げた”との捉え方が一般的であるが，クリティカル・パスの考え方自体に変遷がある．

すなわち，もともと産業界で使われていたクリティカル・パス法（CPM : Critical Path Method）は，①プロジェクトを形成する多くの活動や仕事の中で，プロジェクト全体の時間に影響するクリティカル（決定的）なものがどれか，また②最小のコストで目標となる期日までにプロジェクト内のすべての仕事をいかにスケジュールするか，を決める方法で，手法としては，各仕事の名称と所要時間を小さな丸で囲み，これらをスタートから終了までを矢印で繋ぐプロジェクト・グラフ Project graph を使い，このうちボトルネックとなる経路をクリティカル・パスと読んでいた[6]．言い換えると当初，活動ネットワーク Activity network のアロー・ダイアグラムの中で「プロジェクトの始めから終りに至る多くの経路のうち，最も時間のかかる経路」[7]，あるいは PERT（Program Evaluation and Review Techique）のアロー・ダイアグラム中で「全体の期間（工期）を律する作業を始点から終点まで結んだもの」[8]（これらをここでは，古典的クリティカル・パスと呼ぶ）であったものが，現在では上述のような概念に変化している．さらにクリティカル・パスと同義にも使われることのある Zander らのケア・マップでは，スタッフの介入に対して予想される患者と家族の反応を結果基準と中間評価を使って取り込み[9]，時間の流れに沿った一連の介入と一連の結果 Outcome の関係を示すもの[10]となって，従来のクリティカル・パスから一層改変されたことが示されている．

このように，元々の考え方としては，TQM でも用いられる活動ネットワーク・ダイアグラム（“介入”を示す）に“時間”の要素を含めたものがクリティカル・パスであり，それがマトリックスで表わされるようになって，さらに“結果 Outcome（＝想定される状態）”の要素が含まれてケア・マップに変遷してきたと考えられる．

このうち，古典的クリティカル・パスでは，その時間の掛かる経路に特別な関心を寄せ，その所要時間を短縮すること，あるいはスケジュールを考えることによって全体のプロジェクトに掛かる時間を短縮でき

る．

今回は図２のような独自の解析を基に，古典的クリティカル・パスの方法に準じて，現在のクリティカル・パスで対象となる“疾病治療”には直接関わりのない“患者待ち時間”の問題に適用して，所要時間を含めた活動ネットワーク・ダイアグラムに当てはめてみた（図３）．この解析から，妊産婦検診（ANC）の初回検診では太線のようなクリティカル・パス（最も時間のかかる経路）が判明した．このうち，母親学級（図中：MoC）の各クラスには所定の時間があり，また検査にも一定時間要し短縮できないことから，最も時間を短縮し得るのは，「妊産婦検診受付で登録（ANCrg）してから妊産婦検診の診察室に入り診察を受ける（ANCsv）までの時間」や「入口（Ent）から患者が総合受付（Com）するまでの時間」と言える．これと同様に超音波検査の受付登録（USrg）から実際に検査を受けるまでの所要時間が長いことがわかる．一方，図３において，入口（Ent）と出口（Exit）を結ぶ線より上が妊産婦検診初回患者を表わすことになるが，この上半分では矢印が交錯していることが示され，このことから，外来患者の診療経路が患者により異なっていることがわかる．

今中も指摘しているように[8]，このような調査資料をもとにクリティカル・パスを改善していくプロセスが継続的な質改善活動となり，さらに直接的な意味において調査データがTQMの考え方であるPDCAサイクルを回すデータ（Check）となる[11]．このように古典的クリティカル・パスを使った改善活動は，実際NMCHCでも行ったようにプロセス・マネージメントに利用可能であり，それぞれの部署での処置などを標準化してマトリックスで表記すれば，現状のクリティカル・パスに繋がるものとなる．

今回のカンボジアでの経験は試験的な限られたものであるが，今中らの挙げている12の効用[8]のうち，プロセスの標準化，各プロセスの効率化，全組織的な質改善（TQM）活動の促進，などが着手されたという意味で，開発途上国でもクリティカル・パスの考え方が問題解決に繋がる可能性を示したものと言える．だがそれと同時に，この方法をカンボジアで施行するに当たっていくつかの問題点も見出された．

まず第１に，開発途上国でよく聞かれる，「この仕事は正規の仕事か，それとも追加的仕事か」，また「追加的仕事であれば，割増給与は付くのか」という問題を解決しなければならなかった．これはQCサークル活動や広くTQMを進めるにあたっても付きまとってくる問題である．すなわち患者調査が正規の仕事かという問題については，質改善活動のSustainabilityを考慮し，日本側は調査を正規な仕事と位置付け，調査の労賃をカンボジア人カウンターパートに支払わず，自分たちでできる範囲で行うことを基本とした．しかしながら結局，カンボジア人職員は調査を「追加的仕事」と考え，このため割増給与の払われないこのような調査を，さらに自らが拡大して行うには至らなかった．

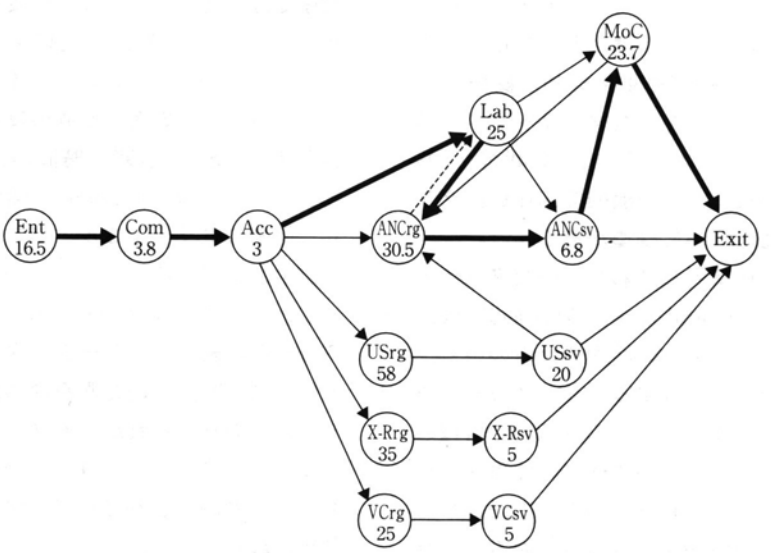



**図３．** 活動ネットワーク・ダイアグラムと各部署での平均所要時間（分）
注１：点線は，ANC受付登録時間の間に，臨床検査（Lab）の受付＋検査を行ったため，ANC登録からLab受診までの時間は平均所要時間より少なくて済んだ（約４分）．
注２：太線が妊産婦検診初回のクリティカル・パスを示すが，Lab→Moc→ANCrg→ANCsv→Exitでも同様の待ち時間．

第２には，グラフなどの基礎教育が十分でなく，必ずしもカンボジア人職員全員がダイアグラムやマトリックスの意味を理解するとは限らないことであった．また同様に図を使うことが必ずしも理解を助けるわけでもなかった．ただ，視覚的には今回カンボジアで用いた表記方法（図２）と所要時間や受診経路に関する日本側の口頭説明は，カンボジア人にとって理解しやすく有用であった．

そして最後の問題は，クリティカル・パスや質管理に関する根本的問題であるが，我々が行ったように個々の作業内容や手順を周知させて標準化したり，最近のクリティカル・パスやケア・マップで行われてきている「マトリックスにして標準化する」という方法は重要であり，一般に問題解決に向けてよく行われることである．しかしながらカンボジアでよく見られる，いわゆるマニュアルや規則はあっても必ずしも従わない，という危険性を孕んでいることにも注意する必要がある．これは，「個々に多様性をもつ患者を考慮してのクリティカル・パスからの変動」[9]，あるいは「プロフェッショナルの裁量」[8]といった理由以前に，「ただ従うのが面倒である」，あるいは「従う必要性を切実に感じていない」ということである．この場合，平気で手術室内を土足で歩くのと同様に，あるいは治療マニュアルを作っても使わないように，折角クリティカル・パスやケア・マップを作っても，全く使われないことが十分考えられるということである．

## 結　語

以上のように，カンボジアでは，クリティカル・パスの考え方は質管理活動の一環として有用であった．しかしながら，クリティカル・パス手法の導入に当たっていくつかの問題に直面した．それには，調査と分析のための割増給与を求める問題や，標準化されても必要性に対する理解が低く使われない問題があり，開発途上国に共通した問題を孕んでいる可能性があった．さらには，図表が形式として当該国国民に理解しやすいかについても考える必要があるものの，今後ほかの開発途上国でも，直接治療に関わる分野以外での利用も含めて，その国特有な新たな問題点を考慮しつつ，いわゆるクリティカル・パス手法の利用は可能であろうと思われる．

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## Abstract

# Experience on using Critical Path Method at the National Maternal and Child Health Center in Cambodia

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**Key words**: Critical Path, Cambodia, Total Quality Management, Patient service, Hospital management

As the number of out-patients increased, the long waiting time of the clients has become a problem at National Maternal and Child Health Center (NMCHC) in Cambodia. To assess the problem, a sample survey (sample size=12 clients) was conducted at the NMCHC. The survey results were analyzed with a "classical" Critical Path Method (CPM). The analysis demonstrated the following findings: 1) Patient's consultation flow (from entrance to various services such as medical examination, laboratory, and/or mothers' class) differed from patient to patient; 2) Waiting time at a registration counter differed from patient to patient; 3) Waiting time from ANC registration to ANC medical examination was reported to be long (30 minutes on average); 4) ANC medical examination time was reported to be short (5 minutes on average) despite long waiting time. Based on these findings above, some problem solving procedures were figured out and carried out to reduce waiting time. This experience proved that a "classical" CPM is useful both in problem identification and in the improvement of the present out-patient services even in developing countries, and contributes to Total Quality Management operations. On the other hand, it is imperative to pay attention to the following difficulties, which are specific to developing countries. First, in developing countries, staffs may request extra-money to perform this survey. Second, even if the standards or manuals are established with CPM, they may not be implemented due to the low awareness of the necessity to follow those standards or manuals. Third, it is necessary to select the forms of graphs, tables, matric, and figures that are fully comprehensible to individual staffs.

〔報　告〕

# インドネシア，スラバヤの三次病院における妊産婦死亡調査；妊婦健診の有用性

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## 要　約

目的：インドネシアは東南アジアの中でも特に妊産婦死亡率が高いとされている．今回著者らは妊産婦死亡症例における妊婦健診の受診状況を明らかにし，妊婦健診の受診状況が妊産婦死亡に与える影響について検討した．

対象と方法：インドネシア，スラバヤ市の三次病院において，1996年から1999年の間に発生した妊産婦死亡75例に対し，同病院で出産した産婦より対照群を291例抽出し，ケースコントロール研究として記述的分析，単変量及び多変量解析を行った．

結果：調査期間中のストモ病院における妊産婦死亡率は出生10万に対し426であった．ロジスティックモデルを用い算定した妊産婦死亡に関するリスクファクターは，1）妊娠5カ月以降の妊婦健診の初診（OR=2.79；95% CI=1.52−5.33），2）4回未満の受診（OR=2.62；95% CI=1.49−4.67），3）医師のいない施設での健診（OR=1.97；95% CI=1.13−3.51），4）2年未満または10年以上の出産間隔（OR=1.74；95% CI=1.01−3.02）で有意であった．

結論：今回の調査から1）妊娠初期におけるリスク評価や2）助産婦から医師への患者紹介システムの確立，また3）産間調節を目的とした家族計画の改善が妊産婦死亡を減少させるために重要であると示唆された．リソースの限られた地域においては，妊娠初期の教育プログラムに妊婦健診の重点が置かれるべきであると考えられた．

キーワード：スラバヤ，妊産婦死亡，妊婦健診，家族計画

## 緒　言

1998年のWHOの統計によれば，年間493,000人の女性が妊娠・出産に関する原因で死亡しており，その99%は途上国で起こっていた[1]．妊産婦死亡は先進国と途上国との差がもっとも顕著なものの一つであり，例えば乳児死亡率が先進国と途上国で7倍の差であるのに比べ，妊産婦死亡率は18倍の差であった[2]．妊産婦死亡率は妊娠可能年齢女性の健康の指標であり，ヘルスケアシステムの質の間接的な指標でもある．にもかかわらず，出生死亡登録システムの整っていない途上国ではその詳細に関して報告されたものは少ないのが実際である．インドネシアは東南アジアの中でも依然として妊産婦死亡率が高く，UNICEFの1990〜1998年の統計では出生10万に対し373という数字が発表されており，出生10万に対しマレーシアの39，タイの44，フィリピンの170に比較しいまだ改善の余地は大きい[3]．

妊婦健康診査（以下妊婦健診）はプライマリヘルスケアの大きな位置を占めている．妊婦健診は妊娠中の疾患を予防し，早期発見し，必要があれば治療を受けられる施設を紹介する目的で行われている．さらに妊娠や出産に関する知識を提供する上でも重要である．しかし先進国では97%の妊婦が妊婦健診を受けているのに対し，途上国での受診率は65%に過ぎない[2]．

これまで妊婦健診の妊娠合併症や妊産婦死亡への有効性に関する多くの調査は先進国で行われており，途上国で評価されたものは少ない[4]．インドネシアにおいて妊婦健診を受診していなかった群の妊産婦死亡率は一度でも受診していた群に対して5.3倍高かった[5]．またインド・ボンベイにおいて1970〜1979年に起こった妊産婦死亡のうち妊婦健診を受診していたものは31.85%，受診していなかったものは68.14%であり，同様に1980〜1989年では41.40%対58.60%であった[6]．しかしいずれも妊産婦死亡例における調査にとどまり，生存群との比較を試みたものではない．そこで今回著者らは，東南アジアの中でも妊産婦死亡の特に多いとされているインドネシアのス

ラバヤ市にある三次病院において妊産婦死亡例の妊婦健診の受診状況を明らかにし，妊婦健診の受診状況が妊産婦死亡に与える影響を検討するため，ケースコントロール研究によって妊婦健診に関する妊産婦死亡のリスクファクターを求めた．

## 対象と方法

スラバヤ市はインドネシアの東ジャワ州の州都であり，ジャカルタに次ぐ第二の人口を持つ都市である．1999年の調査ではスラバヤ市の人口は2,864,105，出生率は17.8（人口1,000対），妊婦健診率は107%（1991年：22%），産後健診率は89%（1991年：33%），訓練された医療従業者による分娩率は90%（1991年：43%），合計特殊出生率は1.80であった[7]．また，1994年のスラバヤ市の妊産婦死亡率は出生10万対325，乳児死亡率は出生1,000対51であった[8]．インドネシアにおいては妊娠期間中少なくとも4回の妊婦健診が勧められており，また産後には1週目と4週目に母子健診がある．標準的な健診内容としては妊婦の身長，体重，血圧，子宮底長の計測，破傷風ワクチンの接種，鉄剤の投与が挙げられ，産後健診では新生児への予防接種，栄養指導，家族計画の指導が行われる[9]．同国で妊娠中一度でも妊婦健診を受診した人の割合は，1998年には87.55%であった[9]．

今回調査を行ったストモ病院はアイルランガ大学医学部の臨床教育病院で，東ジャワ州全体から多くの重症患者が搬送される三次病院である．1995年には日本政府の無償資金援助により救急ユニットが建設され，ストモ病院での分娩の多くがこの救急ユニットで行われている．1997年の調査では，ストモ病院はベッド数1,558，入院患者数40,640人/年，外来患者数2,690人/日，分娩数6,366件/年，医師数1,068人，看護婦・准看護婦1,424人，助産婦109人であった[10]．産婦人科は3つの分娩室を持ち，そのうちの救急ユニットでは産科レジデント7人，助産婦4人，看護婦2人が診療時間外も勤務しており，小児科・麻酔科のレジデントも常駐している．患者の到達から帝王切開施行まで要する時間は10～30分である．来院した妊婦は妊娠12週までは婦人科で管理され，その後産科でフォローアップされる．

ストモ病院において，1996年1月から1999年12月の4年間に97例の妊産婦死亡が発生し，同病院での妊産婦死亡率は出生10万あたり426であった．死亡原因が不明または診療録に記載のなかった3例を除いた94例の直接産科死亡の主な原因は，子癇（36%），出血（21%），産褥熱（10%），子宮破裂（5%）であり，間接産科死亡の主な原因はリウマチ性心疾患を含む心機能不全（10%）が最も多く，その他糖尿病，マラリア，腎不全，悪性腫瘍などであった．

妊産婦死亡97例のうち回答に不備のあった22例を除いた75例を死亡群とした．死亡群の平均年齢は28.7±5.5歳であり，平均経妊回数は2.4±1.1回であった．死亡群の51%がスラバヤ市内に住んでおり，救急搬送されたものは80%であった．死亡群の18%が分娩前，3%が分娩中，78%が分娩後に死亡しており，平均在院日数は4.7±5.8日（範囲；20分～22日）で，児の生存率は57%であった．

対照群として1999年1月から12月に同病院で出産した産婦5,697例より，年齢及び経妊回数をマッチさせた291例を抽出した．妊産婦死亡群との臨床像の比較を表1に示す．年齢（20歳未満や35歳以上）や経産回数（未産婦や4回以上の多産婦）は妊産婦死亡との関連が明らかにされており[11]，また流産や周産期死亡，人工妊娠中絶の経験が妊産婦死亡と関連する[11]ことから，対照群の年齢と経妊回数を死亡群とマッチさせできるだけこれらの要因による影響を減少させた．

患者背景，妊娠分娩経過および妊婦健診に関する質問表をインドネシア語で作成し，助産婦が患者もしくは家族に聞き取りを行い，結果をコード化して記入した．不明な部分に関しては調査者らが診療録をもとにして再確認し，必要があれば患者自宅を訪問し家族へのインタビューによって補った．インタビューの際には調査により得られた情報は解析のみに使用し，対象

**表1．** 対象

| | 死亡群(n=75) | 対照群(n=291) |
|---|---|---|
| 調査期間 | 1996.1—1999.12 | 1999.1—1999.12 |
| 年齢(Mean±SD) | 28.7±5.5歳 | 29.2±5.2歳 |
| 経妊回数(Mean±SD) | 2.4±1.1回 | 2.2±1.2回 |
| 市内在住率 | 51% | 90% |
| 救急搬送率 | 80% | 19% |
| ストモ病院での分娩率 | 47% | 91% |
| 帝王切開率 | 20% | 7% |
| 児の出生体重(Mean±SD) | 2,513±889 g | 2,953±662 g |

者のプライバシーは完全に保護することを口頭で説明し，患者またはその家族に同意を得た．

妊婦健診に関する妊産婦死亡のリスクファクターについてそれぞれ項目ごとにオッズ比を求めた．交絡因子を除くため，ロジスティックモデルによる多変量解析を行い，調整されたオッズ比を求めた．統計学的検討は，JMP ソフトウェアを用い，$\chi^2$ 検定および $t$ 検定により $P<0.05$ を統計学的有意とした．

## 結　果

妊婦健診を受診していなかったのは死亡群 75 例中 4 例，対照群 291 例中 1 例であった．死亡群において 6 例（8%）が妊娠 14～27 週，13 例（17%）が妊娠 28～36 週に死亡していた．また対照群において 23 例（8%）が妊娠 36 週までに早産していた．

妊婦健診の平均初診時期は，死亡群が妊娠 5.3±1.7 カ月，対照群が 3.8±2.0 カ月であり有意に（$P<0.05$ ; Student $t$-test）死亡群のほうが初診時期は遅かった．また，死亡群では 37 人（50%）が妊娠 5 カ月（16 週～19 週）に初診していたのに大して，対照群では妊娠 2～6 カ月（4 週～23 週）に初診時期が分散していた（図 1）．健診回数について死亡群の平均は 4.7±2.7 回，対照群が 6.9±3.1 回であり有意差（$P<0.05$ ; Student $t$-test）を認めた．受診回数が 5 回までは死亡群の割合が高かったのに比較して，6 回以上では対照群の割合が高かった（図 2）．

妊婦健診を受けた施設の内訳は，死亡群では助産婦のクリニックが最も多く（42%），対照群ではヘルスセンターが多かった（28%）（$P<0.05$ ; Chi square test）．インドネシアにおいてはマタニティーホーム及び助産婦クリニックでは助産婦が健診を行っており，医師のクリニックでは医師が，ヘルスセンター，二次病院そしてストモ病院では助産婦と医師が行っている．医療従業者による分類では死亡群では助産婦のみの割合が高かった（54%）のに対し，対照群では助産婦と医師の割合が高かった（46%）（$P<0.05$ ; Chi square test）（図 3）．

さらに家族計画との関連についても検討を行った．2 経妊以上の患者に関して（死亡群 45 人，対照群 196 人）出産間隔を 2 年未満，2 年以上 10 年未満，10 年以上に分類した．死亡群と対照群との比較では出産間隔が 2 年未満（11% 対 5%）あるいは 10 年以上（13% 対 11%）に関してそれぞれ有意差は認めなかった．また避妊の実施の有無，避妊方法の選択については無効回数が多く，解析不能であった．

初産年齢の分布を図 4 に示す．死亡群では 10 代（29%），20 代前半（50%）での初産が多く，平均初産年齢は 22.0±4.4 歳であったが，対照群では 20 代前半（34%），後半（30%）での初産が多く，平均初産年齢は 23.9±5.2 歳であり，死亡群では対照群に比較して有意に（$P<0.05$ ; Student $t$-test）初産年齢が低かった．

上記の結果から，妊産婦死亡のリスクファクターを 1）健診の初診時期が妊娠 5 カ月（16 週）以降，2）健診回数が 0～3 回，3）医師のいない施設での健診，4）2 経妊以上の患者について出産間隔が 2 年未満または 10 年以上であるとし，それぞれのオッズ比を求めたものを表 2 に示す．多変量解析を行い調整したオッズ比は，1）2.79（95% CI 1.52－5.33），2）2.62（95% CI 1.49－4.67），3）1.97（95% CI 1.13－3.51），4）1.74（95% CI 1.01－3.02）であった．初産年齢に関して 18 歳未満の場合と 18 歳以上の場合とでは有意な差を認めなかった．

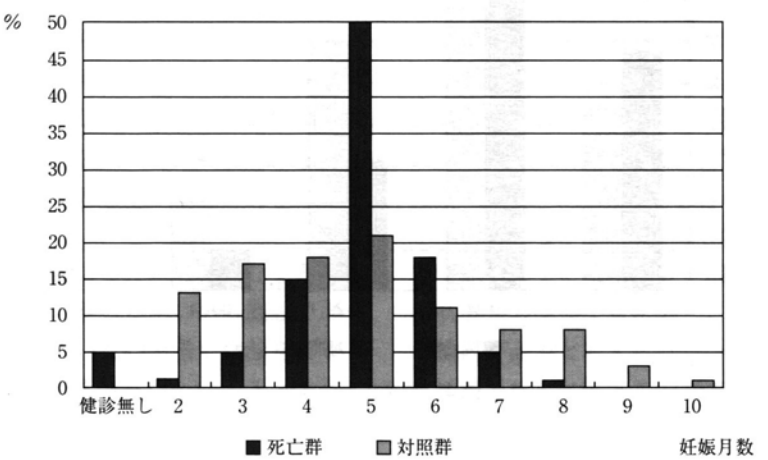


**図 1.** 初診時期の分布

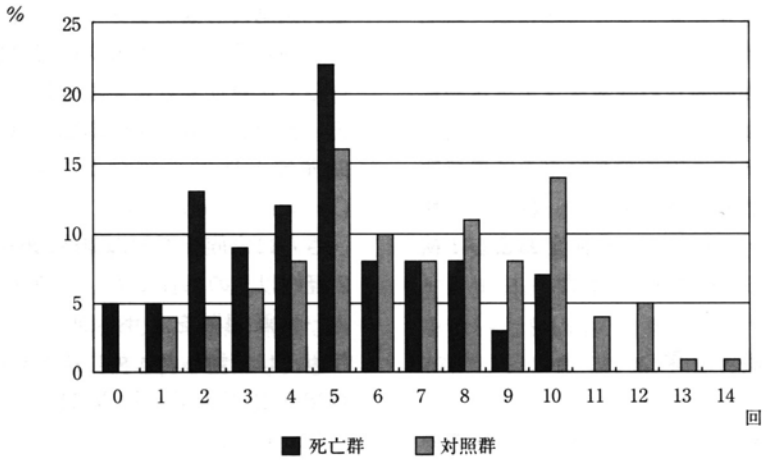


**図 2.** 健診回数の分布

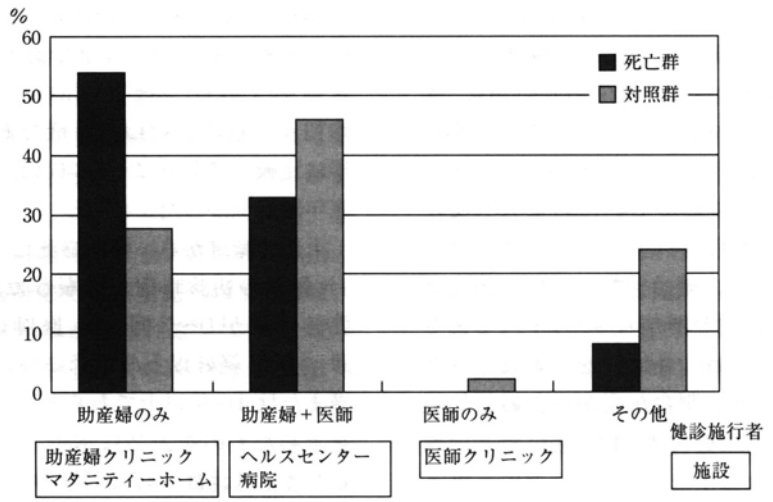


**図 3.** 健診施設の内訳

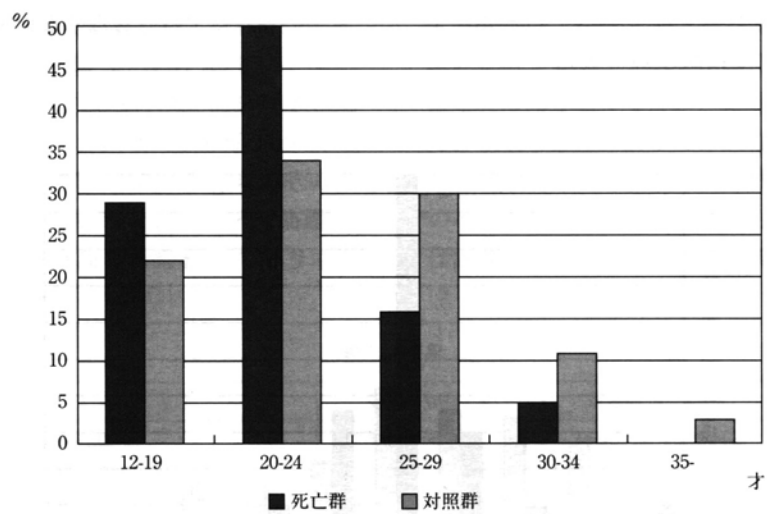


**図 4.** 初産年齢の分布

**表2．** 妊産婦死亡のリスクファクターとオッズ比

| リスクファクター | 死亡群 | 対照群 | オッズ比 | (95%CI) |
|---|---|---|---|---|
| 1．初診の時期 | (n=75) | (n=291) | | |
| 妊娠5カ月以降 | 59(79%) | 150(52%) | 2.79* | (1.52—5.33) |
| 妊娠1—4カ月 | 16(21%) | 141(48%) | 1.00 | |
| 2．健診回数 | | | | |
| 0—3回 | 34(45%) | 63(22%) | 2.62* | (1.49—4.67) |
| 4回以上 | 41(55%) | 228(78%) | 1.00 | |
| 3．健診施設 | | | | |
| 医師なし | 50(68%) | 151(52%) | 1.97* | (1.13—3.51) |
| 医師あり | 25(33%) | 140(48%) | 1.00 | |
| 4．出産間隔 | | | | |
| 2年未満または10年以上 | 11(24%) | 31(16%) | 1.74* | (1.01—3.02) |
| 2年以上10年未満 | 34(76%) | 165(84%) | 1.00 | |
| 5．初産年齢 | | | | |
| 18歳未満 | 11(15%) | 21( 7%) | 1.75 | (0.74—3.97) |
| 18歳以上 | 64(85%) | 270(93%) | 1.00 | |

*$p<0.05$

## 考　察

インドネシア，スラバヤにおける調査では，死亡群では明らかに妊婦健診の初診時期が遅く受診回数が少なかった．健診回数が4回未満の場合は4回以上であった場合と比較し妊産婦死亡のリスクが2.62倍高かったことは，政府の勧める標準回数の4回という数字の妥当性を裏付ける．死亡群では妊娠36週にはいる前に患者の25%が死亡していたため全体の受診回数が少なくなっていたことがバイアスとして考えられるが，健診で適切に異常が発見されていればより頻回にチェックが必要なため健診回数が増えていた可能性もある．しかしWHOによる妊婦健診の調査では健診回数よりもいつ初診するかがより重要であると指摘されている[12]．今回の結果においても妊娠5カ月以降に初診した場合の妊産婦死亡のリスクは妊娠4カ月までに初診していた場合のリスクと比較し2.79倍高かったことから，妊娠初期及び中期での妊婦健診の必要性が示唆された．中村らによれば[13]，前方視的調査において妊娠中期から管理された群では妊娠初期から管理されていた群と比較し，ハイリスク症例，ローリスク症例ともに32週以前の分娩や1,500g未満の出産が多く，妊娠中期での管理が重要であることを指摘している．

健診施設及び健診施行者による比較では少なくとも助産婦が医師に患者を紹介できる体制にある施設での妊産婦死亡のリスクは医師のいない施設で健診を行っていた場合と比較し1.97倍低かったといえる．ただし死亡群の多くはスラバヤ市外に住んでおり，地方に行くほど助産婦や伝統的産婆による分娩率が高い．これは都市と比べ地方では医療施設などのリソースが限られていること，男性医師による診察を希望しない慣習が根強いこと，経済的な問題が大きいことが理由にあげられる．地方においては助産婦や伝統的産婆は妊産婦がアクセスしやすいため，これらのケアワーカーのトレーニングが進められているが，より一層の充実が求められる[14]．

前回との出産が2年未満の場合，頻回の妊娠・出産・授乳のために母体にかかる負担が大きく[11]，また10年以上出産間隔があいた場合には，母体の高齢による合併症が多くなるといわれている[15]．インドネシアでは国策として家族計画が強力に進められており，合計特殊出生率の低下は著しく[9]，一般の人々の間でも，ピルやIUDといった避妊に関する知識は浸透している．しかし出産間隔が2年未満または10年以上の場合は，2年から9年出産間隔をあけた場合と比較し妊産婦死亡のリスクが1.74倍高くなるという今回の結果から，妊産婦死亡を減少させるためには産後健診でのカウンセリングの徹底が必要であることが示唆された．

初産年齢に関しては若年での妊娠は人工妊娠中絶にいたる可能性が高く，また出産時にも骨盤や産道が未発達なことによる難産の可能性が高い[2]．初産年齢の比較では，死亡群と対照群で平均値に明らかに差を認めたものの，18歳いう境界値では，妊産婦死亡に関する明らかなリスクファクターとなり得なかった．初産年齢は女子の就学年数や職業，結婚年齢など社会経済状況とも関連するため，これらの点を含めたさらなる検討が必要と考えられた．

妊産婦死亡に関する調査では，妊婦健診時以外での要因が大きく，また倫理的配慮や大きなサンプルサイズが必要とされることから無作為試験を行うのは現実的に困難である．一方後ろ向き研究では患者自身が死

亡しているため，診療録の整っていない途上国ではデータ収集が困難であり，今回の調査でも健診状況や家族計画などを家族に聞き取りする際に不明な点が多く，結果的に22例を死亡群から外さざるをえなかった．これは選択バイアスとしての問題点であったと考える．

WHOによれば妊婦健診は周産期死亡や低出生体重の予防には効果的であるが，妊産婦死亡を減少させるためのリスクスクリーニングとしては有用でないことが指摘されている[2]．それは妊産婦死亡がまれな出来事であるため，感度や特異度，的中度が低く，言い換えれば疾患の見逃しや過治療になることが多いからである[2)16)]．また妊婦健診で行われるスクリーニングによって子癇や産褥熱，産後出血を予知することは難しい[4]．しかし妊婦健診で行われる母親教室などの教育プログラムは妊産婦に対して妊娠出産への正確な理解を深め，産科的な問題が生じたときに迅速に適切な医療サービスを受診するモチベーションを高める[2)4)]．現在広く行われている妊婦健診は先進国では定期的な受診を前提としている内容であるため，地域のリソースの限られている途上国においては，スクリーニングよりも妊娠初期の教育プログラムに重点をおくべきであると考えられる．

今回の調査の結論として，妊産婦死亡を減少させるためには1）妊娠初期におけるリスク評価，2）施行者の多くを占める助産婦から医師への患者紹介システムの確立，また産後健診の柱として3）安全な妊娠出産を目的とする産間調節の徹底が重要であると示唆された．妊産婦死亡の原因の背景には女性の地位の低さや貧困，低栄養，地理的環境，文化慣習などが複雑にからみあっているため妊婦健診状況が単一のリスクとは結論づけられないが，より効果的な健診を行うことによって妊産婦死亡を減少させる一つの糸口となりえると考える．

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## Abstract

### Maternal Mortality at Referral Hospital in Surabaya, Indonesia ; Validity of Antenatal Care



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**Key words** : Surabaya, maternal mortality, antenatal care, family planning



Objective : Indonesia has still high maternal mortality ratio among South East Asian countries. The authors clarified the situations of antenatal care on maternal deaths and investigated the unavailability of antenatal care have influenced on maternal morthality in Surabaya, Indonesia.

Materials and Meshods : With a retrospective case-control design, descriptive, bivariate and multivariable analyses were conducted between 75 maternal deaths and 291 survival women from 1996－1999 in the main referral hospital in Surabaya, Indonesia.

Results : Maternal mortality ratio was 426 per 100,000 live births in this period. Logistic regression indicated the important risk factors of maternal mortality were 1) first visit to antenatal care facilities after 5 month of pregnancy (OR=2.79 ; 95% CI=1.52－5.33) , 2) less than 4 antenatal visits (OR=2.62 ; 95% CI=1.49－4.67) , 3) antenatal care at the facilities without doctors (OR=1.97 ; 95% CI=1.13－3.51) and 4) birth interval less than 2 years or over 10 years (OR=1.74 ; 95% CI =1.01－3.02) .

Conclusion : This study suggested that it is important to decrease maternal mortality ; 1) risk assessment in the first trimester of pregnancy, 2) establishment of the referral system from midwives to obstetricians and 3) ensuring safer spacing between births. Priority of antenatal care should be given to education programs for pregnant women in the first trimester of pregnancy in the area where medical resources were limited.

〔報　告〕

# 世界保健機関の医薬品製造管理・品質管理規範（GMP）推進プロジェクト前半期の活動

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## 要　約

医薬品の品質確保のために最終製品を試験検査によって確認することはもちろん必須であるが，試験検査だけでは確認しきれない事柄もあり，製造工程での混入や取り違えなどを防止することが品質確保の本質である．原材料の納入から最終製品の流通まで医薬品の品質を確保するため世界保健機関（World Health Organization，以下WHOと記す）は1992年に現在の医薬品の製造管理・品質管理規範（Good Manufacturing Practice，以下GMPと記す）を公表した[2)3)]．

西欧先進諸国で製造される医薬品は発展途上国にとって高価であり，国民の需要を賄うためには自国内で医薬品生産を行うこと（以下，ローカル生産と記す）が推進されてきた．しかし，生産経験もノウハウの蓄積もない新興国で生産される医薬品の品質確保を計るためには，国際的な支援によりGMPを徹底させることが必要であると認識されるようになった[4)]．

このような中でWHOは1998年から3年計画で「WHO GMP実施推進プロジェクト（WHO Project of the Promotion of Implementation of Good Manufacturing Practice，以下，プロジェクト）」を開始した[1)]．このプロジェクトはGMP実施を阻んでいる要因を同定し，その克服に必要な手段や道具（以下，ツールと記す）を提供し，GMPの国際的な普及推進を図るものである．ここでは，このプロジェクトの前半の責任者を勤めた筆者が，プロジェクトの活動報告を通じてWHOプロジェクトの手法を紹介し，今後の医薬品政策・管理（ドラッグマネジメントといわれる）に関する国際プロジェクトの参考に供するものである．

WHOGMP実施推進プロジェクトは，プロジェクトコーディネータを中心にWHOのプロフェッショナルスタッフ5名がワーキンググループを形成し，プロジェクトの運営・遂行にあたった．各地域の実情やプロジェクト協力国の推薦はWHO地域事務局医薬品アドバイザー（以下，地域アドバイザーと記す）から情報・助言を得た．また，国際的に活躍しているGMP専門家である監視員（以下，GMP高度専門家と記す）数名にプロジェクトを通じて技術的側面の協力を得た．

プロジェクト事業は大きく三分野に分かれる：1）実態把握 2）ツールの作成及び3）実施と評価．前半期の主な活動は以下のとおりである：

—プロジェクトの実施計画策定

—地域アドバイザー及びGMP高度専門家からの助言と情報提供：

—政策決定者向け啓発資料開発

—WHOGMPガイドライン及びWHO医薬品製造査察暫定ガイドラインに準拠した研修教材の開発

—ミャンマー及びネパールの初期訪問調査

阻害要因克服のために人材育成などの国際的支援は可能だが，政府及び製薬企業において医薬品の品質確保の重要性を認識しそれを支える体制作りがなされない限り，改善効果を永続させ真に向上に結びつけることは困難である．政策決定者の医薬品の品質確保に対する意識高揚に重点をおいて，プロジェクトを勧めることが重要である．

キーワード：世界保健機関，医薬品の製造管理・品質管理規範（GMP），阻害要因，研修，ミャンマーとネパールの初期訪問調査

## 1. 緒　言

先進国では次々と新薬が開発され，かっての不治の病も克服されてきているが，未だに多くの人々の疾病治療に必要な基本的な医薬品（以下，必須医薬品と記す）すら入手できない状態に世界の三分の一の人々は置かれている．発展途上国では医薬品購入費が健康関連経費の三分の一から三分の二を占め，しかもその大半は個人負担である[5)6)]．購入可能な価格で国民に必要な医薬品を提供することは各国の健康政策の中でも重要目標のひとつである．そのためには高価な輸入医薬品に頼るのではなく，自国の医薬品生産能力を高め国民に安価に医薬品供給する努力が多くの発展途上国でなされている．その結果，医薬品生産の経験及びノウハウの蓄積に乏しい国でも医薬品生産が行われるようになり，品質確保などの面において，海外の専門家による技術的支援が必要と認識されている[4)]．

GMPが遵守されなかったためにローカル生産の医薬品により致命的な事故も発生している．ハイチでジエチレングリコール（DEP）で汚染されたグリセリンを用いてパラセタモールが生産され，1995年から1996年にかけて86名の子供がDEPによる腎不全のため命を奪われた[7)8)]．誤表示や複雑な流通経路の問題はあるが，医薬品製造業者がGMPを遵守して原料を確認していれば防げた事故であった．この事件が示すように医薬品規制当局及び医薬品製造業者がGMPを尊重し，実施することによってのみ医薬品の品質を確保することができるのである．

WHOが1967年に最初のGMPを公表した後に，ヨーロッパ共同体（EC）や東南アジア諸国連合（ASEAN）なども1980年代から1990年代初頭にGMPを公表し医薬品の品質確保の推進を図った[9)10)]．また，国際標準化機構（ISO）も品質システムガイドラインISO 9000からISO 9004を公表した．WHOも内容を刷新し1992年に改定GMPを公表し，順次テキストを追加し現在の包括的なガイドラインとなっている．1994年に世界保健総会（WHA）は決議WHA 47.11でWHOGMPを承認した．また，国際的に流通する医薬品のWHO方式品質保証ガイドライン（Guidelines on the WHO certification scheme on the quality of pharmaceutical products moving in international commerce）は，輸出用医薬品がGMPに則して生産されたことを輸出国が証明することにより品質確保する手段を提供している[11)]．日本を含め多数の国がこの様式を承認している．

WHOや加盟国でGMPの重要性が認識され関連基準が整備されてきているにもかかわらず，その実施状況は必ずしも捗々しくない．GMP実施段階は大よそ次の三つに分類される：

第一段階．製造業者及び製造施設は部分的にGMPを実施しているか，または全く実施していない．

第二段階．GMPは新しく建設された施設で実施されているが，古い施設では改善が必要である．

第三段階．実質的にすべての医薬品の製造施設及び製造工程でGMPが実施されている．

本プロジェクトはGMPの実施状況を世界的視野から把握するとともに，実施を妨げている要因を同定し，その克服に役立つツールを提供する．そして協力国とのモデル事業を通じ各地域・各国で独自に行うことのできるGMP推進方法を提案する．これはWHO医薬品戦略の趣旨に沿うものであり[12)]，本プロジェクトには各方面から大きな期待が寄せられた．

ここではプロジェクト前半期の活動報告を通じ，WHO医薬品プロジェクトの手法を紹介するとともにこのようなドラッグマネジメントプロジェクトの要点を指摘する．プロジェクト後半期において，ツールの完成が計られるとともに，プロジェクト事業の評価が行われる．

## 2. 方　法

(1) プロジェクトの主体

プロジェクトはWHO内にワーキンググループが設置され，地域アドバイザー及びGMP高度専門家の助言・協力を得ながら進められた．

1) ワーキンググループ：WHO内にプロジェクトコーディネータ（筆者）を中心にWHO本部の必須医薬品・医薬品政策部（Essential Drugs and Medicines Policies : EDM．1998年のプロジェクト開始当時は医薬品管理政策部（DMP）と必須医薬品部（DAP）に別れていたが，1999年に合併してEDMとなった．）のプロフェッショナルスタッフ5名からなるワーキンググループ（以下，WGと記す）を設け，プロジェクトの事業計画や活動内容を決定した．プロジェクト専任はコーディネータのみで，他は併任である．事業の緩急により必要に応じてWGが召集された．このWGメンバーとプロジェクト付き秘書1名が活動の遂行にあたった．

2) WHO地域事務局医薬品アドバイザー：世界を6地域に分けたWHO地域事務局に一人ずつ配されている医薬品アドバイザー（地域アドバイザー）から各地域のGMP振興策や協力促補国について情報提供・助言を得た．

3) GMP高度専門家：国際的に活躍しているGMP専門の高度な監視員数名を地理的配分を考慮してWHO外部専門家として，プロジェクトを通じてGMPの技術的側面について協力を得た．GMP高度専門家は情報提供や助言を行うとともにプロジェクト協力国のGMP実施状況の評価，研修及びツール作成をWHOスタッフとともに行った．

(2) プロジェクトの客体

WHOプロジェクトは原則としてWHO加盟国政府を対象として行っている．各国のすべての監視員や個々の企業に対する直接事業は行わない．これは物理的に不可能であり効率も悪い．WHOプロジェクトの直接の参加者がその後GMP指導者として，自国あるいは地域全体の推進後になることが期待されている．

(3) 事業計画，協力国選定基準，GMP実施状況及びGMP阻害要因の同定

WGと地域アドバイザー及びGMP高度専門家との非公式会合を経て，GMP実施状況の情報収集及びGMP阻害要因の同定を行うと共に事業計画と協力国選定基準を作成した[13)14)]．

(4) プロジェクト協力国の選定

プロジェクト協力国の選定基準は以下の通りである[9)]：

—多国籍及び民族系の両方の企業が存在すること
—発展途上国であること
—WHOと実質的協力関係にあること
—機能している医薬品当局が存在すること
—周辺国へも改善の影響が波及しやすいこと
—相当量の医薬品生産が行われていること

さらにGMP向上への関心，事業効果の測定の容易さを考慮し，アジア，アフリカの候補国が絞り込まれ，プロジェクトへの参加の同意が得られた国をプロジェクト協力国とした．また，上記の基準に合致しても他のドナー機関がすでにGMP強化プロジェクトを行っている国は見送られた．

当事国薬務当局との接触は協力国の属する地域の医薬品アドバイザー及び協力国に駐在するWHO代表(以下，WR）を通じて行われた．

(5) プロジェクト協力国での活動

1) 初期訪問調査

協力国の受入れが確認されたところから，WGメンバーと外部専門化が協力国を訪問し，政府特に政策決定者のGMPに対する関心度，法的整備状況，GMP監視の実態及び企業のGMP実施状況を詳細調査し，勧告及び行動計画とともに報告書案にまとめた．報告書案は約一週間の調査の最終日にプロジェクト側から協力国に提示され，合意に達したものを最終報告書とした．前半期の実施国はミャンマーおよびネパールである．

2) 研修

研修に対する協力国側の希望が極めて高いことから，初期訪問調査中，2日間程度の研修を行った．この研修の目的は監視員の特性やGMP習熟度をプロジェクト側が把握するとともに，作成中の教材の試用を行うことであった．

プロジェクトの本格的な研修は，後半期にアジア及びアフリカの2つの協力国で行われる．その目的はGMP上級監視員の研修とプロジェクトで作成した教材の試用である．

## 3. 結　果

(1) プロジェクトの事業計画

プロジェクト事業は大きく分けて次の三分野に別れる：1) 実態把握 2) ツールの準備並びに 3) 実施及び評価．

それぞれの分野の事業計画は次のとおりである．(Figure 1)[15)]

1) 実態把握（1998～1999）
   a) GMP高度専門家による非公式会合（1998年2月）[13)]
   b) WHO地域アドバイザーとの非公式会合（1998年4月）[14)]
   c) プロジェクト協力国の選定：プロジェクト開始初年度に中国，ミャンマー，ネパール及びジンバブエを選定．
   d) 質問表の作成：プロジェクト協力国の初期訪問調査に先立ち事前調査を実施[13)]する為にGMP監視体制，監視状況などに関する質問表を作成．
   e) プロジェクト協力国の初期訪問調査：下記(7) 及び (8) 参照．
2) ツールの準備（1998～2000）
   a) 実践的問題解決法の考案：啓発，研修，プロジェクト協力国の行動計画などに反映
   b) 政策決定者向け啓発資料の作成：下記 (5) 参照
   c) GMP専門家リストの作成：国際的なGMP監視を行っている国々からGMP専門家の推進を受け，プロジェクトの展開や加盟国からの紹介に備え名簿作成
   d) 各国及び他機関のGMP研修教材の収集
   e) 研修教材の作成：下記 (6) 参照
3) 実施及び評価（1999～2000）

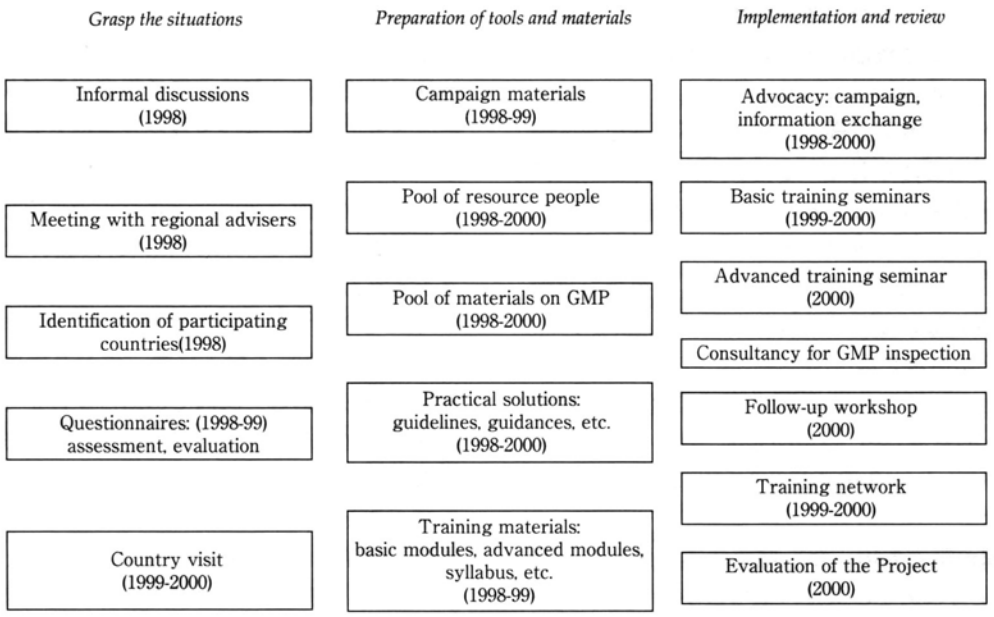


**Figure 1.** THE EDM PROJECT ON THE PROMOTION OF THE IMPLEMENTATION OF GMP

a) GMP 及びプロジェクトの広報：世界薬事当局者会議など種々の国際会合の折にプロジェクトによる GMP 推進事業を広報

b) プロジェクト協力国での活動：協力国でのプロジェクト活動の基本計画は Figure 2 に示した．初期訪問調査及び研修のほか次のような事業が含まれている：

—GMP 監視員育成事業：専門家を派遣して，GMP ガイドラインや GMP 監視マニュアルなどの整備を支援するとともに，GMP 監視を実地指導

—協力国追跡調査：初期訪問調査で掲げた行動計画がどの程度達成されたかを評価し，今後の目標及びプロジェクト活動を再考（後半期事業）

c) 地域ネットワーク設立の検討：本プロジェクト終了後も GMP 推進が地域で計られるよう地域ネットワークの設立について予備的検討

d) プロジェクトの評価：プロジェクト終了に当たり，プロジェクトにより開発された GMP 改善法などプロジェクトの成果を評価し，プロジェクト終了後の GMP 推進方策を検討

(2) GMP 監視員の資質の担保

大学で履修した専門分野のみならず，製薬企業勤務経験，就業訓練（OJT），リフレッシュ教育，生涯の専門職業人としての育成，特に滅菌，バリデーション（検証），コンピュータなど専門分野をもつことなどが高い資質を有する GMP 監視員の養成につながっていると考えられる[13]．

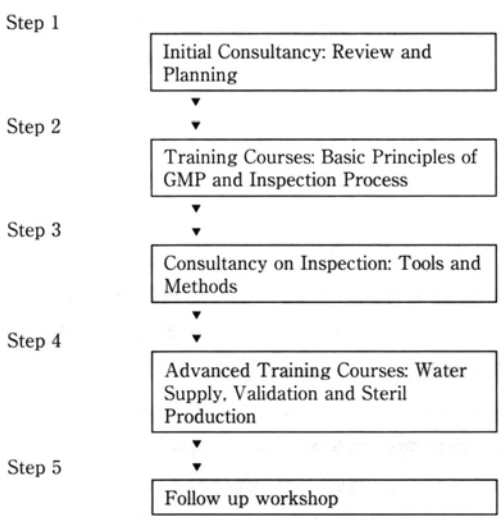


**Figure 2.** COUNTRY AND REGIONAL ACTIVITIES OF THE GMP PROJECT

(3) 世界的な GMP 実施状況の概要

一般に先進地域にある工場は GMP 実施状況が高く，発展途上地域では実施状況が低いと思われている．実際は先進国でも満足すべき GMP 実施状況にない工場がある一方，発展途上国でも厳しい査察に十分耐え得る高水準の GMP を実施している工場もある．GMP 実施は結局，個々の企業・工場の問題であり，国内にある医薬品製造工場の実施状況を良好にすることが医薬品生産国の使命である．

不適合の例としては，古い施設，GMP 関連文書の

欠落，バリデーションの欠落，設備不十分な品質検査所，パイプラインや機器の無い表示の無菌領域に不要物品の放置，工場内のペニシリン粉塵，キャリブレーション不履行や不適切な機器の使用，不適当な空気調整や水流などが認められている．また，海外から提供されたGMP監視員研修に参加しても，配置転換や民間への転出により研修成果が生かされないことも指摘されている．政治的関心の低さを克服し，複雑な政治環境が是正されない限り改善は望めない[13]．

(4) GMPの阻害要因

GMP実施を妨げている要因を (a) 関係者の責任関与 (b) 人的資源 (c) 経済的要因 (d) インフラストラクチャー (e) 文化的背景及び (f) 政治的背景ごとに同定した．

1) 政府側の阻害要因：(a) 健康問題の優先度の低さ，政策決定者の関心の低さ，法令の不十分な整備や未施行，外部提供プログラムの成果の非活用 (b) 専門スタッフ不足，活用されない専門家，人材育成不足，継続教育の欠如，民間への頭脳流出，企業との相互信頼・協力関係の欠如 (c) 利益を優先させ品質を軽視，政府GMP監視員の低賃金，非効率的な財源活用 (d) 監視員不足，薬務当局と監視当局の分断，監視員権限の低さ，監視当局と国立品質検査所の非協力，最新情報や高度な知識へのアクセス欠如，監視業務の文書化と品質管理システムの欠如 (e) 性差別及び階級差別，監視員の地位の低さ，対立回避性行，先輩に対する遠慮，多様な言語 (f) 腐敗．

2) 製造業者側の要因：(a) 品質問題の優先度の低さ，改善誘因の欠如，高度化への無関心，特に管理者の関心の低さ，(b) 施設設備の使用法・整備法ノウハウの欠如，有能なスタッフや管理者の不足，人材の誤用，継続教育の欠如 (c) 品質確保は割高という誤解，財源配分の問題 (d) 時代遅れや不十分な基盤：設備機器，原料供給者との関係，文書，バリデーションプログラムなど．機器の誤用と不適切な整備，最新情報・高度な知識・技術へのアクセス欠如 (e) 対立回避性向，多様な言語 (f) 腐敗[13]．

(5) 啓発資料の開発

医薬品の品質やGMPに関心の薄い政治家，政府高官，製薬企業経営者及び一般大衆にGMPが人の健康保護に重要であることを訴える啓発資料の開発を進めた．政策決定者を始めとし各界の認識を高めるために，様々な機会での活用が計られている．

(6) 研修用教材の開発

研修用教材“GMP基本原則”及び“GMP査察プロセス”の開発を進めた．WHOGMP (Good manufacturing practice for pharmaceutical products)[2] 及びWHO医薬品製造者査察暫定ガイドライン (Provisional guidelines on the inspection of pharmaceutical manufacturers)[16] に則して作成し，講師用教材，研修生用配布資料，スライド，テストなどから構成されている．コントラクターによる素案作成後，GMP高度専門家からのコメント，修正版作成，プロジェクト協力国の初期訪問調査や後半期の研修での試用，再修正を経てWHOGMP研修教材として完成する予定である．

(7) ミャンマー初期訪問調査 (1999年1月)[17]

医薬品の90%を輸入に頼っており国内の医薬品は不足しがちである．国内での増産をはかり新たな国営企業が設立されたばかりだった．このような状況下でGMPの普及は重要課題でありGMP監視は1995年のFood and Drug Administration (FDA) の設立と同時に開始された．FDA，企業 (I) 省及び国防省合同でGMP教育委員会の設置，公用語によるGMP規則や監視マニュアルなど法令やガイドラインの整備及び指導的立場の監視員のWHOGMP研修への参加等を行動計画として提案した．この提案は具体的かつ建設的であるとFDAから評価された．

(8) ネパール初期訪問調査 (1999年1月)[18]

医薬品の80%はインドからの輸入であり，その品質確保が大きな課題である．国内でも相当量の医薬品生産が行われるようになっており，初期訪問調査の結果，GMP監視員のWHOGMP研修への参加，公用語によるGMP規則その他法的ツールの改善と施行，適切なGMP監視の実施を勧告した．ネパールのGMP取組みの改善状況を見て，半年後にプロジェクトとの協力関係について再考することとされた．この報告書がきっかけとなって，ネパール厚生省上層部やマスコミがGMP取組み強化の必要性を認識し，Department of Drug Administration (DDA) 及び国営企業においてGMP取組み強化が始った．また，WHOプロジェクトとの協力関係も維持された．

## 4. 結論及び考察

本プロジェクトはWHOが初めて世界規模で行うGMP推進プロジェクトであり，その重要性とタイミングについて高く評価され注目された．このプロジェクトは研修や研修教材の提供のみを目指しているものではなく，如何にGMPを新興医薬品生産国に普及させるかというノウハウを蓄積し，プロジェクト終了後も各地域，各国独自のGMP普及に役立てることを目指している．

本プロジェクトの進行方法は，医薬品管理政策プロジェクトの基本的枠組みを提供するものである：すなわち，情報収集による実態把握，訪問調査，ツールの

準備，対策の実施，ツールの完成，プロジェクトの評価，国・地域での永続的推進というものである．この枠組みにより着実な成果を積み上げることができる．

多くの発展途上国が今なお輸入医薬品に頼っていることから，生産・輸出国でのGMPの徹底が緊要である．GMP実施には資金も時間も必要と考えられがちであるが，工場内の表示，手順の文書化や記録作成など心掛け一つで実行可能な重要部分もある．また，安全に直結する部分については特に迅速な対応が求められる．

GMP監視員養成のため海外専門家による研修に対する要望が発展途上国では強いが，研修した成果を国内に定着させ生かす体制がない限り，いくら研修を繰り返してもその国のGMP向上には結びつかない．GMPは単なる技術目標ではなく，当局及び製薬企業の健康や安全性に関する意識の高まりによって初めて達成され，定着するものである．プロジェクトもこの点に重点を置いて進められるべきである．決定権及び影響力のある人々の認識を高めることは，ドラックマネジメントプロジェクトにおいて必須である

プロジェクト後半ではさらに協力国との共同事業を進め，教材等の完成及びプロジェクトの評価が行われる．

謝辞：貴重な助言と多大な協力を提供して頂いたWHOGMP推進プロジェクトワーキンググループメンバーMrs Kari Bremer, Dr Juhana Idanpaan-Heikkila, Dr Sabine Kopp-Kubel及びMr Eshetu Wondemagenehuの各氏並びにGMP監視員として専門的見地から助言協力を受けMr David R. Buchley及びMr. Andrey van Zylに心から感謝する．

就中，プロジェクト半ばでプロジェクト責任者の重責を引き継がれ交代による空白期間もなく見事に事業を展開しつつある森本和滋氏に敬意を表すとともに今後のご活躍をお祈りする．

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**Abstract**

## The First Half of the WHO Project of the Promotion of Implementation of Good Manufacturing Practice (GMP)

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**Key words**: World Health Organization (WHO), Good Manufacturing Practices (GMP), obstacles, training, participating countries

Despite the major achievements of WHO and its Member States in defining GMP and other relevant standards, implementation of these standards has varied greatly among countries and pharmaceutical factories. Local production of pharmaceutical products involving new countries with less experience and know-how in drug manufacture is continually increasing. As more countries develop the capacity to produce pharmaceuticals, the need for external advice on various aspects of the manufacturing process and quality assurance in particular is more recognized.

The triennial WHO project[1] which started in 1998 identified the major obstacles encountered in the implementation of GMP, developing practical solutions and providing training in GMP as required. By calling upon the advice of recognized GMP experts and inspectors, guidance and expertise in GMP implementation were directed to participating countries that had indicated their interests in the exercise. In this article the methods as well as activities during the first half of the project, which had been operated at the global level aiming at sustainable improvement, are introduced.

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2) Angell M : The presidential candidates and health care reform.N Eng J Med, 1992 ; 327 : 800－801

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## 編集後記

「国際保健医療」の第16巻第1号をお届けします．最近，投稿原稿数は若干増加しています．お問い合せも多くなり，喜ばしいことだと思っています．今年度は東京の慶応大学で学会が開催され，盛況でした．

今年は21世紀の初めの年でしたが，9月11日には世界を揺るがすような事件が起こり，今後の歴史に残る年となりました．そうした状況の中で，国際保健の役割はいっそう大きなものとなります．現実は，世界の人々の健康の格差が縮まるどころか拡大を続け，相互理解への道はまだまだ遠いことを思い知らされています．だからこそ，未来への目標をもって研究ならびに活動を進めていくことが必要になります．

本号では，英語論文が2本，そして各地での活動報告が3本あります．各国の事情を背景にして，さらに活発に研究が進められていることを願っています．すでに現在，次の号を編集中です．近いうちに本年度の第2号をお届けできるようにしたいと思います．

投稿後にお待たせすることがありましたが，今後できるだけ速やかに掲載できるようにしていきますので，ぜひ国際保健医療に関わる研究論文のご投稿をお願いいたします．

（丸井英二）


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