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The Performance Evaluation on the Electronic Medical Records Project of the Health-Care Systems: A Case Study from the National Audit Office of the Republic of China, Taiwan

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I. INTRODUCTION

a) *Development of the Public Health-Care System in Taiwan*

Taiwan's economic miracle is known to the world. One of the reasons for its success is a sound public health infrastructure, which made this economic miracle possible. The ROC's Department of Health (DOH) has a broad range of duties, including: responsibility for public health, health promotion, disease-prevention monitoring, food safety, drug administration, medical care, National Health Insurance,

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¹ Report on the 14th UN/INTOSAI Seminar, on Government Auditing the Audit of Public Health Care System by SAI, Vienna March 27- 31, 2000, p4.

care for the disadvantaged, biotech research and development and international health affairs. The following is a brief introduction to the history of Taiwan's public health development.

b) *The Missionary Period (1865-1895)*

Several Western missionaries, including the earliest Dr. James Laidlaw Maxwell and the later Dr. George L. Mackay and Dr. David Landsborough came to Taiwan from foreign lands. With confidence and sincerity, they dedicated their lives to Taiwan and allowed let Western medicine to take root in this land, thereby winning the gratitude and respect of the local people. One after another they opened hospitals in Taiwan, such as the Gu Lau Hospital (now the Sin Lau Hospital) in Tainan, the Christian Hospital in Chunghua and the Mackay Hospital in Taipei. These hospitals were the three major privately-run medical facilities in Taiwan during this period.

c) *Medical Development During the Japanese Rule (1895- 1945)*

The foundation for early medical development in Taiwan was laid mostly during the period when Japan colonized Taiwan from 1895-1945. At that time, epidemics were prevalent in Taiwan due to the damp climate and poor hygiene. The Japanese government realized that their lasting rule in Taiwan hinged on the effective control of epidemics, and therefore, attached special importance to this effort, laying a solid foundation for Taiwan's public health system, thereby improving the health of the Taiwanese people.

d) *Public Health After the Government's Relocation to Taiwan (1945-)*

Taiwan's medical facilities were seriously damaged during the Second World War and much needed to be done to fix them. As Taiwan is located in the sub-tropics, epidemics were frequent at that time, so health authorities decided to give precedence to the development of a national health system and put medical construction on the back burner. This policy served to lay a solid foundation for Taiwan's medical development in the years to follow. The major measures at that time included the wide establishment of health

stations, elimination of malaria, plague and cholera, universal vaccinations, promotion of women's and children's health as well as Planned Parenthood². It also promoted the construction of a health network and launched the National Health Insurance (NHI) program in 1995. Following the launch of NHI, it has gradually achieved the goal of reducing people's medical treatment burden, especially on fair medical treatment,

universal health care coverage, and shortened wait times. Under this insurance system people would not be in poverty due to taking medical treatment and the nation enjoys the lowest administrative costs in the world. In 2009, for example, national health expenditures per capita each year were \$ 2,186, (in the United States they were 3.6 times larger) and medical costs occupied only 6.9% of the GDP (Figure 1).

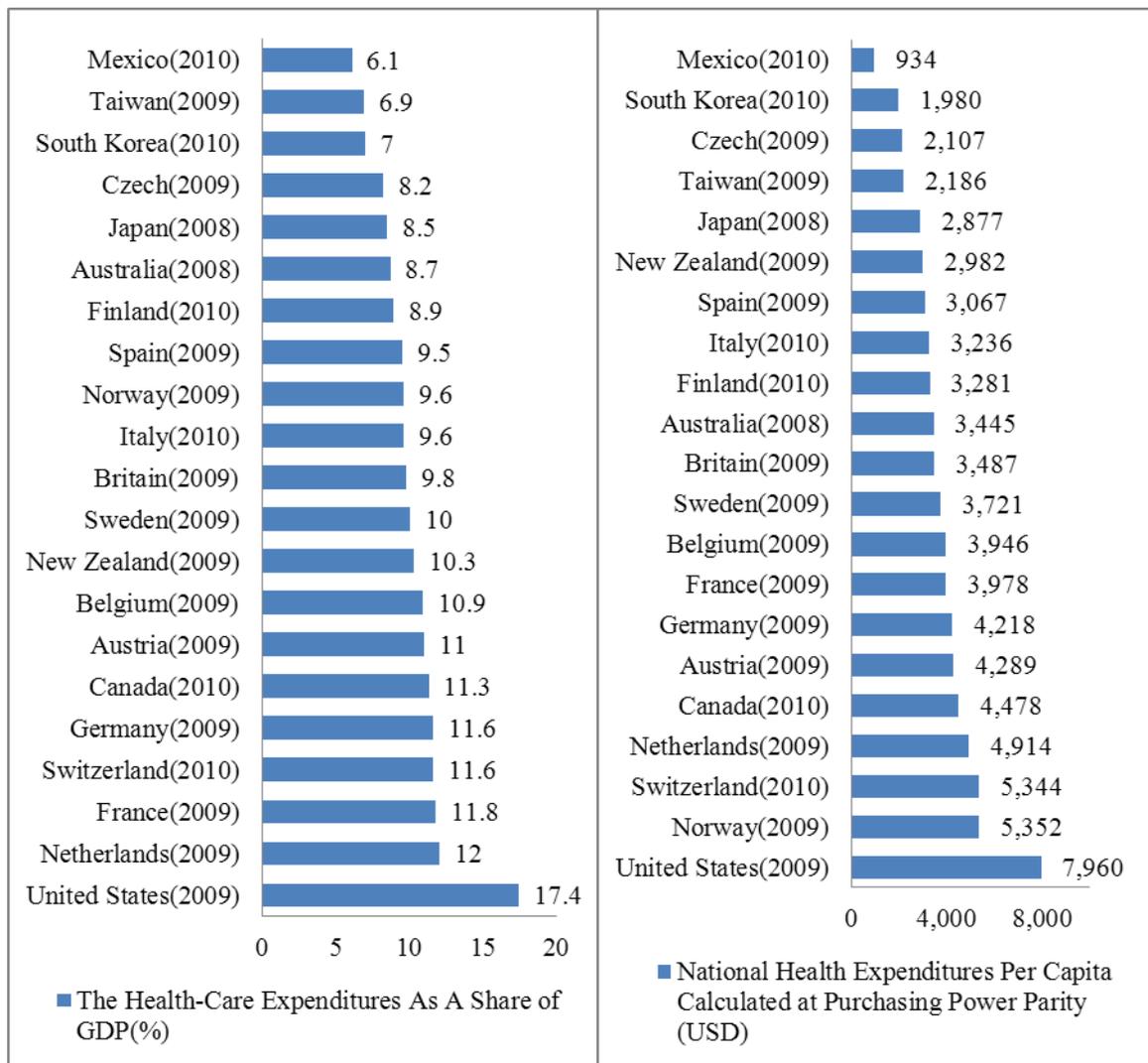


Figure 1 : Taiwan National Health Expenditures Comparing With the Major Countries, Sources: The Bureau of National Health Insurance

Average annual growth rate of National health expenditures was controlled at about 5.1%, which is lower than most of the major countries (Figure 2). Besides, among the 2009's top 20 brand drugs of NHI expenditure, their 2010 NHI paid drug prices are all lower than the drug prices of the major countries (Figure 3).

²http://www.nhi.gov.tw/English/webdata/webdata.aspx?menu=11&menu_id=290&WD_ID=290&webdata_id=1885, latest visit on May 1.

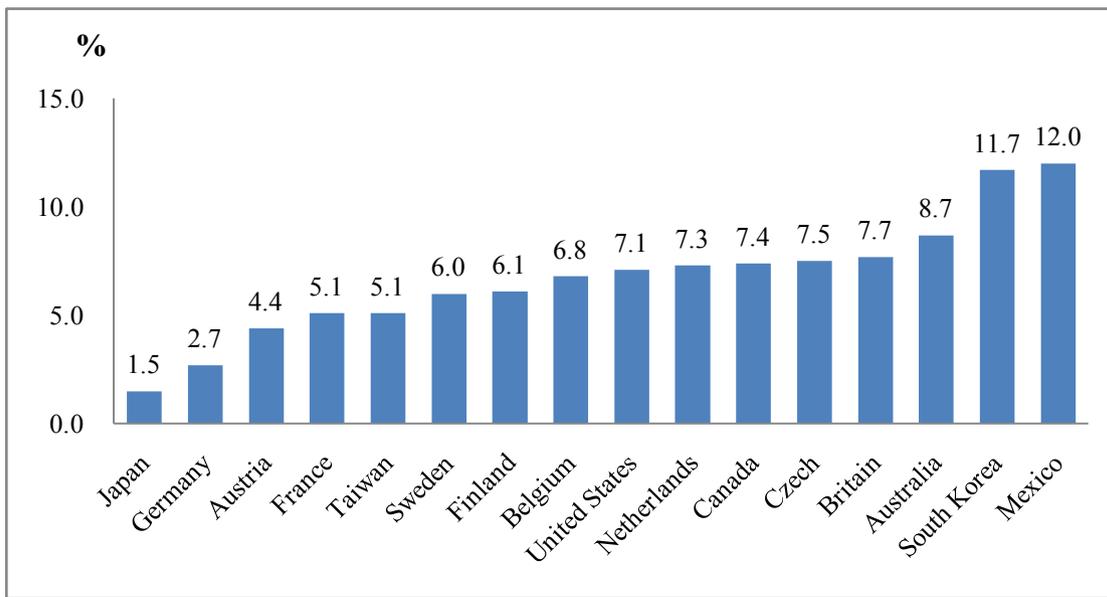
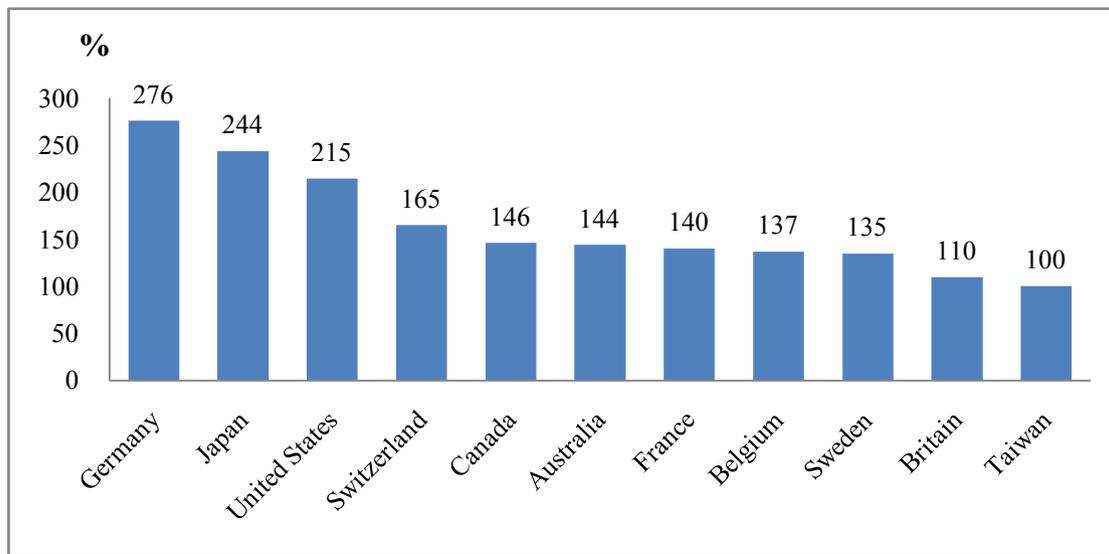


Figure 2 : National Health Expenditures Average Annual Growth Rate among the Major

Notes : Japan (1998-2007), Austria (1998-2007).

Sources : The Bureau of National Health Insurance.



Countries (1999-2008)

Figure 3 : NHI Brand Drugs Prices Are Lower Than the Major Countries

Notes : This data is based on the 2009's top 20 brand drugs of NHI expenditure to compare with their 2010 NHI pay drug prices and the drug prices of the major countries.

Sources : The Bureau of National Health Insurance.

II. CASE STUDY : THE PERFORMANCE EVALUATION BY THE NATIONAL AUDIT OFFICE OF THE REPUBLIC OF CHINA, TAIWAN ON THE ELECTRONIC MEDICAL RECORDS PROJECT

The Department of Health has promoted "National Health Informatics Project (NHIP)" since 2008 and "promoting the implementation of electronic medical

records" is its primary objective. The main implementation strategies include: setting the common format for electronic medical records, promoting the health insurance professional review and hospital evaluation to relate electronic medical records while also providing medical institutions related personnel training and technical counseling for implementing electronic medical records. The Department of Health in 2010 added "Accelerated Medical Institutions Implementing Electronic Medical Records Systems Project (2010-

2012) " branch project in the "Accelerating the execution of Intelligent Medical Care Project" (Appendix 1). To fully implement electronic medical records and medical records exchange system by 2014, the Department of Health speeds up the process of implementing electronic medical records in medical institutions from four dimensions: regulation, standard, safety and promotion, conducting strategy planning and supporting measures. To respond to what INTOSAI suggested that SAIs should pay attention to the new issues of public health-care systems, the National Audit Office planned to evaluate the performance of the electronic medical records projects.

The INTOSAI Working Group on Program Evaluation released "Program Evaluation for SAIs - A Primer" in 2010 to promote this new concept of performance audit. According to this paper, program evaluation is defined as:

A program evaluation is a systematic investigation of an organization or institution, program or project, or process or policy that is intended to benefit society. A program evaluation's purpose may be to help improve, help decide an action, or learn reasons for successes and failures or strengths and weaknesses in meeting objectives. It can document for accountability or increase knowledge. Program evaluations commonly determine criteria that distinguish between high and low quality, measure performance against those criteria, and draw valid and reliable evaluative conclusions.

A program evaluation may be independent while being conducted with participation from community members, consumers, managers, and others to give it multiple perspectives. The evaluation process may involve identifying objectives and key questions, defining assessment criteria, obtaining and analyzing relevant data, reporting results, and promoting the effective use of the findings. Evaluations are conducted by persons well-grounded in research design and methodology, content knowledge and skills in particular specializations, and competencies in evaluation theory, evaluation methodology, and practical knowledge.

The method of this evaluation was adopting the concept of process evaluation in program evaluation, to evaluate the input, process, output, outcome and efficiency of electronic medical records related projects so as to answer the following questions:

1. How many target groups was the electronic medical records services being provided?
2. Did target groups receive appropriate services?
3. Were the projects properly implemented?
4. Were the resources enough?
5. How was the gap between actual and expected outcomes?

We evaluated these related projects based on Cost-Effectiveness, Regulations, Information Security as well as Resources Allocation and Utilization.

The development and the use of Electronic medical records involved professionals from different fields, such as medicine, public health, legal and information technology. The audit process was from September to November in 2011, and auditors made a systematic check by analyzing key documents such as relevant media opinion reports, professional website bulletins, health statistics, related information system database, internal sheets, minutes of meetings, related operational rules and standards, relevant documents, files, and information from other countries promoting similar projects; in order to obtain the objective testimony and instructions, the auditors interviewed the Department of Health officers, major systems suppliers, nine hospitals which use the systems and got descriptive statistics for the data obtained. We found some key findings about the related electronic medical records projects from the 4 areas of Cost-Effectiveness, Regulations, Information Security, Resources Allocation and Utilization³.

The electronic medical records related projects have completed the model of 117 electronic medical records forms and announced 4 types of electronic medical records exchange standards, 93 medical institutes completed ISO27001: 2005 international information security system verification, 211 medical institutions completed the electronic medical record checks, 152 medical institutions completed electronic medical records inspection, and constructed electronic medical records exchange center (142 medical institutions involved in detection). There's considerable success in promoting the medical institutes' medical records electronization, however, there are still many defects that need to be improved, not being able to fulfill certain duties and performing too low on cost-effectiveness, regulations, information security, resources allocation and utilization dimensions.

a) *Cost-Effectiveness*

The projects content significantly adjusted and reduced the challenges of the projects objectives and didn't set project goals on a results-oriented basis and actual performance did not meet the plan original intention.

The NHIP set results-oriented or effectiveness-oriented indicators such as "the number of people owned electronic medical records", "the number of information exchange", and "the number of people who use personal health management demonstration system" (Appendix 2) but in 2009 the project was amended. In addition to deleting three branch projects and the indicators above, it let the challenge of project

³ TanjimaPervin, Ulf-G Gerdtham1 and Carl HampusLyttkens, Societal costs of air pollution-related health hazards: A review of methods and results, Pervin et al; licensee BioMed Central Ltd. 2008, 6:19.p3.

goals fall sharply and lacked results-oriented or effectiveness-oriented indicators, so that it is difficult to assess outcomes of the project. It resulted in achieving the outcome of “the rate of hospitals implementing electronic medical records” performance indicators [the number of hospitals implementing electronic medical record/ the number of national hospitals (500) × 100%] reached up to 222% [target value was 23%, actual value was 51.2% (accumulated

more than 256 hospitals across the country reported the implementation of electronic medical records; 256/500 × 100%)], but observing from the substantive outcomes (EHR campus-wide access to download situation) there were 142 hospitals involved in the electronic medical records exchange and from May 2010 to April 2012, the actual number of retrieving medical records was only about 14,000 times.

The planned value, amended value, and actual value of performance indicators of electronic medical records related projects

Performance Indicator	Planned Value	Amended Value	Actual Value
Encouraging and counseling medical institutions to develop the informatization of medical operations, the electronic and exchange of electronic medical records	Until the end of 2012 : <ul style="list-style-type: none"> The hospitals proportion of implementing electronic medical records all around the country: 80% The hospitals proportion of implementing electronic medical records all the Department of Health's hospitals: 100% The clinics proportion of implementing electronic medical records all around the country: 70% 	Until the end of 2012 : <ul style="list-style-type: none"> The hospitals proportion of implementing electronic medical records all around the country: 26% The hospitals proportion of implementing electronic medical records all the Department of Health's hospitals: 23% The clinics proportion of implementing electronic medical records all around the country: 10% 	Until the end of 2012 : <ul style="list-style-type: none"> The hospitals proportion of implementing electronic medical records all around the country: 41% The hospitals proportion of implementing electronic medical records all the Department of Health's hospitals: 100% The clinics proportion of implementing electronic medical records all around the country: 10%
Promoting the exchange of electronic medical records across hospitals	Until the end of 2012 : <ul style="list-style-type: none"> The cumulative number of hospitals providing retrieving electronic medical records across hospitals: 300 Shortening the patients' waiting time for medical images output time: 1-2 days 	Until the end of 2012 : <ul style="list-style-type: none"> The cumulative number of hospitals providing retrieving electronic medical records across hospitals: 75 Shortening the patients' waiting time for medical images output time: 1-2 days 	Until the end of 2011 : <ul style="list-style-type: none"> The cumulative number of hospitals providing retrieving electronic medical records across hospitals: 142 Shortening the patients' waiting time for medical images output time: 1-2 days
The number of people who own electronic medical records	1 million people until the end of 2011	N/A	N/A
The annual number of information exchange of electronic medical records, referral, or the Bureau of NH's professional review	40,000 until the end of 2011	N/A	N/A
Total visitors of people using personal health management demonstration system	50,000 visitors until the end of 2011	N/A	N/A
Total issued number of second generation medical certificate IC card	N/A	90,000 until the end of 2011	160,000 until the end of 2011
The implementation ratio of public health information integration services	N/A	90% until the end of 2011	94.7% until the end of 2011
The completion rate of health indicators	N/A	100% based on the standards of WHO and OECD until the end of 2011	N/A

Sources : The Department of Health of the Republic of China, Taiwan.

b) Regulations

The relevant laws and regulations for promoting electronic medical records have not been sound yet.

To promote electronic medical records, the Department of Health amended "Medical Care Act" article 69 in 2004: "Medical care institutions which document and store medical records by means of electronic records shall be exempt from producing another written copy...". It made electronic medical records legal, and "Regulations Governing and Development and Management of Electronic Medical Records" was decreed. However, in order to ensure the privacy of patient and the confidentiality of electronic medical records, and to analyze how the release of the "Personal Information Protection Act" impacts Medical Care Act and all kinds of medical personnel regulations related to electronic medical records, the Department of Health in 2010 contracted with Integrating the Healthcare Enterprise Taiwan Association for "the research of 2010 completing electronic medical records legal system". According to research in the final report, it recommended to set related regulations about the transmission of exchanging electronic medical records, the paper and electronic medical records, how the electronic medical records responds to the impact of the Personal Information Protection Act, the public sectors collecting of health information, problems related to the classification of medical records, as well as the outsourcing of electronic medical records processing. Until the auditing date (April 30 2012), the Department of Health has not yet acted on these recommendations so the related administrative process is far from effective. It highlights that the electronic medical records project invested huge funds without conducting the appropriate evaluation of the legal system.

The implementation of electronic medical records regulations are unsound and lack the proper supervision and evaluation mechanisms.

According to the article 69 of the Medical Care Act, electronic medical records can replace paper medical records. Because there is no review threshold or mechanism in Regulations Governing and Development and Management of Electronic Medical Records and the lack of afterward supervision and evaluation mechanisms, if the hospitals in which information security management mechanisms are relatively unsound implement electronic medical records first, when information security events such as medical records tampering or leakage occur, it will cause disputes between doctors and patients and damage patient's rights. According to the NHIP implementation performance evaluation report, by the end of 2011, 274 hospitals have already declared the implementation of electronic medical records, including 211 hospitals (77.01%) passed through the electronic medical records checks, showing that about 20% of hospitals have not yet applied for checks. According to the result of "2011

hospitals electronic medical records checks", about 10 hospitals signed for follow-up examinations but had not applied for re-checks within the check project. Furthermore, the Department of Health has not planned a follow-up monitoring mechanism for those hospitals which passed checks, nor set a deadline for certification, that is, the certification is permanent; unless the hospital applies for another category of electronic medical records check, it is difficult to ensure that the hospital passed checks of which follow-up development of electronic medical records is in line with the relevant provisions.

c) Information Security

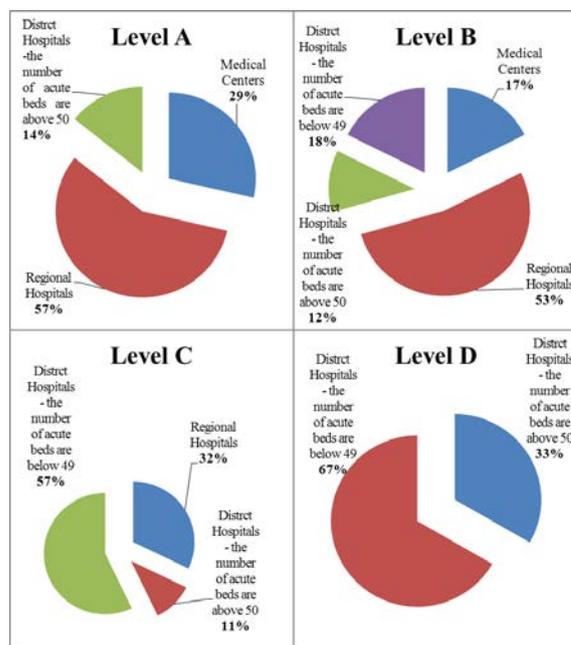
The sensitive personal information such as domestic violence, sexual abuse, mental illness, statutory infectious diseases, or acquired immune deficiency syndrome (AIDS) will cause serious damage to the patients' rights and interests if this information is leaked. In medical records management, such medical records are sensitive medical records; relevant regulatory requirements for the management of retrieving sensitive medical records should be stricter than other general medical records. The current system of EEC exchange mechanism does not set further mandatory encryption and permissions control for sensitive electronic medical records according to the degree of sensitivity; it only depends on the self-management of hospital side. If one hospital's management is loose, the sensitive electronic medical records exchanged from the well managed hospital will be in danger of leakage. It seriously affects the interest of patients whose electronic medical records are leaked, and it's contrary to the relevant laws and regulations. It also highlights the department of health's incomplete planning of electronic health record exchange management.

Small hospitals rely heavily on contractors, and some hospitals, without obtaining any information security certification, still join the exchange system of electronic medical records and it results in the information security vulnerabilities of overall exchange system.

To ensure the security of electronic medical records, the category of information security checks on medical institutions' electronic records can be summarized by the three major aspects of the management of electronic medical records mainframe (computer room), the production of electronic medical records, and the training of personnel and management. The Department of Health has been training hospital security seed personnel, conducting hospital information security workshops, contracting with providers to counsel 93 hospitals to achieve ISO 27001:2005 - Information Security Management Systems Certification, and conducting electronic medical records checks on 211 medical institutions, to make sure that the electronic medical records made by institutions comply with the "Regulations Governing and

Development and Management of Electronic Medical Records”.

According to the NHIP implementation performance evaluation report, by the end of 2011, 274 hospitals have declared the implementation of electronic medical records, including 142 hospitals participated in the electronic health record exchange, however, 24 hospitals dose not passed ISO 27001:2005 or the Department of Health’s information safety checks, but they are still permitted to participate in the exchange of electronic medical records, and it results in the information security vulnerabilities of overall exchange system. On the other hand, in 2011 hospital evaluation, there were 56 hospitals from 122 evaluated hospitals taking in the assessment of electronic medical records management system, and the evaluation results shows that there is about half of level A and B belonging to medium-sized regional hospitals, and small hospitals are in the majority of level C and D, it shows the electronic medical records management system of most small hospitals are not performing as well as they could. Electronic medical records through EEC are exchanged among small and large hospitals; even if large hospitals could effectively implement information security management and control, small hospitals, due to the lack of IT manpower, technology and funding, have to rely on contractors to build and maintain electronic medical records system. However, the Department of Health has not yet established the related supervision and management mechanism of hospital electronic medical records management outsourcing, so the electronic medical records made by either small or large hospitals may leak from small hospitals if contractors make mistakes which results information security vulnerabilities to the overall exchange system. Besides, when personal electronic data leaks, it’s usually in a large number of batches, unlike paper leakage which results in a comparatively small number of files being leaked, so it will cause more damage compared to traditional paper records.



III. RESOURCES ALLOCATION AND UTILIZATION

The electronic medical records projects lacked long-term and integer planning, budgeted separately in the general budget and special budget in addition to having insufficient long-term financial resources.

The promotion of electronic medical records is an important policy of the Department of Health, but it did not take into account the international experience from nations such as the United States, Canada and the United Kingdom to establish a comprehensive plan and failed to properly seek out long-term and stable resources. The implementation funds over the years were separated in the general budget and special budget, so it was hard to get the whole picture of the process of related projects and to evaluate the overall performance⁴. The Department of Health explained that the Minister of Health was changed three times in 2008, which intern caused the policy direction to change. It was revealed that the electronic medical records related projects lacked long-term, comprehensive planning and due to the policy direction changing repeatedly, there was a decrease of general funds in the planned budget, another budget in the special budget, all of which influenced the performance evaluation.

The executive way of subsidized projects was improper and it made the allocation of resources unequal.

The objective of subsidizing hospitals to implement electronic medical records was expanding the hospital's participation, and the principle of

⁴ Kenneth J. Arrow, Economic Welfare and the Allocation of Resources for Invention, National Bureau of Economic Research, Universities-National Bureau, 1962, p3.

subsidizing objects was mainly covering fund-shortages in district hospitals, regional hospitals and medical centers were secondary objectives. However, the actual situation of subsidization in 2010 and 2011, there were 78 district hospitals (counted 20.86% of all local hospitals around the country), 45 regional hospitals (counted 54.22% of all regional hospitals around the country), and 20 medical centers (counted 90.91% of all medical centers around the country) getting the subsidization. On average, each medical center got subsidy of NT\$560 million, each regional hospital got subsidy of NT\$495 million, and each district hospital got subsidy of NT\$2.34 million. The actual situation of subsidization was obviously contrary to the Department of Health's subsidizing principle.

The subsidization focused on the establishment of an electronic information platform and exchange system, and adopted the direct review of results instead of reviewing, planning then reviewing result later to ensure that it achieved its performance goals. Besides, announcing the usage and balance of subsidies on the Department of Health's electronic medical records website help to facilitate the competition. However, compared with small hospitals, large hospitals are more competitive because of relative abundance of human power and material resources, and the Department of Health adopted the direct review of results and the first-come, first-serve review way, so it made the actual subsidies of small hospitals relatively low. This situation not only violated the original projects intention but also caused small hospitals difficulty in enhancing the efficiency of medical services, and it intensified "the big get bigger" uneven competition of the development of domestic medical environment.

IV. CONCLUSION

These points have become the new auditing issue for SAIs. With limited resources available for providing health care, it is important that providers maximize the economy, efficiency and effectiveness of the services they provide. The auditor has an important role to play in helping to ensure that value for money increases, as well as that the expenditure was lawful and accounted for properly. At the same time, patients were rightly becoming more aware of the quality of the service they receive. This had led to calls for more transparency, more comparisons of health outcomes between providers and assurance that best practice is being adopted as part of their treatment. This growing demand for transparency is another reason why the auditing of health systems is increasing in importance.

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