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觸控式電腦問卷與手寫問卷之可行性與相等性評估-以 EORTC QLQ-C30 及 EORTC QLQ-PR25 測量攝護腺癌患者生活品質為例

Measurement Feasibility and Equivalence of Paper and Touch-screen Versions of the EORTC QLQ-C30 and the EORTC QLQ-PR25 Questionnaires in Prostate Cancer Patients

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中　華　民　國　九　十　九　年　七　月

致　謝

出生自今，你愛過什麼嗎?是什麼提升你的靈
魂?是什麼支配你的靈魂，同時又令你喜悅？

~Friedrich Wilhelm Nietzsche

終於提筆寫這段謝詞，兩年的光陰稍縱即逝而隨著鍵盤的敲打，時間的輪軸便將所有酸甜苦辣的情緒一一列印出來。

愛爾蘭劇作家蕭伯納（George Bernard Shaw）說：人生真正的歡欣，就是在於你自認正在為一個偉大目標運用自己。在研究所的階段，我充分享受如此的歡欣。雖然在通過人生的每個轉彎處時，總得放棄某些部分；然而面對痛苦之後享受到的快樂會更大。而這快樂，是許多人賦予我的，藉此我必須要感謝這些曾經幫助過我的人。

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回首二年來追逐夢想的求學歷程，真是「深入寶山，滿載而歸」百感交集，如人飲水點滴在心頭，能夠突破重重難關順利畢業，內心是充滿無限的感激。此篇論文的完成，凝聚許多人的幫助與支持，由你們身上獲得到許多力量，讓我更加成長、茁壯。謝謝你們！

巧伶 謹誌/九十九年七月于中國醫

中文摘要

目的：歐洲癌症治療與研究組織生活品質核心問卷與攝護腺癌生活品質問卷已被廣泛用來評估攝護腺癌患者的生活品質。隨著電子化的進步，已發現電子化問卷可彌補傳統上測量生活品質常面臨的問題：以紙筆形式填寫所得結果無法即時分析並運用於臨床治療等。本研究將利用傳統及現代測量的分析比較觸控式電腦問卷與手寫問卷兩種方式在評估攝護腺癌患者之生活品質是否具有相等性及可行性，作為觸控式電腦問卷取代紙本問卷之依據，並且進行觸控式電腦問卷執行的喜好度評估。

材料與方法：本研究採用隨機交叉設計研究法，樣本為來自中國醫藥大學附設醫院之泌尿科門診，共計收案 99 位攝護腺癌患者，每位患者以歐洲癌症治療與研究組織攝護腺癌生活品質問卷評量其生活品質，分別在不同時間點利用紙本問卷與觸控式電腦問卷施測。分析方法以交叉設計模式、相等性分析、組內相關係數分析、Rasch 模式之試題差別功能分析，比較各範疇及題目的相等性。此外亦記錄施測時間，且以自行發展的問卷來評估患者對以觸控式電腦施測的喜好度，並以描述性統計、t 檢定及卡方檢進行分析。

結果：交叉設計模式分析的結果整體來說並無發現模式效應。相等性分析的結果顯示觸控式電腦問卷與手寫問卷皆拒絕虛無假說，代表兩者具有相等性。兩份問卷中除了 EORTC QLQ-PR25，“與治療相關的症狀”組內相關係數=0.47 之外，在各範疇中組內相關係數範圍為 0.61~0.84。Rasch 分析的結果發現並無試題差別功能產生。在喜好度方面，約 92%的患者表明他們喜歡使用觸控式電腦問卷來完成問卷；約 97%的患者認為觸控式電腦問卷容易使用。

結論：觸控式電腦問卷與手寫問卷兩種方式在評估攝護腺癌患者之生活

品質具有相等性及可行性。大多數的攝護腺癌患者偏好使用電腦問卷，而且年齡越輕的喜好度越高。臨床診斷資訊電腦化幫助醫師診斷及開立處方時能夠掌握最新最完整的資訊，而且對癌症病人來說大大的增加了他們與醫師之間的互動與溝通。

關鍵字：健康相關生活品質、攝護腺癌、問卷、歐洲癌症治療與研究組織生活品質核心問卷、歐洲癌症治療與研究組織攝護腺癌生活品質問卷、交叉設計、觸控式電腦問卷、紙本問卷、可行性、相等性。

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Abstract

The EORTC QLQ-C30（a 30-item European Organization for Research and Treatment of Cancer Core Quality-of-Life Questionnaire） and the EORTC QLQ-PR25（a 25-item questionnaire designed for use among patients with localized and metastatic prostate cancer） are widely used instruments for evaluating the health related quality of life (HRQL) of prostate cancer patients. Over the past two decades, researchers have measured HRQL using paper-and-pencil questionnaires. With the emergence of computer technology, electronic questionnaires are increasingly being used for data collection, particularly in medical practice. Nevertheless, the equivalence and feasibility of touch-screen version and paper-and-pencil version of two questionnaires measuring prostate cancer patients have not been clearly established. Therefore, this study compared data obtained using touch-screen versions of two questionnaires with those obtained using the equivalent paper-and-pencil versions for assessing quality of life.

A crossover design study was used to investigate the equivalence and acceptance of the questionnaires in 99 prostate cancer patients enrolled from China Medical University Hospital's Department of Urology out-patient clinic. Equivalence test and a cross-over model analysis were applied to examine the equity of health-related quality of life scores between the two modes, using Rasch analysis to assess differential item functioning (DIF) between touch-screen and paper versions.

Results of this study showed the equivalence of the paper version and the touch-screen version of two quality of life questionnaires. Intraclass correlation coefficient (ICC) ranged from 0.48~0.83 of the two modes in the EORTC QLQ-C30 and EORTC QLQ-PR25, which indicated moderate to

good reliability. There was no DIF of the EORTC QLQ-PR25 using Rasch analysis to assess for prostate cancer patients. About 92% of patients had indicated that they liked to use the touch-screen to complete the questionnaire. About 97% of patients thought the touch-screen interface was user-friendly.

In conclusion, information collected using the touch-screen version of EORTC QLQ-C30 and EORTC QLQ-PR25 questionnaires is equivalent to that collected using the paper-and-pencil version. The touch-screen version is well accepted for assessing prostate cancer patients' quality of life. Feasibility of touch-screen mode is acceptable for most patients, and preferred in younger prostate cancer patients. The e-data can be easily integrated with other clinical data to provide real time diagnostic information in clinic. It may not only improve medical care quality, but also promote the relationship between physician and patient.

Keywords: health-related quality of life; prostate cancer; EORTC QLQ-C30, EORTC QLQ-PR25; questionnaire; feasibility; equivalence; cross-over design; touch-screen; computer, paper-and-pencil.

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List of abbreviations

AQLQ	Asthma Quality of Life Questionnaire
BMI	Body Mass Index
C30	Core 30-item
DIF	Differential Item Functioning
EORTC	European Organization for Research and Treatment of Cancer
EPIC	Expanded Prostate Cancer Index Composite
FACT-P	Functional Assessment of Cancer Therapy-Prostate
FDA	Food and Drug Administration
HADS	Hospital Anxiety and Depression Scale
HAQ	Health Assessment Questionnaire
HIV	Human Immunodeficiency Virus
HRQL	Health Related Quality of Life
IGFs	Insulin-like Growth Factors
IIEF	International Index of Erectile Function
IPSS	International Prostate Symptom Score
M	Metastasis
N	Lymph Node
PCI	UCLA Prostate Cancer Index
PCI-SF	UCLA Prostate Cancer Index short form
PAQLQ	Pediatric Asthma Quality of Life Questionnaire
PACQLQ	Pediatric Asthma Caregiver's Quality of Life Questionnaire
PCQOL	Prostate Cancer Quality of Life scale

PR25	Prostate Cancer 25-item
PRO	Patient Reported Outcome
PROSQOLI	Prostate Cancer Specific Quality of Life Instrument
PSA	Prostate Specific Antigen
QLQ	Quality-of-Life Questionnaire
QOLM-P14	Quality of Life Module-Prostate 14
RA	Rheumatoid Arthritis
RAQol	Rheumatoid Arthritis Quality of Life Questionnaire
SF-36	Short-Form-36
SGRQ	St George's Respiratory Questionnaire
SSQ	Subjective Significance Questionnaire
STD	Sexually Transmitted Diseases
T	Tumor
VASs	Visual Analogue Scales

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Chapter 1.Introduction

1.1 Background

Traditionally in medical clinical practice, cancer treatments and interventions have been evaluated using biomedical outcomes, such as the biological response to treatments or survival rate[1-2]. Recently, health-related quality of life (HRQL) has been determined to be an important outcome indicator and is measured as a patient reported outcome (PRO) measurement in clinical trials and in clinical practice[2-3]. PRO data may be collected via self-administered questionnaires completed by patients themselves or via interviewer-administered questionnaires completed by interviewers. The latter will be only qualified as a PRO in the situation where the interviewer only gains the patient's views, not in which the interviewer uses patient responses to make a professional assessment or judgment of the impact of the patient's condition. Thus, PRO is a means of gathering patients' view rather than clinical or other views on the content covered by the questionnaire.

PRO include not only health status and quality of life but also reports on satisfaction with treatment and care, adherence to prescribed regimens when directly related to end-result (endpoint), and any other treatment or outcome evaluation obtained directly from patients through interviews, self-completed questionnaires, diaries or other data collection tools such as handheld devices and web-based forms[4]. HRQL is one of several types of PRO data that may be collected in the context of a clinical trial. Other PROs include, but are not limited to, symptoms, patient satisfaction with treatment, functional status, psychological well-being, and treatment adherence[5].

Over the past two decades, researchers have developed and validated questionnaires to measure HRQL in a paper-and-pencil form. However, there are some disadvantages associated with the use of these paper-and-pencil

questionnaires. For instance, in a busy oncology practice it is difficult for the clinician to arrange the questionnaire for their patients[6]. New technologies for automated computer administration are becoming more readily available[7]. It has recently been suggested that these problems could be resolved by changing the assessment mode from a paper-and-pencil to a computerized version of the HRQL[8]. There are advantages of the computerized version in some respects. In the first place, it would allow data automatically entering into a database, and then the scale score is immediately calculated before its response to the physician's screen in real time at clinic. In addition, it can reduce both the data coding errors as well as the workload for health professionals[9]. Several large studies in chronic diseases also suggested that real-time feedback of health status data from patients' view may facilitate communication between patients and clinicians and enhance patients' care[10-12]. An immediately analysis of HRQL scores tailored with clinical data through a developed software in the computer may support clinicians in identifying important problems for discussion or broadening the range of the clinical inquiry for communication during the limited time of the medical consultations. Incorporating standardized HRQL assessments in daily clinical oncology practice facilitates the discussion of HRQL issues and can heighten physicians' awareness of their patients' HRQL. Most patients and clinicians reported that the HRQL summary profile was useful in facilitating communication and in enhancing physician awareness of patients' problems and favored to continue tailoring the use of the intervention of HRQL assessment as a standard part of the outpatient clinic procedure[3].

In addition, computer measurements have been shown to be well accepted by patients who generally consider questionnaires to be useful tools for telling their doctor about their problems[3, 13-14]. The feasibility and possibility of a computer-based HRQL assessment for patients as well as clinicians has been shown to be acceptable in many oncology clinics[7, 15-28]. In

a study for patients with oral and oropharyngeal cancer, the results showed the touch-screen method was easy and ideal for administration prior to the clinician–patient consultation. Most patients were willing to complete the questionnaire on touch-screen at every clinic visit, ensuring continuity of data collection[22]. A research also has confirmed that the application of using computerized mode for collecting symptom and quality-of-life information was easy for patients to use and acceptable across a range of user characteristics, including age, sex, and severe distress[23].

The EORTC QLQ-C30 （a 30-item European Organization for Research and Treatment of Cancer Core Quality-of-Life Questionnaire） and the EORTC QLQ-PR25（a 25-item questionnaire designed for use among patients with localized and metastatic prostate cancer）[29-31] are commonly used in assessment of HRQL for patients with prostate cancer for their paper-and-pencil versions. To our knowledge, the psychological properties and feasibility of the touch-screen versions of these two questionnaires have not yet been reported. Hence, it is important to assess their measurement properties such as the score equivalence between two different modes as well as their feasibility in practice, which are helpful to support their use in clinical practice and their comparability with the previous results more rigorously.

1.2 Study importance

As we know, there were only a few studies to validate the touch-screen version of HRQL for patients with prostate cancer, and even no data for those patients in Taiwan. Our study result can be an empirical evidence to understand whether the touch-screen mode can be an alternative choice of measurement mode in addition to paper-and-pencil mode to assess the patient's report quality of life. If the result shows the equivalence of both modes and feasibility of touch-screen mode, we can push the progress of promoting the technique of touch-screen mode into the clinical assessment, which can help the integration of patient's reported outcome and clinical information to promote the quality of health care.

1.3 Objective

The objective of this study was to assess the feasibility and equivalence of the touch-screen and paper-and-pencil versions of the two health-related quality of life questionnaires EORTC QLQ-C30 and the EORTC QLQ-PR25 by applying in patients with prostate cancer.

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1.4 Study questions and study hypothesis

1. Touch-screen method is easy and feasible for most prostate cancer patients.
2. The younger patients were more feasible in computerized questionnaire than the older patients.
3. The cross-over study design can support the comparison of two health-related quality of life assessment methods more objectively, avoiding the confounding effects such as individual difference and sampling bias.
4. Using the paper-and-pencil mode and the touch-screen mode to assess psychometric characteristics of the EORTC QLQ-C30 and the EORTC QLQ-PR25 questionnaires are the same.

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1.5 Definition

Carry-over effect **—** A Carry-over effect in a crossover design is when the effects of the assessment memory from one method taken during the first assessment period have an effect to the other method taken during the second assessment period[32-33].

Cross-over design **—** A Cross-over design is a type of randomized clinical trial. In this design, each subject is randomized to either group 1 or group 2. All subjects in group 1 receive method A in the first assessment period and method B in the second assessment period. All subjects in group 2 receive method B in the first assessment period and method A in the second assessment period. Often there is a *washout* period between the two assessment periods during which that receive no study intervention. The purpose of the washout period is to reduce the likelihood that assessment taken in the first period will have an effect that carries over to the next period[32-33].

Differential item functioning (DIF) **—** Differential item functioning refers to an item lacking measurement equivalence in different groups or settings[34]. In this study, sets of item difficulties were compared between methods (paper-and-pencil vs. touch-screen) to detect DIF. A criterion of 0.5 logits between item difficulties in different groups was applied to determine whether an item exhibited DIF[35-36].

Equivalence **—** Two methods are said to be equivalent if one is derivable from the other.

Feasibility **—**Feasibility is an assessment which is applied to evaluate the time of filling the questionnaire, the preference and the user-friendly property.

Patient-reported outcome (PRO) **—** A measurement based on a report that comes directly from the patient (i.e., study subject) about the status of a

patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else. A PRO can be measured by self-report or by interview provided that the interviewer records only the patient's response[37].

Washout — A washout period in a cross-over design is a period between assessment periods, during which subjects receive no study intervention [32-33].

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Chapter 2.Literature Review

2.1 Epidemiology of prostate cancer

In recent years, the prevalence of the prostate cancer has grown very quickly. Prostate cancer survival duration is relatively long[2, 38-39]. Over the past 20 years, the 5-year survival rate for all stages combined has increased from 67 to 97%, regardless of the choice of treatment[40]. Although the new treatments have increased survival rates, the side effects of treatment and disease symptoms impact on their quality of life either in physical domain or in psychological domain (urinary, bowel, and sexual dysfunction, etc.[2, 39, 41-53]). Hence, the social loading obtained from prostate cancer has also become an important issue of public health. Assessment of HRQL for prostate patients could guide treatment decisions and track patient-reported responsiveness to intervention in a clinical setting.

Prostate cancer is the most common cancer among men in most western populations, like in the United States and the Europe[54-60]. In the United States, it is the first leading cause of cancer death among U.S. men with 186,000 new cases and 28,600 deaths in 2008[61]. The incidence of prostate cancer in Taiwan, though, unlike the United States, it is also constantly increasing every year. Despite its high morbidity, the etiology of prostate cancer remains largely unknown. Advancing age, race, and a family history of prostate cancer are the only established risk factors. Many putative risk factors, including androgens, diet, physical activity, sexual factors, inflammation, and obesity, have been implicated, but their roles in prostate cancer etiology remain unclear[62-69].

2.1.1 Incidence and mortality of prostate cancer

2.1.1.1 Incidence

Reported age-adjusted prostate cancer incidence rates vary considerably worldwide[70-71]. Prostate cancer is a leading cause of malignancy among men in the United States. The number of male cases who were newly diagnosed with prostate cancer in the United States was 220,000 cases in 2007, and 192,280 cases in 2009. In the United States, rates among African-Americans are the highest in the world (185.4 per 100,000 person-years)[72], followed by Caucasian-Americans (107.8 per 100,000 person-years) (shown in figure 1). Rates within Europe vary almost 7-fold (15~100 per 100,000 person-years), and are highest in Western Europe, in particular Austria, and lowest in Eastern Europe (15~36 per 100,000 person-years)[71].

Prostate cancer is an increasing cause of malignancy among men in Taiwan. The number of male cases who were newly diagnosed with prostate cancer in Taiwan was 909 cases in 2005, 957 cases in 2006, 1,003 cases in 2007, and 892 cases in 2008. According to the 2005 annual report from the Department of Health in Taiwan, the incidence of prostate cancer rose from 1.45 per 100,000 persons in 1982 to 17.41 per 100,000 persons in 2002. In comparison with European countries and the United States, the incidence of prostate cancer is far lower in Taiwanese men[73].

According to cancer registry data, in 1979,100 cases of prostate cancer in Taiwan increased since 1989. Age-standardized incidence rate of 1.86 per 100,000; 481 cases, the age-standardized incidence rate was 6.27 per 100,000 population cases; in 1999 increased to 1,928 cases, the age-standardized incidence rate of 16.71 cases per 100,000 population; until 2005, already as high as 2704 cases, the age-standardized incidence rate of 19.72 cases per 100,000 population[73-74], the future will continue to rise. This is the average male life expectancy increases and the result of improved diagnostic techniques, but may also need to take into account the gradual improve cancer registration system so that the surface has increased the number of cases[66].

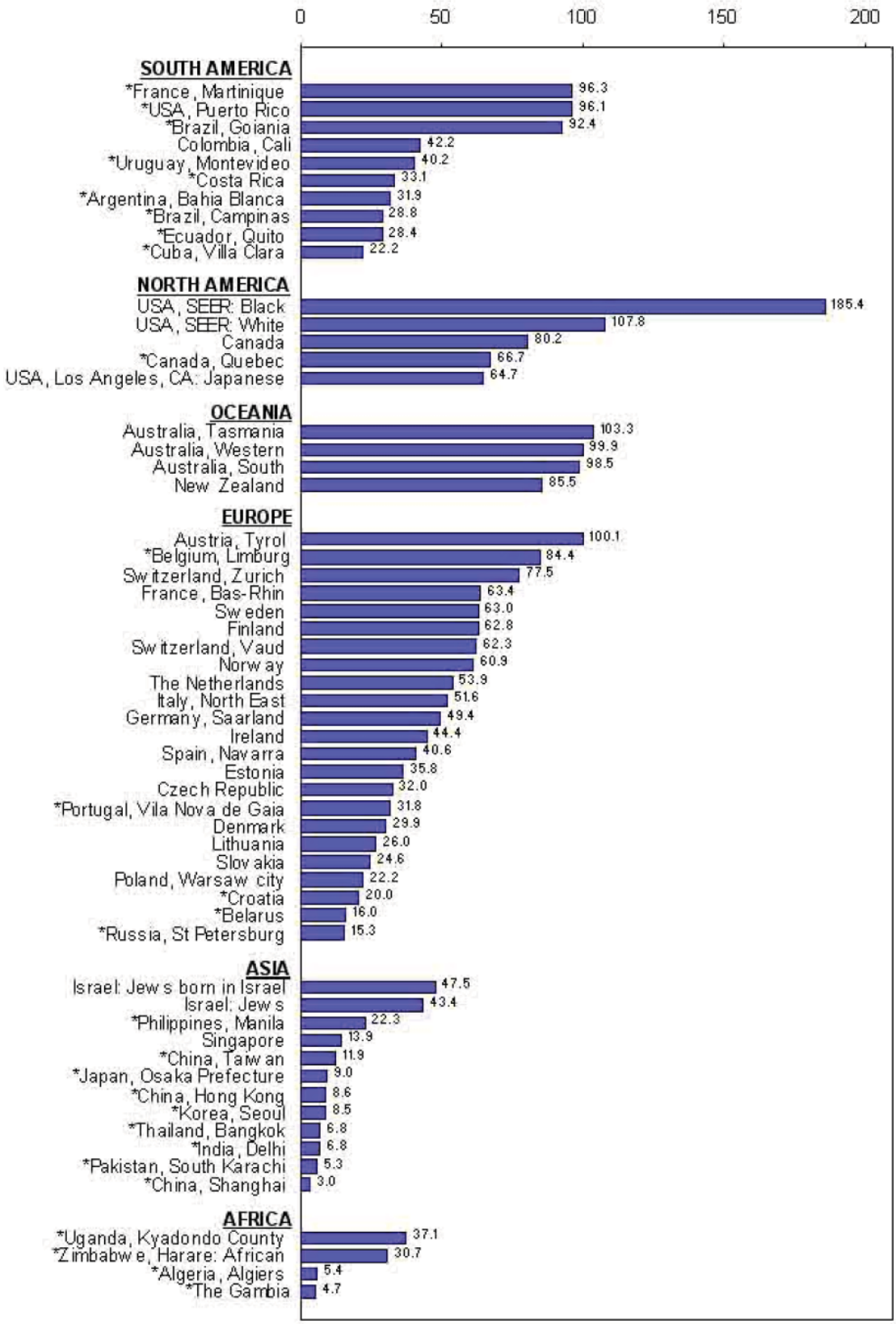

Figure 1. Age-adjusted incidence rates (per100,000 person-years) for prostate cancer in 48 countries, 1993-1997[55].

2.1.1.2 Mortality

In 2009, prostate cancer was the first leading cause of cancer death among U.S. men. The number of male cases who died from prostate cancer in the United States was 28,000 cases in 2007 and 27,360 cases in 2009. The most recent report available on cancer mortality showed that, in 2004, the overall death rate of prostate cancer among American men was 25 per 100,000. Since 1994, this rate has decreased by 4 percent each year, and, in 2004, there were an estimated 2 million prostate cancer survivors in the United States. From the 2004 data, only one in six American men diagnosed with prostate cancer will eventually die from it. Nevertheless, mortality rates are still higher in Western nations than in lower-risk, Asian countries[62, 65]. Interestingly, the world's highest mortality rates (30.3 to 47.9 per 100,000 person-years) were seen in the Caribbean nations of Barbados, the Bahamas, and Trinidad and Tobago, where there were large populations of men of African descent. Prostate cancer's disproportionate impact on African-Americans and Caribbean men suggested that factors associated with African ancestry might also play a role in prostate cancer etiology[75].

Prostate cancer was the most common cancer in elderly men, and the mortality rate suddenly increased after the age of 65[63, 66-67, 69, 76]. Department statistics showed that prostate cancer was the tenth leading cause of cancer death in 1994 and seventh in 2008. Standardized mortality rate is 6.7 in 2007 and 5.7 in 2008 respectively[73]. In Taiwan, for male, there were 67 persons aged 65-69, 120 persons aged 70-74 and 250 persons aged 80-84 who died from prostate cancer in 2008. And also, the overall mortality rate of prostate cancer was 8.9 per 100,000 among 65-69, 19.9 per 100,000 among 70-74, 77.9 per 100,000 among 80-84, and 121.7 per 100,000 over 90. Meanwhile, when it compared across different periods, the mortality rate of prostate cancer was gradually raised every year[73].

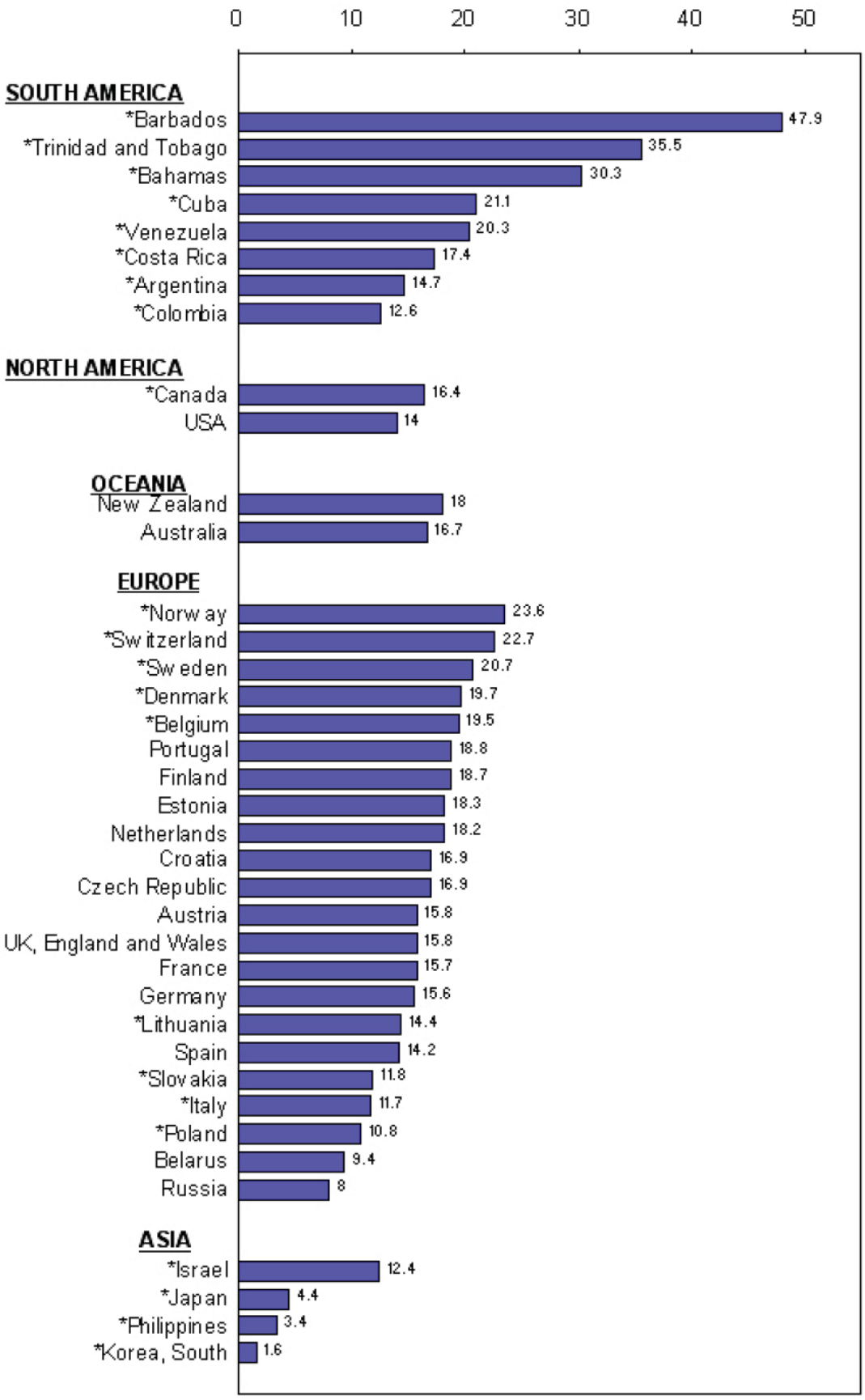

Figure 2. Age-adjusted mortality rates (per 100,000 person-years) for prostate cancer in 38 countries in 1998.[55]

2.1.2 Risk factors of prostate cancer

Many studies reported risk factors of prostate cancer which included age, androgens, diet, physical activity, sexual factors, inflammation, and obesity had been implicated, but their roles in prostate cancer etiology remained unclear.

2.1.2.1 Age

The incidence of prostate cancer increases exponentially with advancing age-an increase that is faster than that for any other malignancy. Over 80% of prostate tumors in Taiwan, average in the age 70 to 72 years old are diagnosed prostate cancer[74].

2.1.2.2 Racial/ethnic variation

Except age, ethnicity is another consistently observed but poorly understood risk factor. African-Americans have the highest incidence rates in the world: roughly 60 times that of men in Shanghai, China, where the rates are the lowest in the world[77-78]. Adjustment of incidence rates for the prevalence of latent disease at autopsy and proportion of localized tumors among all prostate cancers revealed that Japanese men still experience a markedly lower incidence than Americans, indicating that the large international variation cannot be explained by differences in detection alone[75].

2.1.2.3 Hormones and growth factors

Hormones and insulin-like growth factors (IGFs) are related to prostate cancer[79]. Prostate cancer is notably absent in castrated men, and laboratory studies show that administration of testosterone induces prostate cancer in rats and that androgens promote cell proliferation and inhibit prostate cell death[80-81]. Nevertheless, epidemiologic data supporting a role of androgens are inconclusive[82]. Vitamin D, another steroid hormone, is obtained primarily

from dermal synthesis in response to sunlight exposure[83-84]. In addition to steroid hormones, IGFs have been implicated in prostate cancer.

2.1.2.4 Diet

Ecologic studies have shown a strong correlation between the incidence of prostate cancer and dietary fat intake[63, 85]. Fat intake is the most studied dietary risk factor for prostate cancer. However, a recent review of 17 studies showed that fatty fish are rich in potentially tumor-inhibitory marine fatty acids, such as omega-3[86-88]. Dietary calcium, from either dairy products or supplement consumption, has been linked to prostate cancer. Although consumption of fruits and vegetables is associated with a reduced risk of several cancers, their role in prostate cancer is less clear. The only consistent finding is an inverse association with consumption of tomatoes and tomato paste, which has been largely attributed to the antioxidant effect of lycopene[86-89].

2.1.2.5 Obesity

In epidemiologic studies, overall obesity is usually measured by body mass index (BMI: weight in kg divided by the square of height in meters, kg/m^2) and abdominal obesity by the ratio of waist to hip circumference[45, 90]. Recent data suggest that obesity is more consistently related to aggressive prostate tumors and that abdominal obesity may be associated with an increased risk of prostate cancer even in relatively lean men[45, 91-92]. In addition, higher serum levels of insulin have been linked to an increased risk of prostate cancer[91], and higher serum levels of leptin have been linked to larger tumor volume[93]. Although obesity's role in prostate cancer is not clearly defined, it is linked to numerous putative prostate cancer risk factors, including higher meat and fat intake, hormone metabolism, and insulin metabolism.

2.1.2.6 Occupation

Occupation is highly correlated with socioeconomic status and lifestyle factors. There is a large body of literature on prostate cancer and occupation, and one consistent result from these studies is that compared with the other occupations, farmers and other agricultural workers have a 7~12% increased risk[94].

2.1.2.7 Chronic inflammation

Evidence for a role of chronic inflammation in prostate cancer is beginning to emerge[95-98], but an association of prostate cancer with chronic inflammation of the prostate (chronic prostatitis) has been suspected for a long time. A recent meta-analysis of 11 studies of prostatitis and prostate cancer reported that patients with chronic inflammation had an overall relative risk of 1.6 compared with the control[99].

2.1.2.8 Sexually transmitted diseases

Sexually transmitted diseases (STDs) have been linked to prostate cancer. One recent large, population based study showed 2~3 fold prostate cancer risks associated with STDs, particularly syphilis and recurrent gonorrhea infections[100]. While a study of a human immunodeficiency virus (HIV)-infected population found that duration of HIV infection was associated with increased prostate cancer risk[101].

2.1.2.9 Sexual frequency

Some studies have indicated that increased sexual frequency may be associated with an increased risk of prostate cancer, because it may serve as an indicator for either a greater opportunity of infection or higher androgenic activity[99, 102]. A prospective study reported that ejaculation frequency is not associated with risk of prostate cancer; although there was some suggestion that very high ejaculation frequency during a man's 20's (>21 times per

month) is associated with reduced risk[103].

2.1.2.10 Other factors

Other risk factors, such as smoking, use of alcohol, diabetes, and liver cirrhosis, have been investigated, but their roles in prostate cancer are weak or unclear based on data in the current literature[38, 54-55, 66, 104-105].

2.1.3 Clinical manifestations and pathology of prostate cancer

Prostate cancer is the most common noncutaneous cancer among males. The diagnosis and treatment of prostate cancer continue to evolve. With the development of prostate-specific antigen (PSA) screening, prostate cancer is being diagnosed earlier in the disease course. Although prostate cancer can be a slow-growing cancer, hundreds of men die of the disease each year in Taiwan. Education is important to help men understand the concepts of progression and the various treatment options. This part provided a current overview of the biology, pathology, diagnostic techniques, and screening of this disorder.

2.1.3.1 Signs and symptoms

Early prostate cancer usually causes no symptoms. Often it is diagnosed during the workup for an elevated PSA noticed during a routine checkup[2, 56, 61, 107-109]. It is highly advised to avoid sexual intercourse for 3 days prior to a PSA test because that affects the outcome of the test. Sometimes, however, prostate cancer does cause symptoms, often similar to those of diseases such as benign prostatic hyperplasia. These include frequent urination, increased urination at night, difficulty starting and maintaining a steady stream of urine, blood in the urine, and painful urination. Prostate cancer is associated with urinary dysfunction as the prostate gland surrounds the prostatic urethra. Changes within the gland, therefore, directly affect urinary function. Because the vas deferens deposits seminal fluid into the prostatic urethra, and secretions from the prostate gland itself are included in semen content,

prostate cancer may also cause problems with sexual function and performance, such as difficulty achieving erection or painful ejaculation[106].

Advanced prostate cancer can spread to other parts of the body, possibly causing additional symptoms. The most common symptom is bone pain, often in the vertebrae (bones of the spine), pelvis, or ribs[14]. Spread of cancer into other bones such as the femur is usually to the proximal part of the bone. Prostate cancer in the spine can also compress the spinal cord, causing leg weakness and urinary and fecal incontinence[107].

2.1.3.2 Treatments

Prostate cancer treatment options depend on several factors, such as how fast cancer growing, how much it has spread, overall health, as well as the benefits and the potential side effects of the treatment. Different treatment policies such as watchful waiting, radiation therapy, chemotherapy hormone therapy, and radical prostatectomy are introduced as follows[41, 47-53, 108-112].

For men diagnosed with a very early stage prostate cancer, treatment may not be necessary right away. Some men may never need treatment. Instead, doctors sometimes recommend watchful waiting, which is sometimes called active surveillance. In watchful waiting, regular follow-up blood tests, rectal exams and possibly biopsies may be performed to monitor progression of your cancer. If tests show your cancer is progressing, you may opt for a prostate cancer treatment such as surgery or radiation. Watchful waiting may be an option for cancer that isn't causing symptoms, is expected to grow very slowly and is confined to a small area of the prostate. Watchful waiting may also be considered for a man who has another serious health condition or an advanced age that makes cancer treatment more difficult. Watchful waiting carries a risk that the cancer may grow and spread between checkups, making it more difficult to treat.

Radiation therapy uses high-powered energy to kill cancer cells. Prostate

cancer radiation therapy can be delivered in two ways: Radiation that comes from outside of body (external beam radiation)[44]. During external beam radiation therapy, directing high-powered energy beams, such as X-rays, to prostate cancer. Typically undergo external beam radiation treatments five days a week for several weeks. Radiation placed inside body (brachytherapy). Brachytherapy involves placing many rice-sized radioactive seeds in prostate tissue[109]. The radioactive seeds deliver a low dose of radiation over a long period of time. Physician implants the radioactive seeds in prostate using a needle guided by ultrasound images. The implanted seeds eventually stop giving off radiation and don't need to be removed. Side effects of radiation therapy can include painful urination, frequent urination and urgent urination, as well as rectal symptoms, such as loose stools or pain when passing stools. Erectile dysfunction can also occur. Chemotherapy uses drugs to kill rapidly growing cells, including cancer cells. Chemotherapy may be a treatment option for men with prostate cancer that has spread to distant areas of their bodies. Chemotherapy may also be an option for cancers that don't respond to hormone therapy[84, 110, 113].

Hormone therapy is treatment to stop your body from producing the male hormone testosterone[114]. Prostate cancer cells rely on testosterone to help them grow. Cutting off the supply of hormones may cause cancer cells to die or to grow more slowly. Side effects of hormone therapy may include erectile dysfunction, hot flashes, loss of muscle and bone mass, reduced sex drive, and weight gain. Hormone therapy also increases the risk of heart disease and heart attack. Physicians believed long-term use of hormone therapy and the low hormone levels that result may lead to cardiovascular problems.

Surgery for prostate cancer involves removing the prostate gland (radical prostatectomy), some surrounding tissue and a few lymph nodes. There were four ways of radical prostatectomy procedure, which included making an

incision in your abdomen, making an incision between your anus and scrotum, laparoscopic prostatectomy, and using a robot to assist with surgery. Radical prostatectomy carries a risk of urinary incontinence and erectile dysfunction[42-43, 47, 50, 108, 115-117]. Communicating with physician to discuss any possible risks of each way of procedure was suggested. The risk factors included patients' disease stage of prostate cancer, age, body type and overall health.

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2.2 Patient reported outcome

The Food and Drug Administration (FDA) reviews and evaluates existing, modified, or newly created patient reported outcome (PRO) instruments used to support claims in approved medical product labeling. A PRO instrument (i.e., a questionnaire plus the information and documentation that support its use) is a means to capture PRO data used to measure treatment benefit or risk in medical product clinical trials[37].

A PRO is any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else. The outcome can be measured in absolute terms (e.g., severity of a symptom, sign, or state of a disease) or as a change from a previous measure. In clinical trials, a PRO instrument can be used to measure the effect of a medical intervention on one or more concepts (i.e., the thing being measured, such as a symptom or group of symptoms, effects on a particular function or group of functions, or a group of symptoms or functions shown to measure the severity of a health condition).

Generally, findings measured by a well-defined and reliable PRO instrument in appropriately designed investigations can be used to support a claim in medical product labeling if the claim is consistent with the instrument's documented measurement capability. The amount and kind of evidence that should be provided to the FDA is the same as for any other labeling claim based on other data. Use of a PRO instrument is advised when measuring a concept best known by the patient or best measured from the patient perspective. A PRO instrument, like physician-based instruments, should be shown to measure the concept it is intended to measure, and the FDA will review the evidence that a particular PRO instrument measures the concept claimed. The concepts measured by PRO instruments that are most often used in support of labeling claims refer to a patient's symptoms, signs,

or an aspect of functioning directly related to disease status. PRO measures often represent the effect of disease (e.g., heart failure or asthma) on health and functioning from the patient perspective[37].

2.3 Patient reported outcome and health-related quality of life

In a traditional health paradigm, cancer treatments or interventions have previously been evaluated using biomedical outcomes such as the biological response to treatments or survival rate[1-2]. More recently, it has been determined that the health-related quality of life (HRQL) is an important outcome indicator. Today, HRQL is measured as an outcome indicator in clinical trials, outcomes research and in clinical practice[2-3]. The clinicians perceived that the quality of life data broadened the range of the clinical inquiry and helped them identify issues for discussion.

A standardized measurement of patients' quality of life may support clinicians in identifying important problems for discussion during the limited time of the medical consultations[12]. Measuring HRQL in clinical trials usually discriminated between generic and specific questionnaires[118-120].The former commonly used including the short-form 36 (SF-36), the WHOQOL-BREF and the EORTC QLQ-C30, and latter including the EORTC QLQ-PR25 the St George's Respiratory Questionnaire (SGRQ), and so on.

2.4 Health-related quality of life instruments

Many studies failed to collect long-term results, used non-validated questionnaires, or measured HRQL components only incompletely. The following HRQL instruments can be recommended for prostate cancer, the EORTC QLQ-C30, EORTC QLQ-PR25, Expanded Prostate Cancer Index Composite (EPIC), Expanded Prostate Cancer Index Composite short form (EPIC-26), International Index of Erectile Function (IIEF), International Index of Erectile Function short form (IIEF-5), International Prostate

Symptom Score (IPSS) and the Functional Assessment of Cancer Therapy-Prostate (FACT-P)[29-30, 121-135](See the Supplementary Appendix in details Table A6). 42 papers founded in PubMed within 5 years (January 1, 2004~December 31, 2008) with keywords searched: prostate cancer, questionnaire, EORTC QLQ-C30, EORTC QLQ-PR25; 38 papers were founded with IPSS; 43 were founded with IIEF; 16 were founded with FACT-P; 17 were founded with EPIC; It was used commonly more than others instruments evaluated for prostate cancer.

2.5 Administration modes of measurement of health-related quality of life

This part provided some administration modes of measurement of health-related quality of life in recent times, including paper-and-pencil mode and touch-screen mode in our study.

2.5.1 Paper-and-pencil mode

Subjects completed questionnaire with paper-and-pencil mode including face-to-face interview and self-administration methods. Over the past two decades, researchers had developed and validated questionnaires to measure HRQL in a paper-and-pencil form.

However, there were disadvantages associated with the use of these paper-and-pencil questionnaires. For example, in a busy oncology practice it was difficult for nurses to distribute the questionnaire to their patients and collect data from them[136]. In addition, manual data key in and computation were required to work out HRQL scores, which was time consuming and can be a source of error[6]. And usually, the information patients reported could not transfer to physician's clinic in real time, although patients thought they had reported their status in questionnaires.

2.5.2 Touch-screen mode

Although in the past most health-related quality of life questionnaires are self-administered or face-to-face interviewed by means of paper and pencil, new technologies for automated computer administration such as touch-screen mode of PC version, PDA version, mobile version, or Tablet PC are becoming more readily available[7].

The computerized version would allow data to be automatically entered into a database and the score immediately calculated, thus reducing data coding errors as well as the workload for health professionals[9].The time required by the patient to complete the questionnaire was also reduced[9, 137]. And also, promoting the technique of touch-screen mode into the clinical assessment, which can help the integration of patient's reported outcome and clinical information to promote the quality of health care[19].

The computer measurement was well accepted by patients who felt that the questionnaires were a useful tool to tell the doctors about their problems. Hence, patients are willing to complete the questionnaire on a touch-screen and find the equipment easy to use[19]. Allenby & colleagues (2002) recommended using a patient-friendly computer interface, such as a touch-screen monitor that is manipulated by the touch of a finger, because these are easier for patients to use than a keyboard or a mouse[138]. The ease of use of the computerized version was also an important issue in developing the touch-screen measurement system.

2.6 Routine assessment of health-related quality of life

Several large studies in chronic diseases also suggested that feedback of health status data may facilitate communication between patients and clinicians and enhance patients' care[3, 10-13, 139-141].

Many studies confirms that computer-based individual QL assessment in oncology clinics with immediate feedback of results to clinicians is possible

and feasible[12]. Incorporating standardized HRQL assessments in daily clinical oncology practice facilitates the discussion of HRQL issues and can heighten physicians' awareness of their patients' HRQL[3]. Incorporating standardized HRQL assessments in daily clinical oncology practice facilitates the discussion of HRQL issues and can heighten physicians' awareness of their patients' HRQL and helps patients routine assessment. Most patients exposed to the intervention and all of the physicians reported that the HRQL summary profile was useful in facilitating communication and in enhancing physician awareness of patients' problems and favored continued use of the intervention as a standard part of the outpatient clinic procedure[3].

2.7 Feasibility and equivalence assessment of two modes

Before putting this into practice it is necessary to evaluate the equivalence of, and determine the patient preference for, the two modes (i.e., paper vs. computerized)[8]. Many studies examined and validated the measurement equivalence of paper-based version and touch-screen computer-based version, and showed the touch-screen version was accepted for most subjects[1, 19, 27, 142].

Lofland, Schaffer and Goldfarb (2000) estimated and compared the costs for three different methods of administering and evaluating the SF-36 as a routine part of clinical practice from the provider perspective. In an outpatient pain management practice, a computer touch-screen system was assessed with facsimile and scanning scoring methods. Equipment, supply, and labor costs needed to construct, maintain, and generate reports for each system were measured. The system implemented in a clinical practice is dependent not only on questionnaire volume but also on personnel availability, equipment access, required speed of results, and the acceptable level of data error[143].

A computerized touch-screen system, namely RHEUMATISM (RHEUMA Touch-screen Italian System) was developed to capture rheumatoid arthritis (RA) patient-reported outcome (PRO). To investigate the

acceptability, feasibility, reliability and score agreement of the RHEUMATISM system, eighty-seven rheumatoid arthritis (RA) patients completed both the touch-screen and conventional paper-administered set of questionnaires. The results showed the computer touch-screen questionnaires were well accepted by RA patients, with good data quality, reliability and score agreement[27].

2.8 Crossover design researches for assessing the equivalence

Touch screen computer-assisted health-related quality of life data collection in variety of disease patients is feasible. The comparative of paper and computer usually use crossover randomized design in different diseases[3, 7, 9, 19, 21, 137], including gastroesophageal reflux disease, asthma, rheumatoid arthritis, cancer, and head and neck cancer.

Kleinman (2001) compared 134 patients with gastroesophageal reflux disease the psychometric characteristics (score equivalence and structure, internal consistency, and reproducibility reliability and construct validity) of the Quality of Life in Reflux And Dyspepsia (QOLRAD) questionnaire when self-administered by means of paper and pencil versus touch-screen computer. This crossover trial randomized The present study suggest that the QOLRAD is reliable and valid when self-administered by means of computer touch-screen or paper and pencil[21].

Bushnell (2003) compare paper and electronic administration of the standardized Asthma Quality of Life Questionnaire (AQLQ(S)), Pediatric Asthma Quality of Life Questionnaire (PAQLQ(S)), and Pediatric Asthma Caregiver's Quality of Life Questionnaire (PACQLQ). Using a crossover design, adults and children with asthma and caregivers of children with asthma were recruited from clinics. Subjects were asked to complete both forms of the appropriate HRQL measures at enrollment and 24~48 hours later. In addition, 30 subjects from each group were asked to participate in a 1-week

reproducibility assessment of the electronic versions of the three questionnaires. As in previous studies comparing electronic with paper questionnaires, this study revealed statistical evidence to support the use of EDC of the AQLQ(S), PAQLQ(S), and PACQLQ for populations with asthma[7].

Greenwood (2006) included forty patients with RA completing the touch-screen and paper Rheumatoid Arthritis Quality of Life Questionnaire (RAQol) in the clinic and rated ease of use and preference. Forty-five others completed the Stanford Health Assessment Questionnaire (HAQ) and visual analogue scales (VASs) for pain, fatigue and global arthritis activity on touch screen and paper and a joint assessment on touch screen. To investigate the feasibility of collecting rheumatoid arthritis (RA) patient self-administered outcome data using touch-screen computers in a routine outpatient clinic. Touch-screen questionnaires in the clinic can produce comparable results to paper, eliminate the need for data entry and afford immediate access to results. It is an acceptable, and in many cases a preferable, option to paper, regardless of age and previous experience of computers[25-26, 144-145].

Touch screen computer-assisted HRQL data collection in head and neck cancer patients is feasible. Touch screen computer-assisted HRQL data collection can be used for scientific documentation as well as in clinical setting. Patients are willing to complete the questionnaire on a touch-screen and find the equipment easy to use. Compliance needs improvement by instructing clinicians and nurses and a better alert system[19].

In a randomized crossover trial, 149 cancer patients completed the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-Core 30, version 2.0 (EORTC QLQ-C30), and the Hospital Anxiety and Depression Scale (HADS) on paper and on a touch screen. Computer touch-screen HRQL questionnaires were well accepted by cancer

patients, with good data quality and reliability[137].

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Chapter 3.Material and Methods

3.1 Research design and data collection

A randomized crossover design was applied in this study. A total of 106 prostate cancer patients in various stages of disease and treatment were enrolled from September 2008 to October 2009 from China Medical University Hospital Department of Urology outpatient clinic. Patients who could not read, speak and write Chinese were excluded. All patients provided written informed consent.

All sample subjects were randomly assigned to one of the two groups: one group completed paper version first followed by touch-screen version (denoted as paper/touch-screen group) and the other group completed touch-screen version first followed by paper version (denoted as touch-screen/paper group). Randomization was performed using computer generated random numbers. Each participant was asked to complete one survey administration at clinic check-in and one after a 120-minute waiting period prior to their clinical visit with the oncologist. In the HRQL assessment, four questionnaires, including the EORTC QLQ-C30, EORTC QLQ-PR25, IIEF-5, and IPSS were used and the completion time for these four assessments was recorded. Among them, the questionnaires IIEF-5, and IPSS were not evaluated in this analysis, the proportion of time spent for these two questionnaires was about one third of the overall time according to our experience. The time taken to complete the four paper questionnaires was recorded manually, and for the touch-screen questionnaire was recorded by computer automatically. After completing HRQL questionnaires, a self-developed questionnaire, was administered to examine patients' preference, acceptance, and feasibility in regard to the touch-screen version of questionnaires. (For questionnaires details see the Supplementary Appendix.)

3.2 Study structure

Initially, a total of 106 patients with prostate cancer enrolled and randomly assigned to two groups, 54 in the paper-and-pencil version first group and 52 in the touch-screen version first group, each patient was requested to complete both paper and touch-screen questionnaires, with a 120 minutes interval apart. There were 99 cases successfully fulfilled both assessments. The study structure was shown as Figure 3.

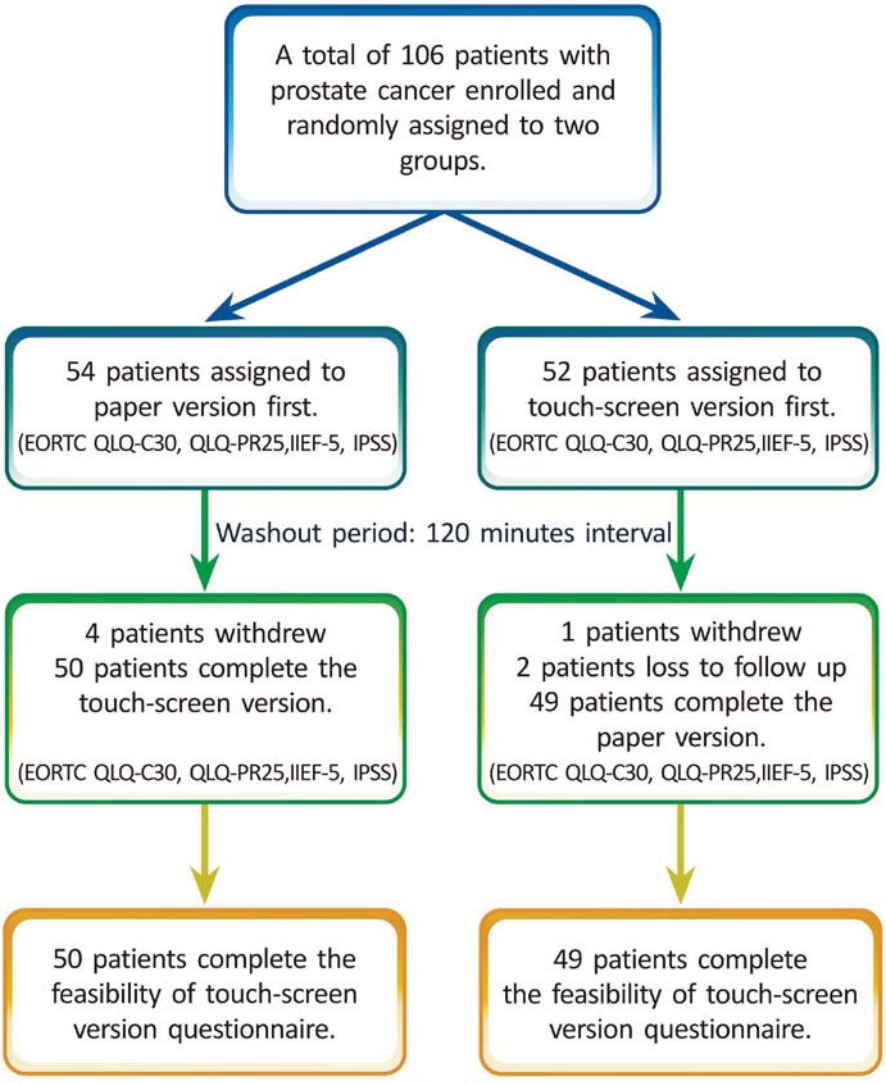

Figure 3. Study structure in the study

3.3 Health-related quality of life measures

The EORTC QLQ-C30 is a self-administered questionnaire to patients and organized into 5 functional domains (physical, role, cognitive, emotional, and social), and a global HRQL domain[29-30, 129, 146]. It also includes a number of multi-item domains and single items that assess a range of physical symptoms (fatigue, nausea and vomiting, pain, dyspnea, sleep disturbance, loss of appetite, constipation, and diarrhea), as well as financial difficulties. Each item is scored from 1 to 4 (1, "Not at all"; 2, "A little"; 3, "Quite a bit"; and 4, "Very much"), with the exception of items in the global quality-of-life scale, which range from 1 ("Very poor") to 7 ("Excellent").

The prostate-specific module EORTC QLQ-PR25 includes subscales assessing urinary symptoms (nine items), bowel symptoms (four items), treatment-related symptoms (six items), and sexual function (six items). This questionnaire is presently being validated in an international study[76]. Resulting domain scores for both instruments are linearly transformed to a 0–100 score, with higher values in functional domain (sexual) representing a more favorable HRQL, with lower values in the symptom domains (urinary, bowel, hormonal treatment-related symptoms) representing a more healthier status[29-30, 121, 127, 146].

In addition the EORTC QLQ-C30 and the EORTC QLQ-PR25, the questionnaire of the International Index of Erectile Function short form (IIEF-5), which include 5 items with 6 responses for each item, was used to assess the patients' erectile function in the last six months; and the questionnaire of the International prostate symptom score (IPSS) which include 8 items with 6 responses for each item, was used to assess the patients' urinary function in the last one months. However, the latter two questionnaires were no included in our analysis, except for analyzing the time to completion the questionnaires, the time for answering the IIEF-5 and the

IPSS were counted into the total time as a whole. According to our experience, to answer these two questionnaires spend about one seventh of the overall time.

3.4 The setting of the touch-screen version system

The touch-screen version system we applies in this study was developed by our team members including physicians specialized in prostate cancer, technicians specialized in system design and programming, epidemiologist and statisticians, who had several routine discussions to set up the final version of this system. The JAVA software was used to develop the system based on the basis of the ORACLE database. The procedure of how to manipulate touch-screen version questionnaire was described in the Supplementary Appendix.

3.5 Statistical analysis

In this study, we use descriptive, inferential statistics, equivalence test, crossover model analysis, and Rasch analysis to assess difference between touch-screen and paper versions of the EORTC QLQ-C30 and the EORTC QLQ-PR25 only. For the urinary symptom domain, item “Has wearing an incontinence aid been a problem for you?”, patients answered this question only if when he wore an incontinence aid.

3.5.1 Sample size estimation

Sample size estimation was based on the hypothesis of no clinical difference between the domain scores of two administration modes (paper and touch-screen) under a crossover design study. The Minimum clinically important difference (MID) of the domain score for the EORTC QLQ-C30 was set to be 5 points, and the standard error of domain score was set to be 8 based on empirical data. In order to detect equivalence difference of 5 with

80% power for a 5% size, a sample size 80 was obtained by using the statistical software PASS.

3.5.2 Descriptive and inferential statistics

Descriptive statistics, equivalence test, crossover regression model analysis, and Rasch analysis were used to assess the equivalence of measure properties of two different modes, touch-screen and paper versions of the EORTC QLQ-C30 and the EORTC QLQ-PR25.

We assessed differences of demographic characteristics between two crossover groups using Chi-square for categorical data and independent t-test for continuous group. To assess feasibility of using the touch-screen versus paper administration modes of the HRQL questionnaires, time to completion was shown as mean and standard deviation. Patients' acceptance and patients' preference to the touch screen version were shown as count and percentage. Results stratified by age (<= 70 years and > 70 years) and computer experience (yes and no) were demonstrated in the same way. Global agreement was defined as agreement within 1 response category in either direction[137, 147].

3.5.3 Equivalence test of two modes – a minimum clinically important difference approach

According to scoring manual of the EORTC QLQ-C30 and the EORTC QLQ-PR25, items and scale scores of the EORTC QLQ-C30 and the QLQ-PR25 were linearly transformed to a 0–100 scale, with higher scores reflecting either more symptoms (e.g., urinary, bowel, hormonal treatment-related symptoms) or higher levels of functioning (e.g., sexual). Based on the suggestions from the previous research, for the EORTC QLQ-C30, the range of changes about 5 to 10 denoted as "a little" change, "moderate" change had changed about 10 to 20, and "very much" change

corresponded to a change greater than 20[31, 148]. Therefore, in our measurement equivalence test of two modes, we defined a minimum clinically important difference (MID) to be 5; and we used the symbol δ representing this five point score.

Equivalence test method was applied to test the equivalence test of two modes. The equivalence hypotheses are

$$\begin{cases} H_0 : D = \left|\mu_P - \mu_C\right| \geq \delta \\ H_A : D = \left|\mu_P - \mu_C\right| < \delta \end{cases}$$

Where δ represented five point score. Rejecting null hypothesis indicates the two modes is equivalent[4, 149-152].

3.5.4 Mode effect assessment – a cross-over regression analysis

The crossover regression model recommended by Pocock was used to assess whether the measurement properties of two modes would be no difference. We first used the model with mode-effect, order-effect as well as their interaction. The interaction term is accounted for the carry-over effect if it exists; in addition, the gender and age effects were also put in the model for adjustment. After testing the mode-order interaction, we refit the model without interaction term, if the carry-over effect is not significantly shown. The mode effect was then assessed by using the t-test for regression coefficient, which accounted for the mode effect in the model [32, 153]. In this analysis, all items and scale scores were linearly transformed to a 0–100 scale, with higher scores reflecting either more symptoms (e.g., urinary, bowel, hormonal treatment-related symptoms) or higher levels of functioning (e.g., sexual).

3.5.5 Equivalence test of two modes – a summated response difference approach

Except that we derived the equivalence test of two modes by using a minimum clinically important difference (MID) approach, which was based on a linearly transform domain scores. To express our analysis more clearly and complete, we also exploited the equivalence properties base on the item level. The proportion of agreement for each item between two assessment modes was presented, and two kinds of agreement terms were defined. Exact agreement was defined as exact agreement between two modes. Global agreement was defined as agreement within 1 response category in either direction[137, 147].

We also develop the other equivalence test approach. First, we calculate the possible difference score for each item, 0 indicative no difference between two modes, for example, if there is 4 responses for one item, the range of difference score for this item will be 0, 1, 2, 3. Second, we compute the possible total difference scores for each domain, for example, if one domain including 5 items with 4 responses for each, then range of the total difference score for this item will be from 0 to 15. Third, a 15% of the total difference score (denoted as δ) for each domain is computed, for example, in the previous example, the value will be 2.25 (=15*0.15). We then use this value δ as the maximum different range that allowed for equivalence to derive our test.

Based on above, the Equivalence hypotheses are

$$\begin{cases} H_0 : D = \left|\mu_P - \mu_C\right| \geq \delta \\ H_A : D = \left|\mu_P - \mu_C\right| < \delta \end{cases}$$

Where δ represented 15% of the total difference score for each domain. Rejecting null hypothesis indicates the two modes is equivalent[4, 149-152].

3.5.6 Intraclass correlation coefficient – reliability measurement

Lachin (2004) has demonstrated that a coefficient of variation does not

measure reliability. The best measure of reliability for continuous data is the intraclass correlation coefficient (ICC)[154]. We had 99 subjects and measured 2 replicates from each subject. The correlation between two replicates from the same subject is referred to as the intraclass correlation coefficient, denoted by ρ_I. Mixed model was used to estimate the ρ_I. The model was as followed.

$$Y_{ij} = \mu + \alpha_i + \varepsilon_{ij}, \alpha_j \sim N(0, \sigma_A^2), \varepsilon_{ij} \sim N(0, \sigma^2)$$

Mixed model, which allowed including fixed effect factor and random effect factor as the independent variables, was used, where then it can be shown that $\rho_{I=} \sigma_A^2/(\sigma_A^2+\sigma^2)$; i.e., ρ_I is the ratio of the between-person variance divided by the sum of the between-person and the within-person variance.

The intraclass correlation ranges from 1.0 to 1.0. It is large and postive when there is little variation within the pairs but the means between the pairs differ. It is large and negative when the variation within a pair is much greater than that between the pairs. The present research will use the classification scheme as follows: Poor: 0–0.39, Fair: 0.40–0.59, Good: 0.60–0.79, Excellent 0.80–1.0. This scheme is a combination of the classification categories as used by Bartko (1976)[155] and Stokdijk (2000)[156].

3.5.7 Differential item functioning analysis from Rasch model

We use a rating scale model, one of the Rasch series model to deal with the polytomous response data, to assess the equivalence of two modes. The differential item functioning (DIF) analysis approach was applied to achieve our purpose. DIF refers to an item lacking measurement equivalence in different groups or settings[34]. In this study, sets of item difficulties were compared between methods (paper-and-pencil vs. touch-screen) to detect DIF. A criterion of 0.5 logits between item difficulties in different groups was applied to determine whether an item exhibited DIF[35-36].

All analyses were performed with the use of SAS 9.2 software and SPSS version 15.0. All Rasch analyses were performed using WINSTEPS software ver. 3.68[157]. A two-sided *p*-value of less than 0.05 was considered to indicate statistical significance

Chapter 4.Results

4.1 Demographic characteristics

Table 1 showed the demographic characteristics of the patients with prostate cancer. The range of the patients' age was from 57 to 87 years. About 80% of patients had no experience in using a computer. Half of the participants had graduated from high school. No statistically significant differences were found for background characteristics between paper/touch-screen and touch-screen/paper groups.

4.2 Time to complete questionnaire

Time to completion of the four questionnaires the EORTC QLQ-C30, the EORTC QLQ-PR25, the IIEF-5, and the IPSS was shown in Table 2. Although in our study we focused on the former two questionnaires such as the EORTC QLQ-C30 and the EORTC QLQ-PR25, the time to complete questionnaires was recorded for the above four questionnaires together. The latter two questionnaires IIEF-5 with 5 items and IPSS with 7 items applying to assess the erecting and urinary-related functions were used to supplement the sex and urinary information for our patients. Since these two questionnaires were not our emphasis in this thesis, we did not analyze their equivalence of the measurement properties, while attaching the contents of these two questionnaires in appendix to keep the completeness of our thesis.

For all patients, the mean time to complete the paper-and-pencil version was 16.3 minutes, compared with 18.1 minutes for the touch-screen version, which had a significant difference. For paper first followed by touch-screen version group (paper/touch-screen group), time completed was 17.9 minutes for paper mode, and 15.7 minutes for touch-screen mode; for touch-screen version first followed by paper version (touch-screen/paper group), time completed were 20.5 minutes for touch-screen mode and 14.7 minutes for

paper mode. The data showed the first administration mode took longer time to complete in both groups.

4.3 Time to complete questionnaire – stratified by age

We further stratified the time to complete questionnaires by two age groups, the patients aged greater than 70 took longer time to complete the questionnaires than the patients aged below 70 (20.4 vs. 15.1 minutes for paper version in the paper/touch-screen group; 16.8 vs. 14.5 minutes for touch-screen version in the paper/touch-screen group; 16.6 vs. 13.2 minutes for paper version in the touch-screen/paper group; 22.2 vs. 19.1 minutes for touch-screen version in the touch-screen/paper group, shown in Table 2).

From the minimal and maximal time, we can see no matter in the paper/touch-screen group or in the touch-screen group, the time to complete the questionnaires was varied dramatically, from 5 to 39 minutes for the paper version, and from 5 to 41 minutes for the touch-screen version. When stratified by age, the first administration mode still took significant longer time ($p<0.0001$) to complete than the second administration mode except for the patients with age less than 70 in the paper/touch-screen group ($p=0.9367$).

4.4 Acceptance and preference of touch-screen mode

A short survey was conducted to assess patients' views about the touch-screen questionnaire (see Table 3). About 92% of patients thought that the touch-screen questionnaire was easy to use and about 97% thought the user-interface was friendly. Some patients (10%) indicated that the size of the text on the screen was too small, 21% felt that it was not easy to read and understand the items, and 24% thought there were too many words on the screen. Overall, about 92% of patients said they liked using the touch-screen to complete the questionnaire and 67% said they preferred using the

touch-screen to fill out the questionnaire compared with 30% who preferred using the paper-and-pencil version. Based on the results stratified by age, higher percentages of acceptance and preference were seen in patients aged less than 70 group than patients aged beyond 70 group, however, there were no statistically significant difference for each question when two age groups compared.

Considering the experience of computer use of these prostate cancer patients, 100% experienced computer-use patients, and 90%~96% inexperienced computer-use patients thought touch-screen mode is easy to use and is user-friendly. Although near 80% prostate cancer patients had no computer-use experience, but overall the proportion of acceptance and preference of touch-screen mode was quite high and had no significant difference when compared with the results between the experienced and the inexperienced computer-use patients.

4.5 Equivalence between two modes

4.5.1 Domain/item score

Table 4 showed the results of the domain scores, crossover regression analysis, and equivalence test based on the minimal important difference (MID) approach for comparison of touch-screen and paper modes. The means of the domain scores were from 81.0 to 93.2 in functional domains (“Physical, Role”, “Emotional”, “Cognitive”, and “Social”), and 1.8 to 17.3 in symptoms domain in the EORTC QLQ-C30; and in the EORTC QLQ-PR25, the domain scores were from 5.3 to 19.5 in symptoms domains (“Urinary”, “Bowel”, and “Treatment-related”), 19.4 and 23.1 score in two functional domains “sexual activity” and “sexual functioning” separately. Higher functional score indicates better functional capacity; and lower symptom score indicates less symptom limitation.

4.5.2 Crossover regression model analysis

For the crossover regression model analysis, first we run the model with two main effects (accounted for the mode effect and the order effect respectively) and their interaction (accounted for the carry-over effect), the results showed the carry-over effects were not shown for most of domains or items. There were only two out of domains/items showed the carry-over effect may be existed, they are “Diarrhea item” in the EORTC QLQ-C30 and “Bowel Symptom domain” in the EORTC QLQ-PR25 (data shown here). We then removed the carry-over effect and rerun the models, the results were shown in Table 4. Among twenty domains/items scale, there were only five domains, e.g., “Global health status”, “Social Functioning”, “Nausea/Vomiting”, “Insomnia” and “Diarrhea”, showed order effect. However, there was no any mode effect shown (all $p > 0.05$), which indicated the measurement were not significantly difference between two modes.

4.5.3 Equivalence test based on minimal important difference approach

Equivalence test based on the minimal important difference (MID) approach were applied to assess the equivalent properties between two modes, all p value were less than 0.05 indicating the measurement scales between two modes for all domains/items scales were equivalent. (Shown in Table 4)

4.5.4 Exact and global agreement analysis

Table 5 showed the results of agreement analysis and equivalence test based on a summated response difference approach. In Table 5, we showed the distribution of the summated differences of each response for each domain/item scale, for example, in the “Global health status/Qol” domain including 2 items, there were 198 response (2 items*98 subjects), among them, 137 responses were identical resulting the exact agreement being

137/198=0.69. Our results showed the percentages of exact agreement for the domain/item scales in the EORTC QLQ-C30 were ranged from 0.69 to 0.96; and 0.50 to 0.89 in the EORTC QLQ-PR25. The percentages of global agreement for the domain/item scales in the EORTC QLQ-C30 were ranged from 0.92 to 1; and 0.84 to 1 in the EORTC QLQ-PR25. (Shown in Table 5)

4.5.5 Equivalence test based on a response difference approach

Equivalence test based on using 15% of the total difference score for each domain to measure equivalence test of two modes were applied to assess the equivalent properties between two modes, all P value were less than 0.05 indicating the measurement scales between two modes for all domains/items scales were equivalent. (Shown in Table 5)

4.5.6 Distribution and equivalence test of each item response

Tables 6 and 7 showed the distribution and equivalence test of each item response. Patients responded “not at all” were 0.40 to 0.81 in functional domains, and 0.36 to 0.96 in symptom domains of paper version (Also response of touch-screen version, 0.38~0.98; 0.42~0.96 respectively). Moreover, we found a high ceiling effect in the “bowel symptom” domain and in the “treatment-related symptom” domain of the EORTC QLQ-PR25 (76~88% and 74~89% answer “not at all” in paper version and touch-screen version, indicated most patients had less symptoms limitation). As shown in Tables 6 and 7, the percentages of global agreement between two modes in both EORTC QLQ-C30 and EORTC QLQ-PR25 questionnaires were about 90% in each item, which indicated the equivalence of the measurement between two modes for each item was good.

4.5.7 Intraclass correlation coefficient analysis

In Table 4, the results show the intraclass correlation coefficients (ICCs) with a range from 0.66 (“Appetite loss” domain) to 0.84 (“Emotional

Functioning" domain) in the EORTC QLQ-C30, and from 0.47 ("Treatment-related symptom" domain) to 0.80 ("Sexual functioning" domain) the EORTC QLQ-PR25 was, which indicated moderate to good reliability.

4.6 Differential item functioning analysis

Figure 4 to Figure 8 showed the results of differential item functioning of Rasch analysis. Our study found there was no differential item functioning of the EORTC QLQ-PR25 for prostate cancer patients, which indicated the measurement property were equivalent between two modes for each item. (See the Supplementary Appendix for additional details in Table A3~ Table A5.)

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Chapter 5.Discussion

This Study demonstrates that the touch-screen version of questionnaires was shown to be feasible in prostate cancer patients, and it appeared to be preferable to use than the paper version of the same questionnaires. In addition, the equivalence of the paper version and the touch-screen version of the EORTC QLQ-C30 and the EORTC QLQ-PR25 is shown, in terms of no mode effect in domain level by using cross-over regression analysis, high exact and global agreement in both item and domain level, and no DIF by using the modern test measurement analysis.

5.1 Feasibility assessment of two modes

Many studies examined the measurement equivalence of paper-based version and touch-screen computer-based version, and showed the touch-screen version was well accepted for most subjects[1, 19, 27, 142]. In this study, most people preferred touch-screen version questionnaire than paper version, the result was consistent with previous studies (range 39%~57%). About 92% of patients indicated that they liked using the touch-screen to complete the questionnaire; about 97% of patients thought the touch-screen interface was user-friendly; and about 67% patients reported that they prefer the touch-screen version to paper version. Moreover, most patients (92%) in our study reported that the touch-screen was easy to use. Similarly, Pouwer (1998) noted that a touch-screen questionnaire was easy (easier) for patients to complete even if they have rarely or never used a computer[6].

As to suggestions to the touch-screen version questionnaire, 10%~24% patients suggested improving some drawbacks on touch-screen version questionnaire, for example: font size and layout of the touch-screen.

5.1.1 Feasibility for the elderly

The average age of prostate cancer patients (eighty years old in this study)

is higher than the other diseases [3, 7, 9, 19, 21, 137] such as gastroesophageal reflux disease, asthma, rheumatoid arthritis, cancer, head and neck cancer [3, 7, 9, 19, 21, 137], in those diseases the average age ranged from 52.1~59.3 years. Even though, our results showed the feasibility assessment findings were fine. There was just one item question on a screen in the touch-screen version questionnaires, for the elderly patients, can be clear about what they saw.The younger patients(less than 70 years old) were more feasible in touch-screen questionnaire than the older patients (greater than 70 years old). Furthermore, younger patients(less than 70 years old) spent less time than older patients (greater than 70 years old) to complete the questionnaires in both versions.

5.1.2 Feasibility for inexperienced computer user

Greenwood (2006) investigated the feasibility of collecting rheumatoid arthritis (RA) patient self-administered outcome data using touch-screen computers in a routine outpatient clinic. Forty patients with RA completed the touch-screen and paper Rheumatoid Arthritis Quality of Life Questionnaire (RAQol) in the clinic and rated ease of use and preference. The touch-screen RAQol took less time to complete, was preferred by 64% (33% had no preference) and also was significantly higher for ease of use (p=0.003, n=40) even by inexperience computer-using patients (p=0.031, n=24). In our study, inexperienced computer-using patients (n=80) showed comparable feasibility of touch-screen version in terms of acceptance, preference, suggestions with experienced computer-using patients (n=19).

5.2 Time management

On the average, touch-screen took more time than paper version (18.1 min vs. 16.3 min, p value=0.0018). This resulted from several reasons: first, the respondents have to acquaint with computer using; second, the respondents in both groups spent fewer time on the followed questionnaires than first one. According to our results, touch-screen would take more time.

However, it would be expected that it will take less time in the future, because when patients answer routine assessment of HRQL, they will be more familiar with questionnaires. Besides, the touch-screen version allows data to be automatically entered into the database of a computer server and to immediately calculate the scores, thereby saving the time of manual entry, scoring, and analyzing the data[31, 158].

Comparing the time to completion between paper/touch group and touch/paper group, it took almost the same length of time to complete the paper and the touch-screen versions for paper version first followed by touch-screen version group. Interestingly, for touch-screen version first followed by paper version group, it took longer time to complete the touch-screen version. In both groups the first questionnaire took longer to complete, which is consistent with the pattern reported by others[1, 19, 27, 142]. All patients were given a two-hour break between the two questionnaires to avoid washout effect. However, we can recognize that time on first questionnaire indeed takes more time than followed questionnaire and this result is same as previous studies. This finding suggests the time management will become more and more efficient in the follow-up assessment.

In addition, the touch-screen version of the questionnaire was able to guide patients to skip some non-relevant items which is not needed to response based on their previous response, in such way, the patients can save the response time by eliminating the need to “click” through all non-relevant items and the response error can also be reduced.

5.3 Data management

The use of the touch-screen questionnaire may reduce the missing data, because in this way, respondents were guided through the screen driving and were unable to skip any item which is relevant to answer. The touch-screen version can also eliminate the invalid data by permitting patients to select

only one of the on-screen response options. However, in the paper version, the respondent could further proceed even some items were not completed; and some out of range or ambiguous data could be answered.

5.4 Equivalence assessment of two modes

To access the health-related quality of life by using touch screen mode has been shown to be feasible; the crossover randomized design for this comparison of both modes of paper-and-pencil and computerized version was commonly used in various diseases[3, 7, 9, 19, 21, 137], including gastroesophageal reflux disease, asthma, rheumatoid arthritis, cancer, head and neck cancer. Many studies examined the measurement equivalence of paper-based version and touch-screen computer-based version, and showed the touch-screen version was well accepted for most subjects[1, 19, 27, 142]. Our finding showed that all domains in the EORTC QLQ-C30 and the EORTC QLQ-PR25 were equivalence in prostate cancer patients. This finding can be an empirical evidence to understand the touch-screen mode can be another valuable option to assess the patient's report quality of life.

Using crossover regression model analysis, overall, the mode effect was all no statistically significant, which supported the equivalence of measure properties. Global agreement in all domains reaches greater than 96% in the EORTC QLQ-C30 and the EORTC QLQ-PR25. Differential item functioning (DIF) analysis based on the modern test theory also supported the equivalent properties between two modes.

5.5 Advantages of the crossover design

There were advantages to crossover design. The reason to consider a crossover design when planning a clinical trial (or methodology) is that it could yield a more efficient comparison of treatments than a parallel design, i.e., fewer patients might be required in the crossover design in order to attain the same level of statistical power, precision, etc. Intuitively, this seems

reasonable because each patient serves as his/her own matched control. Every patient receives both treatments (methods) A and B. Crossover designs are popular in medicine, agriculture, manufacturing, education, and many other disciplines and a comparison is made of their response on A vs. B. Our results from crossover regression analysis showed there was no mode-order interaction effect for most domains, which implicated the carry-over effect did not exist; and when we refit the main effect removing the interaction term, the results showed the order effect did not exist for most domain. The above results supported the crossover randomized design in our study is rigorous.

5.6 Confirmation from modern measurement theory

Rasch model analysis is based on the modern measurement theory, originally developed in the fields of education and psychology, has been proven to be a powerful tool for patients reported outcome assessment[159-160]. This model comprises a set of statistical models suitable for analyzing a scale or survey instrument with multiple items that measure the same construct (e.g., physical functioning). Rasch model specifies how both person–trait level and item characteristics are related to a person's item responses. This is different from the classical test theory (CTT) approach in which items and the person latent trait being measured are considered separately and, therefore, cannot be meaningfully and systematically compared [161-162]. Many limitations of CTT approach can be solved rationally using modern measurement theory approach. Many useful statistics, such as differential item functioning (DIF) can be examined for measurement invariance[161-162]. Our analyses of the DIF revealed that four domains in the EORTC QLQ-PR25 to assess for prostate cancer patients exhibited no DIF across the two method groups (touch-screen vs. paper) displayed.

5.7 Improvement of quality of care

First, as mentioned in the literature review, paper questionnaire would

require more manpower to collect questionnaires and key-in data[6, 136], so that touch-screen mode could save more time, manpower. For example, in our proceeding, the patients' responses to the EORTC QLQ-C30 and the EORTC QLQ-PR25 were automatically entered into a desktop computer, scored, and printed as a graphic summary profile (see Figure 9). Although our results showed the touch-screen mode took more time to finish (see Table2), however, it can be expected that when the routine assessment of HRQL is required, the assessment time will become more shortly afterward. Before the start of the consulting in the visiting room, each patient completes a touch-screen version HRQL questionnaire in the waiting room, and then physicians receives the patients reported outcomes later immediately; in such way, the quality of care will be upgraded.

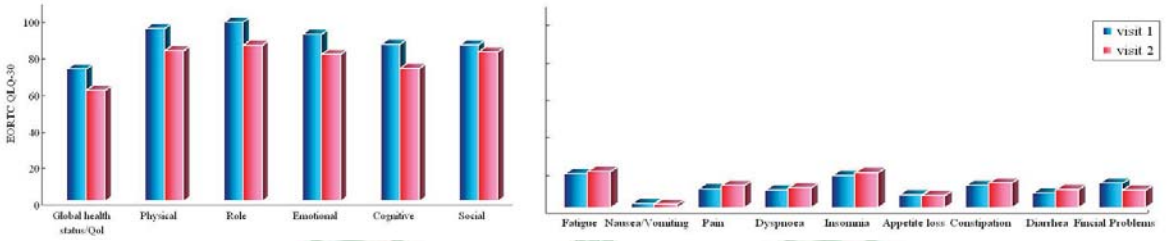

Figure 9. Example of graphic summary profile of quality of life questionnaire EORTC QLQ-C30

Second, the proceeding of data collection through touch-screen mode can help the integration of patient's reported outcome and clinical information to promote the quality of health care. Paper-and-pencil would raise the manpower required to administer, collect, enter data and score an HRQL questionnaire[6, 136]. We postulate (believe) that the establishment of the touch-screen version would be useful to the integration of clinical informatics.

Third, several large studies in chronic diseases also suggested that incorporating standardized HRQL assessments in routine clinical oncology practice facilitates the discussion of the progression of HRQL issues and can heighten physicians' awareness of their patients' HRQL[3, 10-13, 139-141]. Copies of the summary were given to the patient and physician immediately before

consultation. A copy was also placed in the medical records. At the each subsequent outpatient visits, a summarized report from patient's report questionnaires included both the patients' current scores and those elicited at the previous visit(s) can be displayed in the physician screen in real time, which can be an useful information to facilitate the communication between physicians and patients.

Finally, oncology settings system assessed the manner in which clinicians use this touch-screen questionnaire and identify the benefits and challenges that oncology clinics may face when adopting[9, 137]. For example, one research reported challenges included patient burden from the frequent need to answer the questionnaires, the development of short version of questionnaire could be one solution to solve the challenge. In addition, the setting of the overall computerized environment such as the integrated system of clinical informatics and the setting of computerized hardware plays an important key role in the performance and contribution of the data collection though the touch screen mode. In summary, touch-screen questionnaire assessments can be linked to the integration of routine assessment of patients' symptoms and health-related quality of life into the daily flow of an oncology clinic, it offers advantages in terms of promote health care quality.

Chapter 6.Conclusion

6.1 Conclusion

The touch-screen mode had good feasibility, and was accepted for most prostate cancer patients, 92% patients showed the touch-screen version was easy to use. High percentages of patients thought they preferred touch-screen version to the paper-and-pencil version, which were 74% for the patients below 70 years old and 59.2% for the patients aged greater than 70 years. The younger patients spent less time than older patients to complete the questionnaires in both versions. As to suggestions to the touch-screen version questionnaire, only 10%~24% patients suggested improving some drawbacks on touch-screen version questionnaire, for example: font size and layout of the touch-screen.

The measurement properties of the EORTC QLQ-C30 and the EORTC QLQ-PR25 data by using the touch-screen version were shown to be equivalent to the paper-and-pencil version. The measurement effect between the touch-screen mode and the paper-and-pencil mode were no significant difference from the crossover regression model analysis. The percentages of global agreement in all domains reached greater than 96% in both the EORTC QLQ-C30 and the EORTC QLQ-PR25. Most ICC indices greater than 0.7 in both questionnaires indicated good equivalence. Differential item functioning (DIF) analysis based on the modern test theory also supported the equivalent properties between two modes.

Our study result provided an empirical evidence to support the touch-screen mode of the QLQ-C30 and the EORTC QLQ-PR25 for patients with prostate cancer can be an alternative choice of measurement mode in addition to paper-and-pencil mode to assess the patient's report quality of life. The e-data from the touch screen questionnaire can be easily integrated with other clinical data to provide real time diagnostic information in clinic. It may

not only improve medical care quality, but also promote the relationship between physician and patient.

6.2 Limitation

There are some limitations in the present study. First, since we excluded patients who could not read, speak and write Chinese, and who could not complete these questionnaires by themselves for the whole procedure, the results cannot be generalized to these patients. Second, the study was conducted in a single disease and a single hospital so the representative of all patients with prostate cancer in Taiwan may not be enough. In addition, the sample subjects were from the outpatient clinic, thus the results may not suit to the inpatients.

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Table 1. Demographic characteristics of the two groups of prostate cancer patients

	Paper/Touch-Screen (n=49)	Touch-Screen/Paper (n=50)	*p* value
Age (years, mean±SD)	70.1±7.6	69.0±8.1	0.4632[a]
<=65	12 (24.5)	13 (26.0)	0.7779[b]
65<age<=70	11 (22.5)	14 (28.0)	
70<age<=75	12 (24.5)	13 (26.0)	
>75	14 (28.5)	10 (20.0)	
Education level			0.7012[b]
College or above	14 (29.8)	13 (26.0)	
Senior high	11 (23.3)	15 (30.0)	
Junior high	11 (21.4)	7 (14.0)	
Primary school or less	12 (25.5)	15 (30.0)	
Previous experience using computers			
Yes	10 (20.4)	9 (18.0)	0.8366[b]
No	39 (79.6)	41 (82.0)	

[a]Using independent t test
[b]Using chi-square test

Table 2. Comparison of the mean time for completion of the two questionnaire modes stratified by the order of administration and age group

	No. of Patients	Paper Version		Touch-Screen Version		*p* value
		Mean time[§]	Min~Max	Mean time	Min~Max	
All patients	99	16.3	5.0~39.0	18.1	5.0~41.0	0.0018
Paper/touch-screen Group	49	17.9	5.0~39.0	15.7	5.0~30.0	0.0082
age <=70	23	15.1	5.0~27.0	14.5	9.0~26.0	0.9367
age >70	26	20.4	8.0~39.0	16.8	5.0~30.0	<.0001
Touch-screen/paper Group	50	14.7	6.0~31.0	20.5	9.0~41.0	<.0001
age <=70	27	13.2	6.0~25.0	19.1	9.0~35.0	<.0001
age >70	23	16.6	8.0~31.0	22.2	10.0~41.0	<.0001

[§]Mean time for completion of the two questionnaire modes by four questionnaires, including the EORTC QLQ-C30,QLQ-PR25, IIEF-5, and IPSS.

Table 3. Feasibility assessment for the touch-screen version

	All	<=70	>70		Computer experience		
	(n=99)	(n=50)	(n=49)	*p* value	Yes (n=19)	No (n=80)	*p* value
	percent (%)	*percent (%)*			*percent (%)*		
Touch-screen questionnaire was easy to use				0.161			0.353
Yes	91.9	96.0	87.0		100.0	90.0	
User-interface was user-friendly				0.124			1.000
Yes	97.0	100.0	93.9		100.0	96.3	
Did you like touch-screen version of the questionnaire ?				0.162			
Yes	91.9	96.0	87.8		100.0	90.0	
Which version did you like ?				0.121			0.565
Neither	2.0	0.0	4.1		5.3	1.3	
Paper and pencil version	30.3	24.0	36.7		31.6	30.0	
Touch-screen version	66.7	74.0	59.2		63.2	67.5	
Both	1.0	2.0	0.0		0.0	1.3	
For improving readability of items[§]				0.471			1.000
Yes	21.2	18.0	24.5		21.1	21.3	
For improving font size[§]				0.539			0.681
Yes	10.1	8.0	12.2		5.3	11.3	
For improving the layout of the screen[§]				0.362			1.000
Yes	24.2	20.0	28.6		21.1	25.0	

[§]Age group (<=70 and >70) answered suggests for the touch-screen version n=25 and 22 respectively; computer experience response n=8 and 39 respectively

Table 4. Domain scores, cross-over regression analysis, and equivalence test for comparison of touch-screen and paper modes

Domain	Paper Version		Touch-Screen Version		*p* value[#]		*p* value[##]		ICC
					Mode	Order	Equivalence test[&]		
	Mean	SD	Mean	SD	effect	effect	Left tail	Right tail	
EORTC QLQ-30[§]									
Global health status/Qol (2 items)	67.5	22.1	67.5	20.1	0.9199	0.0332	0.0014	0.0014	0.70
Physical Functioning (5 items)	89.8	10.5	89.3	11.4	0.2474	0.0675	<0.0001	<0.0001	0.81
Role Functioning (2 items)	93.2	12.8	92.2	15.4	0.3644	0.3456	0.0003	<0.0001	0.72
Emotional Functioning (4 items)	86.8	14.4	87.1	13.7	0.7194	0.1103	<0.0001	<0.0001	0.84
Cognitive Functioning (2 items)	81.0	18.4	79.5	17.4	0.2545	0.4081	0.0047	<0.0001	0.72
Social Functioning (2 items)	88.0	17.3	88.7	15.9	0.5687	0.0185	<0.0001	0.0002	0.75
Fatigue (3 items)	18.1	14.6	19.4	16.3	0.2952	0.1601	<0.0001	0.0009	0.76
Nausea/Vomiting (2 items)	1.8	5.8	1.8	6.7	0.9617	0.0335	<0.0001	<0.0001	0.71
Pain (2 items)	10.2	15.7	11.8	18.6	0.1256	0.6021	<0.0001	0.0110	0.72
Dyspnoea (1 items)	9.3	17.8	10.7	16.3	0.3038	0.5944	<0.0001	0.0041	0.73
Insomnia (1 items)	17.3	22.5	18.7	22.4	0.3222	0.0492	<0.0001	0.0071	0.82
Appetite loss (1 items)	7.0	13.7	6.7	13.4	0.7206	0.7206	<0.0001	<0.0001	0.72
Constipation (1 items)	12.0	17.4	13.3	17.1	0.3315	0.1822	<0.0001	0.0055	0.66
Diarrhea (1 items)	8.0	16.5	9.7	15.9	0.2147	0.0187	<0.0001	0.0055	0.68
Fincial Problems (1 items)	10.3	16.9	9.3	15.8	0.7505	0.3922	0.0013	<0.0001	0.70
EORTC QLQ-PR25									
Urinary Symptoms (8 items)[$]	19.5	13.5	21.1	13.3	0.0772	0.0547	<0.0001	0.0001	0.78
Bowel Symptoms (4 items)	5.3	8.6	5.7	7.9	0.8051	0.1066	<0.0001	<0.0001	0.72
Treatment-Related Symptoms (6 items)	11.1	10.2	10.3	9.2	0.3570	0.6769	<0.0001	<0.0001	0.47
Sexual Activity (2 items)	19.4	20.2	20.2	20.8	0.5173	0.6647	0.0003	0.0227	0.61
Sexual Functioning (4 items)	23.1	16.5	20.5	18.5	0.7241	0.1090	0.0808	0.0041	0.80

[§] EORTC QLQ-C30: all scores were linearly converted to a 0 to 100 scale, with higher scores indicating a higher level of functioning and more severe symptoms.

[$] Urinary Symptoms(8 items) not include p38

[#] Based on the cross-over regression model

[##] Based on the Equivalence test

Table 5. Equivalence test between touch-screen and paper questionnaire modes

Domain	Difference between two modes (paper minus touch-screen)					Equivalence test[&]			
	Difference equal to zero (Exact agreement)	Difference of 1	Difference of -1	Difference of above	Difference within 1[#] (Global agreement)	Range (min~ max)	δ	p value	
EORTC QLQ-30[§]									
Global health status/Qol (2 items)	137/198(0.69)	21/198	24/198	16/198	182/198(0.92)	0-6	0.9	<0.0001	<0.0001
Physical Functioning (5 items)	434/495(0.88)	29/495	28/495	7/495	488/495(0.99)	0-15	2.3	<0.0001	<0.0001
Role Functioning (2 items)	175/198(0.88)	11/198	10/198	2/198	196/198(0.99)	0-6	0.9	<0.0001	<0.0001
Emotional Functioning (4 items)	342/396(0.86)	26/396	27/396	1/396	395/396(1.00)			<0.0001	<0.0001
Cognitive Functioning (2 items)	155/198(0.78)	24/198	13/198	6/198	192/198(0.97)	0-6	0.9	<0.0001	<0.0001
Social Functioning (2 items)	167/198(084)	12/198	18/198	1/198	197/198(0.99)	0-6	0.9	<0.0001	<0.0001
Fatigue (3 items)	231/297(0.78)	37/297	25/297	4/297	293/297(0.99)			<0.0001	<0.0001
Nausea/Vomiting (2 items)	190/198(0.96)	4/198	4/198		198/198(1.00)	0-6	0.9	<0.0001	<0.0001
Pain (2 items)	163/198(0.82)	20/198	11/198	4/198	194/198(0.98)	0-6	0.9	<0.0001	<0.0001
Dyspnoea (1 items)	85/99(0.86)	9/99	5/99		99/99(1.00)	0-3	0.5	<0.0001	<0.0001
Insomnia (1 items)	83/99(0.84)	10/99	6/99		99/99(1.00)	0-3	0.5	<0.0001	<0.0001
Appetite loss (1 items)	90/99(0.92)	4/99	5/99		99/99(1.00)	0-3	0.5	<0.0001	<0.0001
Constipation (1 items)	81/99(0.82)	11/99	7/99		99/99(1.00)	0-3	0.5	<0.0001	<0.0001
Diarrhea (1 items)	84/99(0.85)	10/99	5/99		99/99(1.00)	0-3	0.5	<0.0001	<0.0001
Fincial Problems (1 items)	85/99(0.86)	6/99	8/99		99/99(1.00)	0-3	0.5	<0.0001	<0.0001
EORTC QLQ-PR25									
Urinary Symptoms (8 items)[$]	629/791(0.80)	90/791	59/791	13/791	778/791(0.99)	0-24	3.6	<0.0001	<0.0001
Bowel Symptoms (4 items)	351/396(0.89)	24/396	21/396		396/396(1.00)	0-12	1.8	<0.0001	<0.0001
Treatment-Related Symptoms (6 items)	500/591(0.85)	28/591	43/591	20/591	574/591(0.97)	0-18	2.7	<0.0001	<0.0001

Sexual Activity (2 items)	142/196(0.72)	20/196	25/196	9/196	187/196(0.95)	0-6	0.9	<0.0001	0.0043
Sexual Functioning (4 items)	192/386(0.50)	78/386	53/386	63/386	323/386(0.84)	0-12	1.8	<0.0001	0.0173

[$] Urinary Symptoms(8 items) not include p38

[#] Missing data: one, three, two, ten items in US,TS, Sexual activity, Sexual functioning separately

[&] Based on Equivalence test; δ: 15% of summative domain different score

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Table 6. Distribution and equivalence test between touch-screen and paper questionnaire modes of each item in the EORTC QLQ-C30

	Percentage of response for each item									% of absolate difference Different between P-T			
	Paper Version					Touch-Screen Version							
	n	Not at all	A little	Quite a bit	Very much	n	Not at all	A little	Quite a bit	Very much			
		1	2	3	4		1	2	3	4	0	1	2	3
Physical Functioning														
PF1 難從事費力活動	99	0.58	0.40	0.02		99	0.62	0.35	0.03		0.82	0.17	0.01	
PF2 長距離步行困難	99	0.51	0.45	0.03	0.01	99	0.53	0.41	0.05	0.01	0.81	0.18	0.01	
PF3 短距離步行困難	99	0.85	0.14	0.01		99	0.85	0.14	0.01		0.92	0.08		
PF4 白天需要坐臥	99	0.69	0.25	0.06			0.61	0.31	0.07	0.01	0.86	0.12	0.01	0.01
PF5 日常需他人輔助	99	1.00				99	0.98	0.02			0.98	0.02		
Role Functioning														
RF6 工作受限	99	0.81	0.19			99	0.85	0.13	0.02		0.89	0.1	0.01	
RF7 休閒娛樂受限	99	0.79	0.20	0.01		99	0.76	0.19	0.04	0.01	0.88	0.11		0.01
Emotional Functioning														
EF21 緊張	99	0.66	0.33	0.01		99	0.68	0.31	0.01		0.86	0.14		
EF22 焦慮	99	0.66	0.31	0.03		99	0.63	0.35	0.02		0.91	0.08	0.01	
EF23 易怒	99	0.59	0.40	0.01		99	0.63	0.37			0.89	0.11		
EF24 情緒低落	99	0.60	0.37	0.03		99	0.58	0.39	0.03		0.80	0.2		
Cognitive Functioning														
CF20 注意力不集中	99	0.66	0.31	0.03		99	0.61	0.31	0.08		0.78	0.18	0.04	
CF25 記憶減退	99	0.40	0.44	0.12	0.02	99	0.38	0.49	0.11	0.01	0.79	0.19	0.02	
Social Functioning														
SF26 家庭生活	99	0.68	0.29	0.03		99	0.71	0.27	0.02		0.85	0.14	0.01	

SF27 社交活動	99	0.68	0.28	0.03	0.01	99	0.65	0.34		0.01	0.84	0.16		
Fatigue symptoms														
FA10 需要休息	99	0.36	0.60	0.04		99	0.42	0.53	0.05		0.74	0.25	0.01	
FA12 感到虛弱	99	0.58	0.39	0.03		99	0.57	0.38	0.05		0.84	0.15	0.01	
FA18 疲倦	99	0.55	0.42	0.02	0.01	99	0.42	0.54	0.03	0.01	0.76	0.22	0.01	0.01
Nausea/Vomiting symptoms														
NV14 噁心	99	0.93	0.07			99	0.94	0.05	0.01		0.94	0.06		
NV15 嘔吐	99	0.96	0.04			99	0.96	0.04			0.98	0.02		
Pain symptoms														
PA9 疼痛	99	0.71	0.25	0.03	0.01	99	0.67	0.27	0.06		0.81	0.16	0.02	0.01
PA19 疼痛干擾生活	99	0.76	0.20	0.03		99	0.76	0.17	0.06	0.01	0.84	0.15	0.01	
Single item symptoms														
DY8 呼吸喘	99	0.75	0.23	0.01	0.01	99	0.69	0.30	0.01		0.86	0.14		
SL11 失眠	99	0.58	0.34	0.07	0.01	99	0.54	0.38	0.07	0.01	0.84	0.16		
AP13 食慾不振	99	0.79	0.21			99	0.80	0.20			0.91	0.09		
CO16 便秘	99	0.67	0.31	0.02		99	0.62	0.37	0.01		0.82	0.18		
DI17 腹瀉	99	0.79	0.18	0.03		99	0.72	0.27	0.01		0.85	0.15		
FI28 財務困難	99	0.72	0.26	0.02		99	0.73	0.26	0.01		0.86	0.14		

Table 7. Distribution and equivalence test between touch-screen and paper questionnaire modes of each item in the EORTC QLQ-PR25

	Percentage of response for each item										% of absolate difference Different between P-T			
	Paper Version					Touch-Screen Version								
	n	Not at all	A little	Quite a bit	Very much	n	Not at all	A little	Quite a bit	Very much				
		1	2	3	4		1	2	3	4	0	1	2	3
Urinary symptom														
US31 白天頻尿	99	0.41	0.51	0.07	0.01	99	0.29	0.55	0.14	0.02	0.69	0.27	0.04	
US32 夜晚頻尿	99	0.25	0.61	0.13	0.01	99	0.25	0.61	0.13	0.01	0.82	0.16	0.02	
US33 尿急	99	0.27	0.67	0.05	0.01	99	0.24	0.61	0.13	0.02	0.66	0.31	0.03	
US34 夜尿	99	0.34	0.55	0.08	0.03	99	0.33	0.59	0.06	0.02	0.80	0.19	0.01	
US35 尿急影響外出	98	0.58	0.34	0.06	0.02	98	0.54	0.40	0.05	0.01	0.87	0.11	0.02	
US36 尿失禁	99	0.54	0.42	0.04		99	0.53	0.42	0.05		0.86	0.14		
US37 小便疼痛	99	0.88	0.12			99	0.86	0.13	0.01		0.92	0.07		0.01
US39 因排尿活動受限	99	0.71	0.24	0.04	0.01	99	0.67	0.31	0.02		0.76	0.24		
Bowel symptom														
BS40 因排便活動受限	99	0.84	0.13	0.03		99	0.81	0.19			0.80	0.20		
BS41 大便失禁	99	0.89	0.11			99	0.88	0.12			0.91	0.09		
BS42 大便帶血	99	0.89	0.11			99	0.90	0.10			0.97	0.03		
BS43 腹脹	99	0.77	0.23			99	0.75	0.24	0.01		0.87	0.13		
Treatment-related symptom														
TS44 熱潮紅	99	0.80	0.18	0.02		99	0.87	0.12	0.01		0.92	0.08		
TS45 乳頭或乳房酸痛增大	99	0.92	0.08			99	0.92	0.08			0.96	0.04		
TS46 腿部或腳踝腫脹	99	0.82	0.15	0.03		99	0.80	0.17	0.03		0.84	0.12	0.04	
TS47 體重減輕	98	0.79	0.16	0.04	0.01	99	0.77	0.17	0.04	0.02	0.85	0.11	0.03	0.01
TS48 體重增加	98	0.62	0.33	0.02	0.02	99	0.68	0.26	0.05		0.78	0.18	0.03	0.01

TS49 缺乏男人味	98	0.41	0.45	0.10	0.04	99	0.42	0.45	0.08	0.03	0.73	0.18	0.06	0.02
Sexual Activity														
SX50 興趣的程度	98	0.45	0.45	0.08	0.02	99	0.40	0.44	0.12	0.02	0.72	0.22	0.04	0.01
SX51 性生活活躍的程度	98	0.57	0.37	0.05	0.01	99	0.60	0.34	0.04	0.02	0.72	0.23	0.04	
Sexual functioning														
SX52 愉快的程度	36	0.11	0.72	0.17		37	0.19	0.57	0.24	0.00	0.69	0.27	0.00	0.00
SX53 勃起困難	36	0.25	0.56	0.17	0.03	39	0.21	0.59	0.15	0.05	0.81	0.15	0.00	0.00
SX54 射精問題	36	0.50	0.33	0.08	0.08	38	0.39	0.39	0.11	0.11	0.62	0.23	0.08	0.04
SX55 性接觸不舒服	36	0.69	0.28	0.00	0.03	39	0.77	0.18	0.00	0.05	0.69	0.27	0.00	0.04

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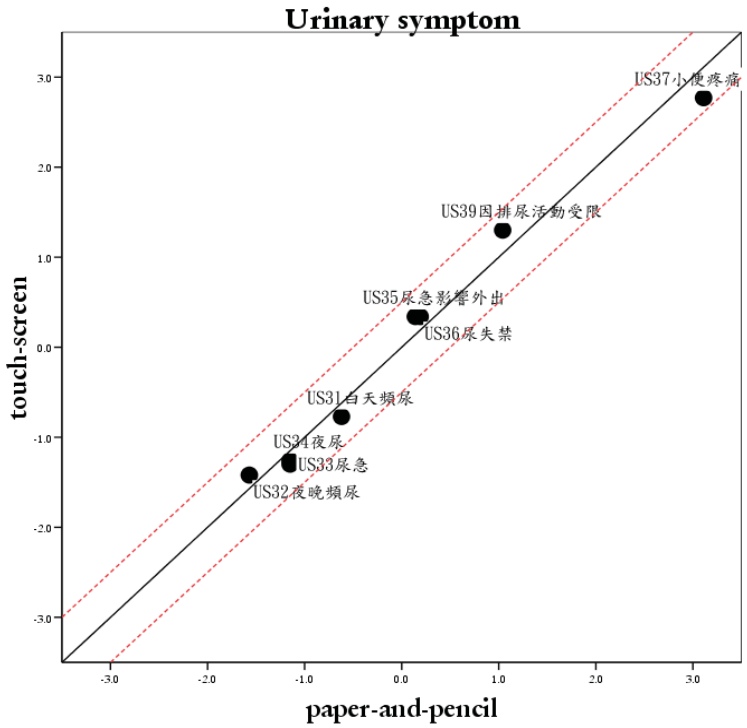

Figure 4. Differential item functioning plot between touch-screen and paper questionnaire modes in urinary symptom of the EORTC QLQ-PR25

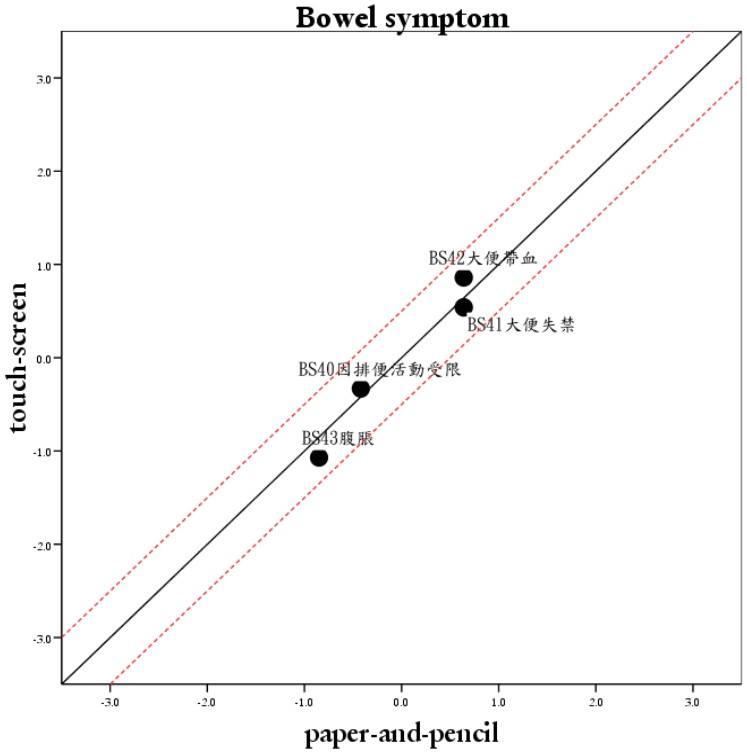

Figure 5. Differential item functioning plot between touch-screen and paper questionnaire modes in bowel symptom of the EORTC QLQ-PR25

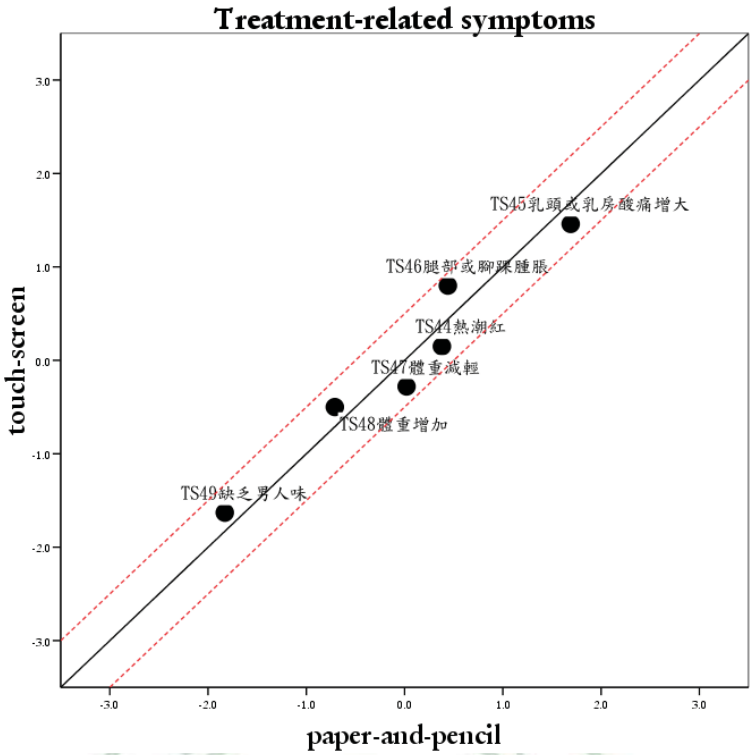

Figure 6. Differential item functioning plot between touch-screen and paper questionnaire modes in treatment-related symptom of the EORTC QLQ-PR25

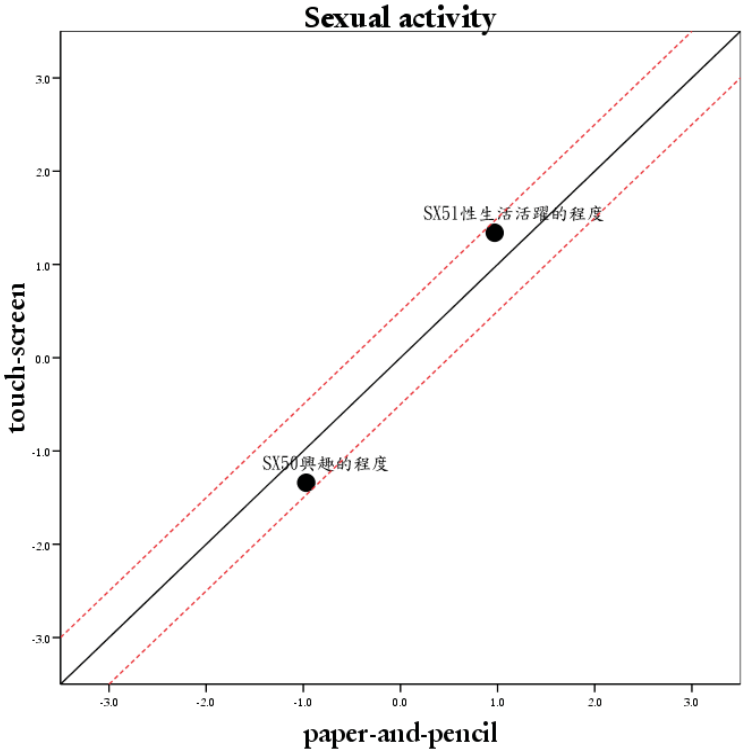

Figure 7. Differential item functioning plot between touch-screen and paper questionnaire modes in sexual activity of the EORTC QLQ-PR25

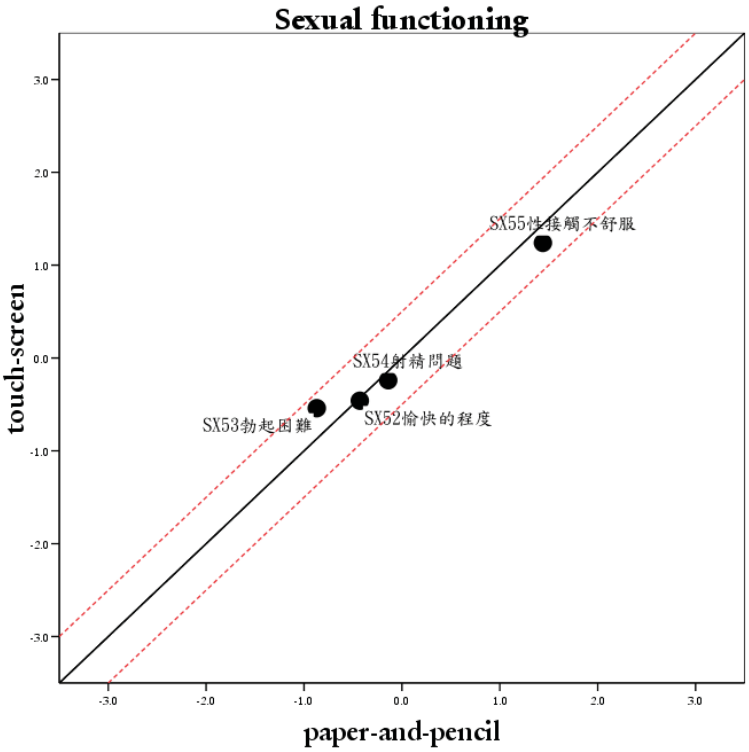

Figure 8. Differential item functioning plot between touch-screen and paper questionnaire modes in sexual functioning of the EORTC QLQ-PR25

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Supplementary Appendix

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中國醫藥大學附設醫院泌尿腫瘤科吳錫金主任所提臨床試驗「建立以攝護腺癌臨床資訊測量為基礎之即時決策支援系統」之修正案已獲同意。計畫編號：CMU96-225，CMU96-226，CMU96-227，CMU96-228; Protocol Version Date: 97/06/26; CMU96-225 Informed Consent Form Version Date: May 26, 2008。
本院編號：DMR97-IRB-003-1。

計劃有效期限到 2009 年 03 月 26 日為止。在有效期屆滿之前，研究計劃主持人應向人體試驗委員會報告研究計劃的進行狀況。若屆時尚未完成，應重新申請。

該計劃任何部分若欲更改，需向人體試驗委員會重新提出申請。計劃主持人對受試者任何具有危險而且未能預期之問題，例如：對藥物、放射性元素或對醫療器材產生不良反應等，需立即向人體試驗委員會主任委員提出書面報告。

中國醫藥大學附設醫院 人體試驗委員會 台中市北區育德路2號

主任委員 傅武松

中 華 民 國 九 十 七 年 七 月 十 五 日

中國醫藥大學附設醫院
CHINA MEDICAL UNIVERSITY HOSPITAL
台灣省台中市北區育德路 2 號
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人體試驗委員會人體試驗計劃同意書

Tel: 886-4-22052121 ext: 1925　　Fax: 886-4-2207-1478
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中國醫藥大學附設醫院泌尿腫瘤科吳錫金主任所提臨床試驗「建立以攝護腺癌臨床資訊測量為基礎之即時決策支援系統」之持續試驗案已獲同意。

計畫編號：CMU96-225，CMU96-226，CMU96-227，CMU96-228。

本院編號：DMR97-IRB-003-2。

計劃有效期限從 2009 年 03 月 27 日至 2010 年 03 月 26 日為止。在有效期屆滿之前，研究計劃主持人應向人體試驗委員會報告研究計劃的進行狀況。若屆時尚未完成，應重新申請。

該計劃任何部分若欲更改，需向人體試驗委員會重新提出申請。計劃主持人對受試者任何具有危險而且未能預期之問題，例如：對藥物、放射性元素或對醫療器材產生不良反應等，需立即向人體試驗委員會主任委員提出書面報告。

中國醫藥大學附設醫院 人體試驗委員會 台中市北區育德路2號

主任委員 陳武祖

中　華　民　國　九　十　八　年　四　月　三　日

中國醫藥大學附設醫院受試者同意書

試驗主題：建立以攝護腺癌臨床資訊測量為基礎之即時決策支援系統

子計畫一：以現代測量理論探討攝護腺癌患者生活品質的評估

執行單位：泌尿部	電話：22052121-4323
計畫總主持人：吳錫金	職稱：泌尿腫瘤科主任/副教授
計畫主持人：梁文敏	職稱：環境醫學研究所/副教授
研究人員：廖文禎、周玉媛、葉懿諄	職稱：研究助理
緊急聯絡人：吳錫金	二十四小時緊急聯絡電話：0972357629

受試者姓名：	病歷號碼：
性別：	出生日期：
身分證字號：	
聯絡電話：	
通訊地址：	

有同意權人姓名：	
與受試者關係：	
性別：	出生日期：
身分證字號：	
聯絡電話：	
通訊地址：	

(1) 試驗簡介：

本子計劃配合攝護腺癌臨床資訊測量(CIPC)研究團隊之整合型計劃，以歐洲癌症治療與研究組織(EORTC)的生活品質問卷為核心，建構整合性的網路化資訊平台。

在生活品質測量部分，我們擬以觸控式電腦問卷取代傳統手寫問卷，觸控式電腦問卷不但能節省資料處理時間，並且能提供醫師看診時最即時的訊息，達到以病患為中心(patient-centered)的治療效益。然而觸控式電腦問卷所得結果與手寫問卷結果一樣嗎？他們所得的結果有一樣的信效度？能互相比較?以

及對問卷的接受度等問題，都是在新方法推出前需先解決的問題。

(2) 試驗目的：

本計畫目的為比較傳統手寫問卷與觸控式電腦問卷所測得之生活品質是否相同，以作為以觸控式電腦問卷取代手寫問卷之基礎。

(三) 試驗之主要納入與排除條件：

收案對象為攝護腺癌病患，且需識字、能自行完成手寫問卷、並能配合問卷填答的流程者。

(四) 試驗方法及相關檢驗：

(1) 預計將收 106 位病患。

(2) 施測問卷：EORTC QLQ-C30，EORTC QLQ-PR25

(3) 試驗流程：若您符合收案條件，則醫師會先徵求您的同意，並請您填寫同意書，隨後，您將被隨機分派到不同問卷執行方式的組別，並安排施測時間。不同問卷執行方式的組別有兩組，A組為先填手寫問卷，再填觸控式電腦問卷；B組為先填觸控式電腦問卷，再填手寫問卷。兩種問卷執行方式之間以相差一天之內為原則。您在兩份問卷填答完成後，我們會再請您填寫“觸控式螢幕的滿意度及偏好調查”的問卷。

(五) 可能產生之副作用、發生率及處理方法：

本試驗僅採用手寫問卷或觸控式電腦問卷調查，將不會對您的身體造成或產生任何副作用及危險，對於獲得之資料，將嚴格保密處理。

(六) 試驗預期效益：

經由比較傳統手寫問卷及觸控式電腦問卷之差別，以達到以使用者為中心的使用原則。

（七）試驗進行中受試者之禁忌、限制與應配合之事項：

本試驗僅採用手寫問卷或觸控式電腦問卷調查，將不會對您的身體造成產生任何副作用及危險，且無任何禁忌與限制事項；但需要您配合安排，假如您被分派到A組請您於看診時先填手寫問卷，並於隔天與研究助理安排時間填觸控式電腦問卷；假如是B組則為先填觸控式電腦問卷，隔天再填手寫問卷。

（八）機密性：

經由簽署受試者同意書，即表示您同意您的原始醫療紀錄可直接受監測者、稽核者、人體試驗委員會及主管機關檢閱，以確保臨床試驗過程與數據符合相關法律及法規要求；而我們將嚴格保密所獲得的資料，如果發表試驗結果，您的身分仍將保密。

（九）受試者權利：

1. 試驗過程中，與您的健康或是疾病有關，可能影響您繼續接受臨床試驗意願的任何重大發現，都將即時提供給您。
2. 如果您在試驗過程中對試驗工作性質產生疑問，對身為患者之權利有意見或懷疑因參與研究而受害時，可與本院之人體試驗委員會聯絡請求諮詢，其電話號碼為：04-22062121 轉 4132。
3. 為進行試驗工作，您必須接受吳錫金醫師的照顧。如果您現在或於試驗期間有任何問題或狀況，請不必客氣，可與吳錫金醫師聯絡（24 小時聯繫電話：0972357629）。

本同意書一式 2 份，醫師已將同意書副本交給您，並已完整說明本研究之性質與目的。

（十）試驗之退出與中止：

您可自由決定是否參加本試驗；試驗過程中也可隨時撤銷同意，退出試驗，不需任何理由，且不會引起任何不愉快或影響其日後醫師對您的醫療照顧。試驗主持人亦可能於必要時中止該試驗之進行。

（十一）簽名：

主要主持人、或協同主持人已詳細解釋有關本研究計畫中上述研究方法的性質與目的，及可能產生的危險與利益。

1. 試驗主持人/協同主持人簽名：梁敏 日期：97 年 6 月 26 日
2. 受試者已詳細瞭解上述研究方法及其所可能產生的危險與利益，有關本試驗計畫的疑問，業經試驗主持人詳細予以解釋。

   本人同意接受為臨床試驗計畫的自願受試者。

   受試者簽名：_____ 日期：_____年_____月_____日

   法定代理人簽名：_____ 日期：_____年_____月_____日

   有同意權人簽名：_____ 日期：_____年_____月_____日
3. 見證人姓名：(　　)

   與受試者關係:

   見證人簽名：_____ 日期：_____年_____月_____日

   身分證字號：_____ 聯絡電話：_____

   通訊地址：

A1. Tables

Table A1.Comparison of the mean time for completion of the two questionnaire modes based on order of administration and age group

	No. of	Paper Version		Touch-Screen Version	
	Patients	Mean time	Min~Max	Mean time	Min~Max
All patients	99	16.3	5.0~39.0	18.1	5.0~41.0
Patients by order of administration					
Paper/touch-screen	49	17.9	5.0~39.0	15.7	5.0~30.0
Stratified by age (years)					
<=65	12	12.4	5.0~21.0	15.1	9.0~26.0
65<age<=70	11	18.1	9.0~27.0	13.8	9.0~22.0
70<age<=75	12	18.8	10.0~31.0	14.6	5.0~21.0
>=75	14	21.6	8.0~39.0	18.6	11.0~30.0
Patients by order of administration					
Touch-screen/paper	50	14.7	6.0~31.0	20.5	9.0~41.0
Stratified by age (years)					
<=65	13	13.0	6.0~25.0	15.3	10.0~21.0
65<age<=70	14	13.3	7.0~22.0	22.6	9.0~35.0
70<age<=75	13	16.6	10.0~30.0	19.4	10.0~31.0
>=75	10	16.6	8.0~31.0	25.9	17.0~41.0

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Table A2. Feasibility questionnaire about the touch-screen version by age group

	All (n=99)	<=65 (n=25)	65<age<=70 (n=25)	70<age<=75 (n=25)	>=75 (n=24)
	percent（%）				
Touch-screen questionnaire was easy to use					
Yes	92.0	100.0	92.3	88.0	87.5
User-interface was user-friendly					
Yes	97.0	100.0	100.0	96.0	91.7
Did you like touch-screen version of the questionnaire？					
Yes	92.0	92.0	100.0	92.0	83.3
Which version did you like？					
Neither	2.0	0.0	0.0	8.0	0.0
Paper and pencil version	30.0	16.0	30.8	32.0	41.7
Touch-screen version	67.0.	84.0	65.4	60.0	58.3
Both	1.0	0.0	3.8	0.0	0.0
For improving readability of items					
Yes	21.0	19.0	23.8	19.0	38.2
For improving words size					
Yes	10.0	0.0	6.7	26.0	7.2
For improving the layout of the screen					
Yes	24.0	25.0	16.7	29.2	29.2

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Table A3.Using Rasch analysis with Rating scale model in paper-and-pencil mode

Domain	Item	Count	Item difficulty	S.E.	Infit index	Outfit index	Person reliability (Separation)	Item reliability (Separation)
Urinary symptom	US32Urinate frequently at night	99	-1.57	0.21	0.68	0.74	0.74(1.67)	0.96(5.04)
	US33Urinary Urgency	99	-1.15	0.21	0.67	0.69		
	US34Nocturia	99	-1.15	0.21	1.06	1.06		
	US31Urinate frequently during the day	99	-0.62	0.21	0.85	0.84		
	US35Difficulty going out	98	0.14	0.23	1.07	0.93		
	US36Urinary incontinence	99	0.19	0.23	1.24	1.24		
	US39Urinary disturbance	99	1.04	0.25	1.16	1.00		
	US37Dysuria	99	3.11	0.37	1.79	2.25		
Bowel symptom	BS43Bloating	99	-0.85	0.32	1.13	1.16	0.00(0.00)	0.66(1.41)
	BS40Bowel disturbance	99	-0.42	0.33	1.15	1.12		
	BS41Fecal incontinence	99	0.64	0.40	0.67	0.64		
	BS42Fecal blood	99	0.64	0.40	0.89	0.94		
Treatment-related symptoms	TS49Maleness	98	-1.83	0.17	0.84	0.82	0.05(0.23)	0.94(3.88)
	TS48weight gain	97	-0.71	0.20	0.96	0.89		
	TS47weight loss	98	0.02	0.24	1.32	1.13		
	TS44Hot flushes	99	0.38	0.26	1.12	0.97		
	TS46Oedema	99	0.44	0.26	1.06	1.07		
	TS45Gynecomastia	99	1.69	0.39	1.02	0.73		
Sexual activity	SX50Sexual interest	98	-0.97	0.33	0.91	0.70	0.11(0.35)	0.88(2.68)
	SX51Sexually active	98	0.97	0.35	0.98	0.81		
Sexual functioning	SX53Erectile problems	49	-0.87	0.24	0.66	0.70	0.44(0.88)	0.89(2.89)
	SX52Maintaining an erection	50	-0.43	0.25	1.54	1.48		
	SX54Ejaculation problems	50	-0.14	0.26	1.04	0.96		
	SX55Uncomfortable during intimating	50	1.44	0.32	0.91	0.74		

Table A4.Using Rasch analysis with Rating scale model in touch-screen mode

Domain	Item	Count	Item difficulty	S.E.	Infit index	Outfit index	Person reliability (Separation)	Item reliability (Separation)
Urinary symptom	US32Urinate frequently at night	99	-1.42	0.20	0.74	0.74	0.75(1.73)	0.96(5.19)
	US33Urinary Urgency	99	-1.30	0.20	0.68	0.71		
	US34Nocturia	99	-1.26	0.20	0.89	0.91		
	US31Urinate frequently during the day	99	-0.77	0.21	0.85	0.86		
	US35Difficulty going out	98	0.34	0.23	0.88	0.73		
	US36Urinary incontinence	99	0.34	0.23	1.28	1.48		
	US39Urinary disturbance	99	1.30	0.25	1.22	1.51		
	US37Dysuria	99	2.77	0.32	1.94	1.76		
Bowel symptom	BS43Bloating	99	-1.07	0.32	1.18	1.17	0.00(0.00)	0.76(1.77)
	BS40Bowel disturbance	99	-0.33	0.33	1.04	1.00		
	BS41Fecal incontinence	99	0.54	0.38	0.81	0.67		
	BS42Fecal blood	99	0.86	0.41	0.88	0.91		
Treatment-related symptoms	TS49Maleness	98	-1.63	0.17	0.98	0.92	0.00(0.00)	0.92(3.47)
	TS48weight gain	98	-0.50	0.21	0.89	0.84		
	TS47weight loss	99	-0.28	0.22	1.41	1.25		
	TS44Hot flushes	99	0.15	0.24	0.91	0.95		
	TS46Oedema	99	0.80	0.30	1.17	1.04		
	TS45Gynecomastia	99	1.46	0.38	0.87	0.62		
Sexual activity	SX50Sexual interest	98	-1.34	0.31	0.91	0.84	0.29(0.65)	0.94(4.05)
	SX51Sexually active	99	1.34	0.33	0.99	0.94		
Sexual functioning	SX53Erectile problems	49	-0.54	0.23	0.54	0.54	0.30(0.65)	0.87(2.54)
	SX52Maintaining an erection	94	-0.46	0.21	1.24	1.21		
	SX54Ejaculation problems	47	-0.24	0.24	1.02	1.09		
	SX55Uncomfortable during intimating	48	1.24	0.29	1.37	1.37		

Table A5.Using Rasch analysis with Rating scale model in differential item functioning analysis

Domain	Item	paper	computer	DIF
Urinary symptom	US32Urinate frequently at night	-1.57	-1.42	-0.15
	US33Urinary Urgency	-1.15	-1.30	0.15
	US34Nocturia	-1.15	-1.26	0.11
	US31Urinate frequently during the day	-0.62	-0.77	0.15
	US35Difficulty going out	0.14	0.34	-0.20
	US36Urinary incontinence	0.19	0.34	-0.15
	US39Urinary disturbance	1.04	1.30	-0.26
	US37Dysuria	3.11	2.77	0.34
Bowel symptom	BS43Bloating	-0.85	-1.07	0.22
	BS40Bowel disturbance	-0.42	-0.33	-0.09
	BS41Fecal incontinence	0.64	0.54	0.10
	BS42Fecal blood	0.64	0.86	-0.22
Treatment-related symptoms	TS49Maleness	-1.83	-1.63	-0.20
	TS48weight gain	-0.71	-0.50	-0.21
	TS47weight loss	0.02	-0.28	0.30
	TS44Hot flushes	0.38	0.15	0.23
	TS46Oedema	0.44	0.80	-0.36
	TS45Gynecomastia	1.69	1.46	0.23
Sexual activity	SX50Sexual interest	-0.97	-1.34	0.37
	SX51Sexually active	0.97	1.34	-0.37
Sexual functioning	SX53Erectile problems	-0.87	-0.54	-0.33
	SX52Maintaining an erection	-0.43	-0.46	0.03
	SX54Ejaculation problems	-0.14	-0.24	0.10
	SX55Uncomfortable during intimating	1.44	1.24	0.20

A2. Prostate cancer-specific HRQL questionnaires

Table A6. Prostate cancer-specific HRQL questionnaires

Name	Description	Numbers of items	Domains	Validity and Reliability		
				Construct validity	Cronbach's alpha	ICC coefficient
EORTC QLQ-PR25	Official EORTC module designed to supplement the QLQ-C30 for any application in prostate cancer	25	· urinary symptoms (9 items) · bowel symptoms (4 items) · treatment-related symptoms from surgery, radiotherapy and hormonal therapy (6 items) · sexual function (6 items)			
Expanded Prostate Cancer Index Composite (EPIC)	Expanded from the PCI to enable more comprehensive assessment of outcomes from radical prostatectomy, external beam radiation, brachytherapy and hormonal treatment in men with localized disease	50	· Urinary (23 items, see note): - Function (5 items) - Bother (7 items) - Incontinence (4 items) - Irritative/ Obstructive (7 items) · Bowel (14 items): - Function (7 items) - Bother (7 items) · Sexual (13 items): - Function (9 items) - Bother (4 items) · Hormonal (11 items): - Function (5 items) - Bother (6 items) Note: function and bother, and incontinence and irritative/obstructive items are combined.	Correlations between EPIC and SF-12 subscales supported distinctness (r=0.17-0.56); moderate correlations between EPIC and FACT-P subscales (r=0.44-0.61) suggested greater overlap; strong correlation (r=0.77) as hypothesized between EPIC urinary subscale and IPSS. Sexual and hormonal domains discriminated progression-free men from those with increased prostate-specific antigen (PSA). Urinary and sexual function subscales correlated strongly with those of PCI in Japanese	0.51-0.93	0.73-0.91

				men (r =0.85, 0.93); bowel function subscale less so (r = 0.47).		
Expanded Prostate Cancer Index Composite short form (EPIC-26)	A 26-item version (EPIC-26) that had been derived by reducing the original 50-item EPIC	26	· Urinary (9 items, see note): - Bother (1 items) - Incontinence (4 items) - Irritative/ Obstructive (4 items) · Bowel (6 items): - Function (5 items) - Bother (1 items) · Sexual (6 items): - Function (5 items) - Bother (1 items) · Hormonal (5 items): - Function (5 items) Note: function and bother, and incontinence and irritative/obstructive items are combined.		> 0.7	> 0.95
International Index of Erectile Function (IIEF)		15	· Erectile function (3 items) · Orgasmic function (3 items) · Sexual desire (3 items) · Intercourse satisfaction (3 items) · Overall satisfaction (3 items)	Convergent validity was shown by comparison of patient IIEF scores with independent, blinded clinician ratings of sexual function. Finally, divergent validity was demonstrated by comparison of IIEF scores with other scale scores of marital adjustment and social desirability, which measure different constructs.	0.73 – 0.99	test – retest reliability =0.64 – 0.84
International	Five items chosen	5	· Erectile function (1 items)			

Index of Erectile Function short form (IIEF-5)	for the IIEF		· Orgasmic function (1 items) · Sexual desire (1 items) · Intercourse satisfaction (1 items) · Overall satisfaction (1 items)			
International prostate symptom score (IPSS)		8	7 symptoms: incomplete emptying, increased frequency, intermittency, urgency, weak stream, hesitancy and nocturia. The disease-specific quality of life question was phrased as follows: 'If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?'			
Functional Assessment of Cancer Therapy-Prostate (FACT-P)	Includes the FACIT core measure, the FACT-G	39	· physical wellbeing · emotional wellbeing · social/family wellbeing · functional wellbeing · urinary symptoms (3 items) · bowel symptoms (1 item) · sexual functioning (1 item) · pain and discomfort (4 items) · cachexia (2 items) · feelings of masculinity (1 item)	Discriminated men grouped by performance status, disease stage and baseline PSA; responsive to changes over treatment in performance status and PSA in a subsample with advanced hormone refractory disease.	0.65-0.69	
Prostate Cancer Quality of Life scale (PCQOL)	Developed to assess HRQL in prostate cancer patients with clinically localized	52	Assesses severity, impact on functioning and concern relating to: · urinary symptoms (14 items) · sexual symptoms (18 items) · bowel symptoms (16 items)	Discriminated groups: treatment (surgery vs radiotherapy vs watchful waiting). Subscales correlated with SF-36, PCI, Satisfaction with Life Scale,	0.70-0.90	0.59-0.92

	disease		Also includes a supplementary scale assessing anxiety over disease course and effectiveness of treatment	PANASN/P as expected.		
Prostate Cancer Specific Quality of Life Instrument (PROSQOLI)	Developed to be an outcome measure for clinical trials in symptomatic men with advanced hormone resistant prostate cancer. Includes the Present Pain Intensity item from the McGill Pain Questionnaire	10	· Pain (1 item) · Fatigue (1 item) · Appetite (1 item) · Constipation (1 item) · Physical activity (1 item) · Mood (1 item) · Family/marriage relationships (1 item) · Overall well-being (1 item) · Passing urine (1 item) · Present pain intensity (1 item)	Relative efficiency statistics for PROSQOLI vs. QLQC30 & QOLM-P14 favored the ROSQOLI for physical symptoms and physical function but the QLQ-C30 for emotional function, social function, and global perceptions; ROSQOLI pain scale most responsive. Discriminated groups: PSA, performance status, Hb levels and analgesic score; predicted survival.		
Quality of Life Module - Prostate 14 (QOLM-P14)	Developed for use with the EORTC QLQ-C30 in a trial of prednisone vs. mitoxantrone and prednisone in men with hormone resistant, metastatic prostate cancer	14	· pain impact on mobility · pain relief · drowsiness · hair loss · change in taste · urinary problems · sleep disturbance	Subscales generally correlated as hypothesised.		
UCLA Prostate Cancer Index	Designed for use with the RAND generic HRQL	20	· urinary function (5 items) · sexual function (8 items) · bowel function (4 items)	Exploratory factor analysis identified 3 factors: urinary, sexual and bowel function.	0.65-0.87	0.66-0.93

(PCI)	measures in men treated for early stage prostate cancer. A 15 item version also exists but has not been extensively validated.		· urinary bother (1 item) · sexual bother (1 item) · bowel bother (1 item)	Subscale correlations with subscales of the SF-36 were broadly as hypothesised (r=0.10-0.71); PCI and SF-26 subscales shared only 10% to 20% of variance, supporting their distinctness; the sexual function correlated with corresponding subscale on the CARES-SF (r=0.43). Neither the PCI nor other measures distinguished men grouped according to tumour grade or stage. Urinary and sexual function subscales correlated strongly with those of EPIC in Japanese men (r= 0.85, 0.93); bowel function subscale less so (r= 0.47). In English and French-speaking Canadians, subscale correlations with subscales of the SF-36 supported their hypothesized distinctness (r =0.07-0.37). The PCI tracked changes during and after prostatectomy in sexual and urinary functioning.	0.87-0.91	0.76-0.97

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UCLA Prostate Cancer Index short form (PCI-SF)	The PCI-SF was co-validated with a shortened version of the SF-12	12	· urinary function (3 items) · sexual function (3 items) · Mental health (3 items from SF-12) · Physical health (3 items from SF-12)	Combined short forms of the PCI and SF-12 accounted for 85% of full-scale variance.	0.72-0.90	0.92-0.99
Unnamed questionnaire developedby Dale et al. (1999)	Developed to assess HRQoL in men undergoing external beam radiotherapy.	35	· bowel function (12 items) · urinary function (11 items) · sexual function (9 items) Plus an item for each domain asking how bothersome it is.	Principle components factor analysis identified two subscales within each domain: BF, urgency and daily living; UF, urgency and weakness of stream; and SF, interest/satisfaction and impotence. Urinary and sexual function subscales discriminated group according to tumor stage and grade.	0.63-0.94	
Unnamed questionnaire developed by Cleary et al. (1995)	Designed to assess HRQL in men with metastatic prostate cancer undergoing surgery or hormonal treatment. Some domains were newly constructed; others were adapted from existing instruments (e.g., the SF-20)	29	· general health perceptions (1 item) · pain (4 items) · emotional well-being (5 items) · vitality (3 items) · social functioning (2 items) · physical capacity (6 items) · sexual interest (3 items) · sexual functioning (3 items) · activity limitation (1 item) · bed disability (1 item)		0.74-0.96	

A3. EORTC QLQ-C30

EORTC QLQ-C30 (version 3) 台灣中文版

我們很希望瞭解有關您和您的健康狀況。請您親自回答以下所有的問題，圈選最合適於您的答案。

答案中沒有「對」或「錯」。您所提供的資料將完全保密。

受訪者代碼：_____（由研究者依照順序編列或用姓名譯音英文縮寫）

您的生日：____年____月____日

今天的日期：____年____月____日

	完全沒有	有一點	相當多	非常多
1. 您從事一些費力的活動，如攜帶重的購物袋或手提箱，是否有困難？	1	2	3	4
2. 您從事長距離步行，是否有困難？	1	2	3	4
3. 您在戶外從事短距離步行，是否有困難？	1	2	3	4
4. 您在白天是否需要待在床上或椅子上？	1	2	3	4
5. 您進食、穿衣、洗澡或上廁所需要別人幫助嗎？	1	2	3	4

在過去一星期內（過去七天內）：	完全沒有	有一點	相當多	非常多
6. 您在從事工作或日常活動上是否受到限制？	1	2	3	4
7. 您在從事嗜好或休閒活動上是否受到限制？	1	2	3	4
8. 您呼吸會喘嗎？	1	2	3	4
9. 您曾感到疼痛嗎？	1	2	3	4
10. 您需要休息嗎？	1	2	3	4
11. 您睡眠曾有困難嗎？	1	2	3	4
12. 您曾感到虛弱嗎？	1	2	3	4
13. 您曾缺乏食慾嗎？	1	2	3	4
14. 您曾感到噁心嗎？	1	2	3	4
15. 您曾嘔吐嗎？	1	2	3	4

請接下頁

在過去一星期內（過去七天內）：	完全沒有	有一點	相當多	非常多
16. 您曾便秘嗎？	1	2	3	4
17. 您曾腹瀉嗎？	1	2	3	4
18. 您疲倦嗎？	1	2	3	4
19. 疼痛干擾您的日常活動嗎？	1	2	3	4
20. 您曾否難將注意力集中在一些事情上，如看報紙或看電視？	1	2	3	4
21. 您覺得緊張嗎？	1	2	3	4
22. 您感到憂慮嗎？	1	2	3	4
23. 您覺得容易發怒嗎？	1	2	3	4
24. 您覺得情緒低落嗎？	1	2	3	4
25. 您曾感到記憶困難嗎？	1	2	3	4
26. 您的身體狀況或醫療過程是否曾干擾您的家庭生活？	1	2	3	4
27. 您的身體狀況或醫療過程是否曾干擾您的社交活動？	1	2	3	4
28. 您的身體狀況或醫療過程是否曾造成您財務上的困難？	1	2	3	4

以下問題，請在 1 到 7 之間圈選最適合您的答案。

29. 您如何評定過去一星期內（過去七天內）您整體的健康？

1	2	3	4	5	6	7
非常差						極好

30. 您如何評定過去一星期內（過去七天內）您整體的生活品質？

1	2	3	4	5	6	7
非常差						極好

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A4. EORTC QLQ-PR25

EORTC QLQ-PR25 台灣中文版

病人有時會表示他們有下列的症狀或問題，請您指出在過去一星期內（過去七天內），您所經驗到這些症狀或問題的程度。請圈選最合適於您的答案。

在過去一星期內（過去七天內）：	完全沒有	有一點	相當多	非常多
31. 您是否曾在白天時間有頻尿現象？	1	2	3	4
32. 您是否曾在夜晚有頻尿現象？	1	2	3	4
33. 您是否因為尿急而必須趕去廁所？	1	2	3	4
34. 您是否因為晚上需要經常起來小便，而無法得到充足的睡眠？	1	2	3	4
35. 您是否曾因為需要就近上廁所，而覺得出門有困難？	1	2	3	4
36. 您是否曾有不自主漏尿的現象？	1	2	3	4
37. 您在小便時是否會疼痛？	1	2	3	4
38. 如果您穿戴尿失禁用的尿片或護墊，才須回答此題。				
穿戴尿片或護墊對您而言曾是一個問題嗎？	1	2	3	4
39. 您的日常活動曾因為排尿問題受到限制嗎？	1	2	3	4
40. 您的日常活動曾因為排便問題受到限制嗎？	1	2	3	4
41. 您曾不自主的排（漏）出大便嗎？	1	2	3	4
42. 您曾有過大便帶血嗎？	1	2	3	4
43. 您是否感到腹脹？	1	2	3	4
44. 您會有熱潮紅嗎？	1	2	3	4
45. 您曾覺得乳頭或乳房酸痛或增大嗎？	1	2	3	4
46. 您曾覺得腿部或腳踝腫脹嗎？	1	2	3	4

請接下頁

在過去四星期內...	完全沒有	有一點	相當多	非常多
47. 體重減輕對您而言曾是一個問題嗎？	1	2	3	4
48. 體重增加對您而言曾是一個問題嗎？	1	2	3	4
49. 您是否曾覺得因為您的疾病或是治療而使您較為缺乏男人味？	1	2	3	4
50. 您對「性」感到興趣的程度如何？	1	2	3	4
51. 您的性生活活躍的程度如何？(有或沒有性生活？)	1	2	3	4
如果您在過去四星期內曾有性生活，才須回答以下四題：				
52. 您覺得性生活愉快的程度如何？	1	2	3	4
53. 您在達到或維持陰莖勃起上會有困難嗎？	1	2	3	4
54. 您有射精方面的問題嗎？（例如：射精時沒有精液）	1	2	3	4
55. 您對性方面的親密接觸是否曾感到不舒服？	1	2	3	4

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A5. International Index of Erectile Function short form (IIEF-5)

簡版國際勃起功能量表(IIEF-5)

過去六個月以來，

Q1. 你對於自己能勃起，且能維持勃起狀態有多大信心?	毫無把握 0	非常低 1	低 2	中度 3	有信心 4	信心滿滿 5
Q2. 你嘗試性交時，陰莖勃起的堅硬度能讓你順利進入女性陰道嗎?	無性行為 0	幾乎或完全不可以 1	少數幾次可以 2	一半左右可以 3	多數可以 4	幾乎每次都可以 5
Q3. 性交中，未射精前你可以維持陰莖的堅硬度嗎?	無性行為 0	幾乎或完全不可以 1	少數幾次可以 2	一半左右可以 3	多數可以 4	幾乎每次都可以 5
Q4. 從性交開始到結束，你覺得維持陰莖勃起很困難嗎?	無性行為 0	極度困難 1	非常困難 2	困難 3	有點困難 4	不困難 5
Q5. 你對於自己性交時的整體表現滿意嗎?	無性行為 0	極度不滿意 1	只有少數幾次滿意 2	一半左右滿意 3	大多數滿意 4	幾乎每次都很滿意 5

A6. International prostate symptom score (IPSS)

國際前列腺症狀量表（IPSS）

過去一個月以來，

	無	5 次中有 1 次	少於一半	約一半	多於一半	幾乎每次
Q1. 排尿後仍有殘尿感？	0	1	2	3	4	5
Q2. 如廁後 2 小時內，要再去廁所？	0	1	2	3	4	5
Q3. 有排尿中斷現象？	0	1	2	3	4	5
Q4. 無法控制的尿意感？	0	1	2	3	4	5
Q5. 有尿流速變弱的現象？	0	1	2	3	4	5
Q6. 開始排尿或排尿中需用力？	0	1	2	3	4	5
	無	1 次	2 次	3 次	4 次	5 次或↑
Q7. 睡覺時需如廁的次數？	0	1	2	3	4	5

A7. Feasibility questionnaire of touch-screen version

觸控式螢幕接受度調查

1. 在螢幕上作答，您覺得操作容易嗎?

☐容易　　☐不容易

2. 在螢幕上作答，您覺得語音協助有幫助?

☐有　　☐沒有

3. 在螢幕上作答，您覺得題目容不容易看?

☐容易　　☐不容易

4. 您覺得下列哪些問題需要改善?（可複選）

☐A. 題目不容易讀懂

☐B. 題目字太小

☐C. 螢幕上內容太多

5. 整體來說，您喜歡用電腦觸控式螢幕回答問題嗎?

☐喜歡　　☐不喜歡

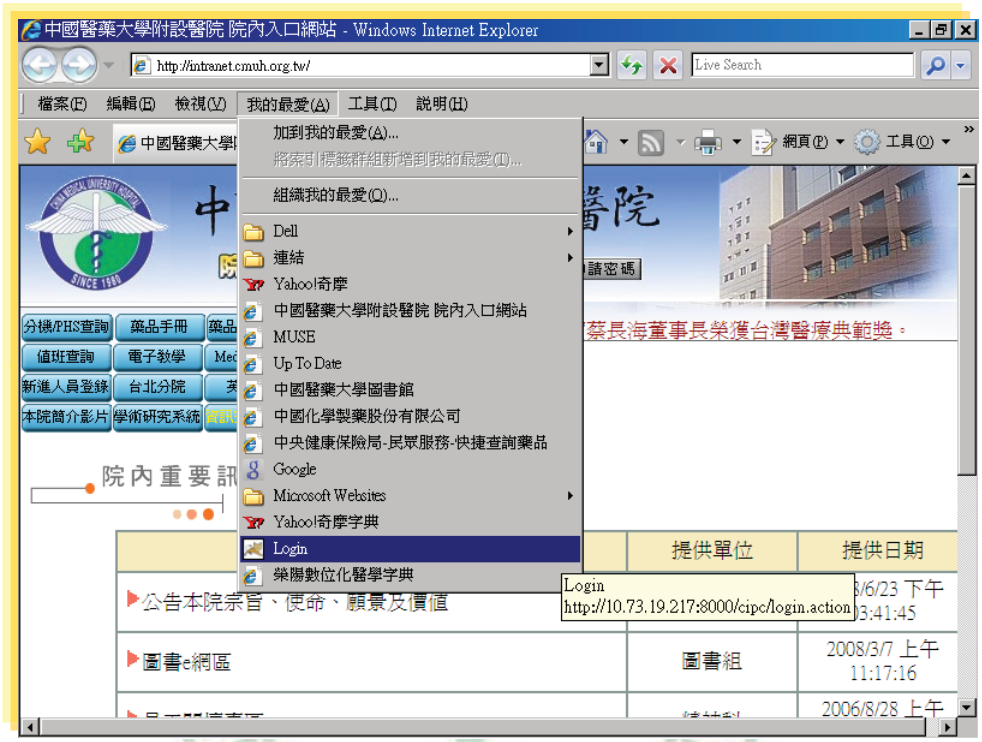
6. 您比較喜歡哪一種回答問題的方式?

☐紙本問卷　　☐電腦問卷

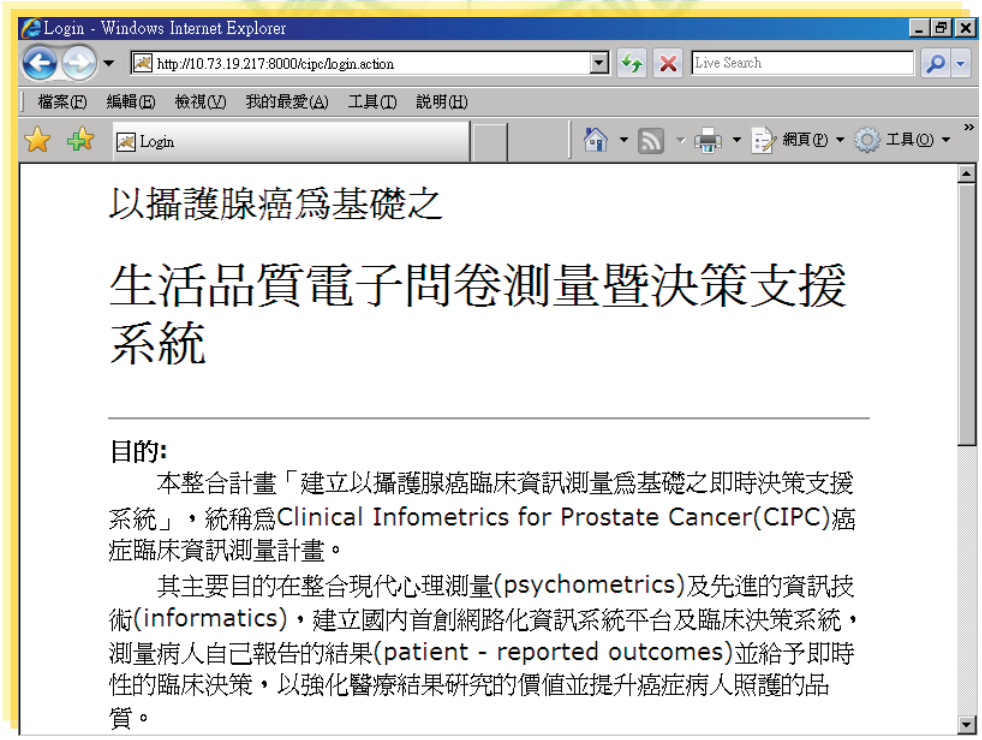
A8. Procedure of manipulate touch-screen version questionnaire

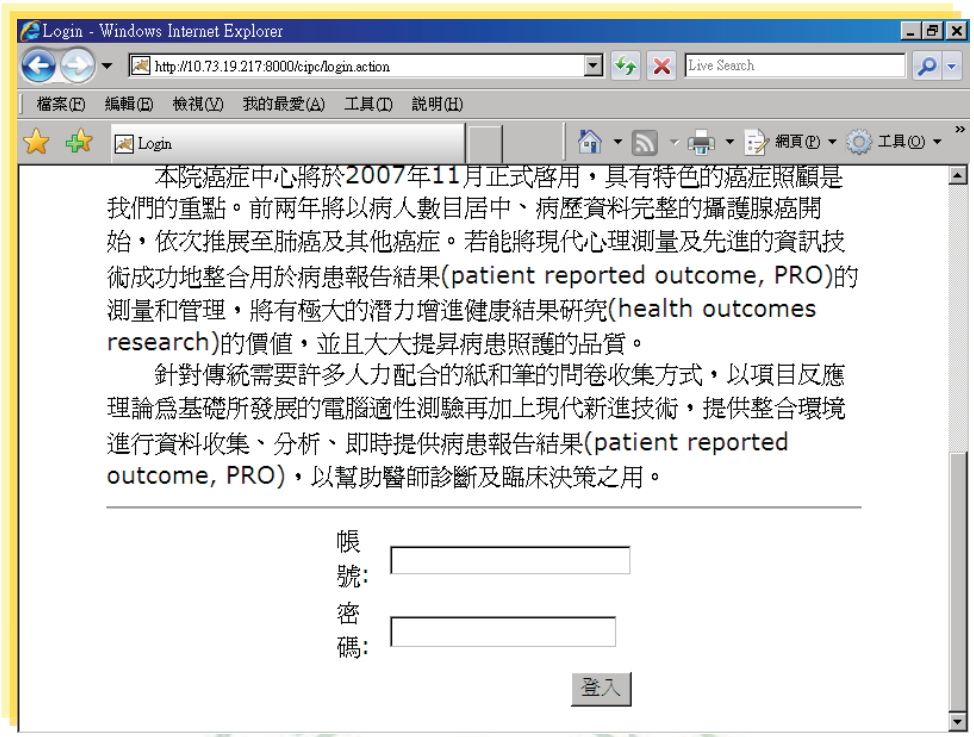
使用觸控式問卷螢幕操作流程

Step1. 開啟中國醫藥大學附設醫院院內入口網站，到「我的最愛」點選「Login」

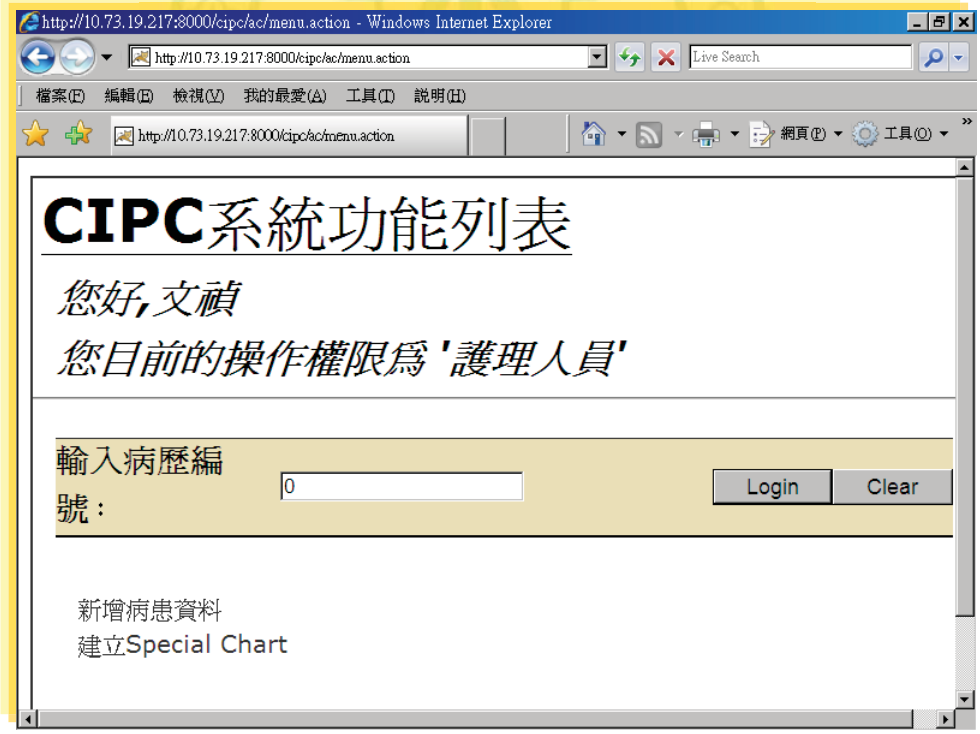


Step2. 進入「Login」，輸入帳號、密碼，登入系統。

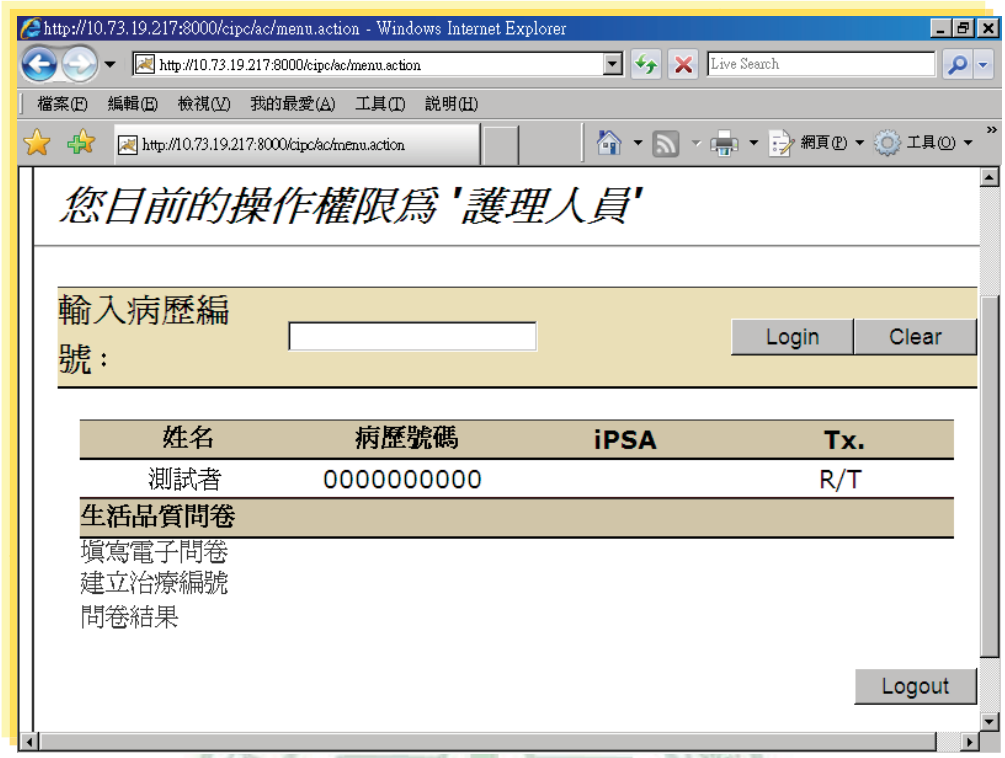




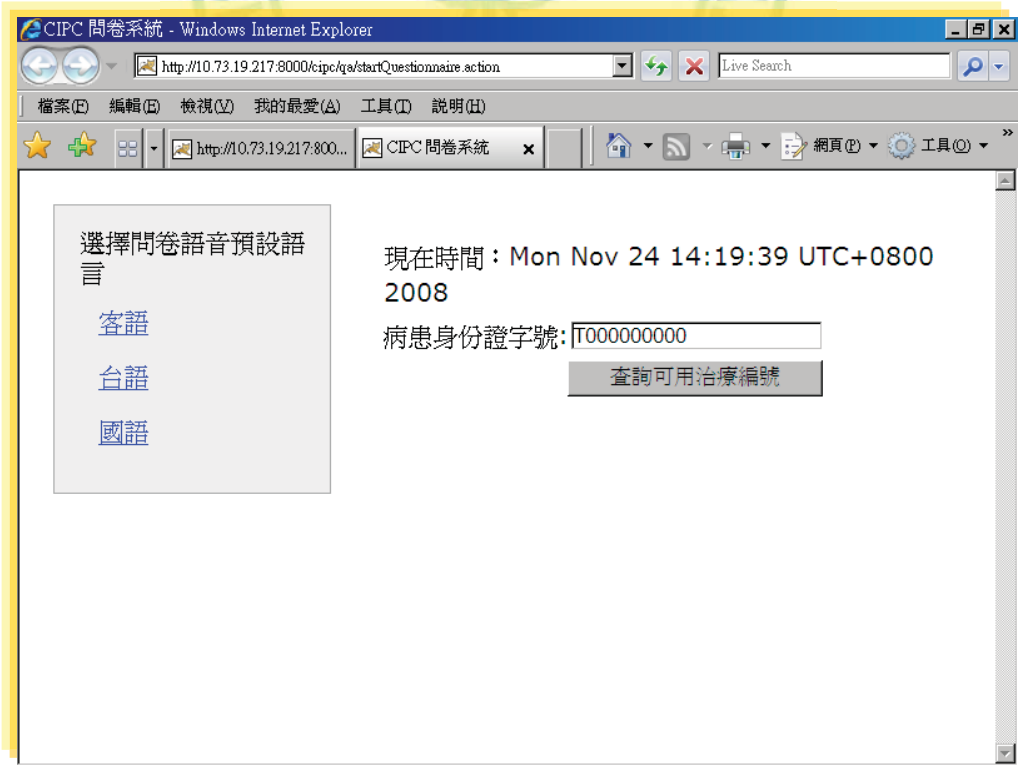
Step3. 輸入病歷編號：0，按 Login。



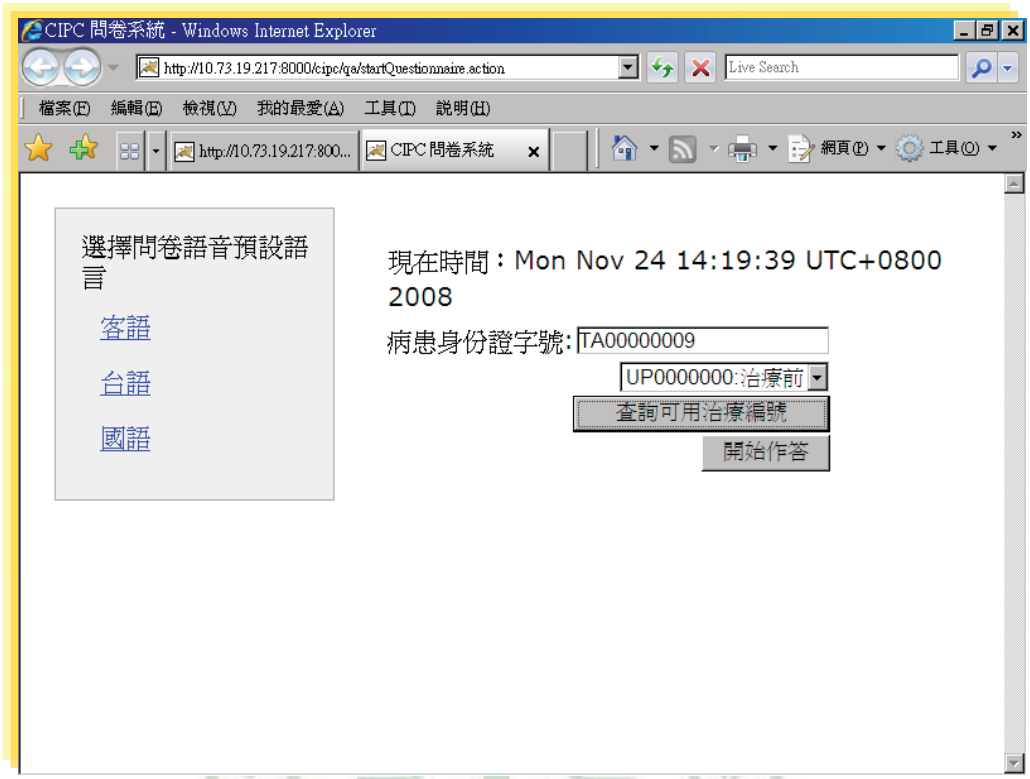
Step4. 按填寫電子問卷，Logout。



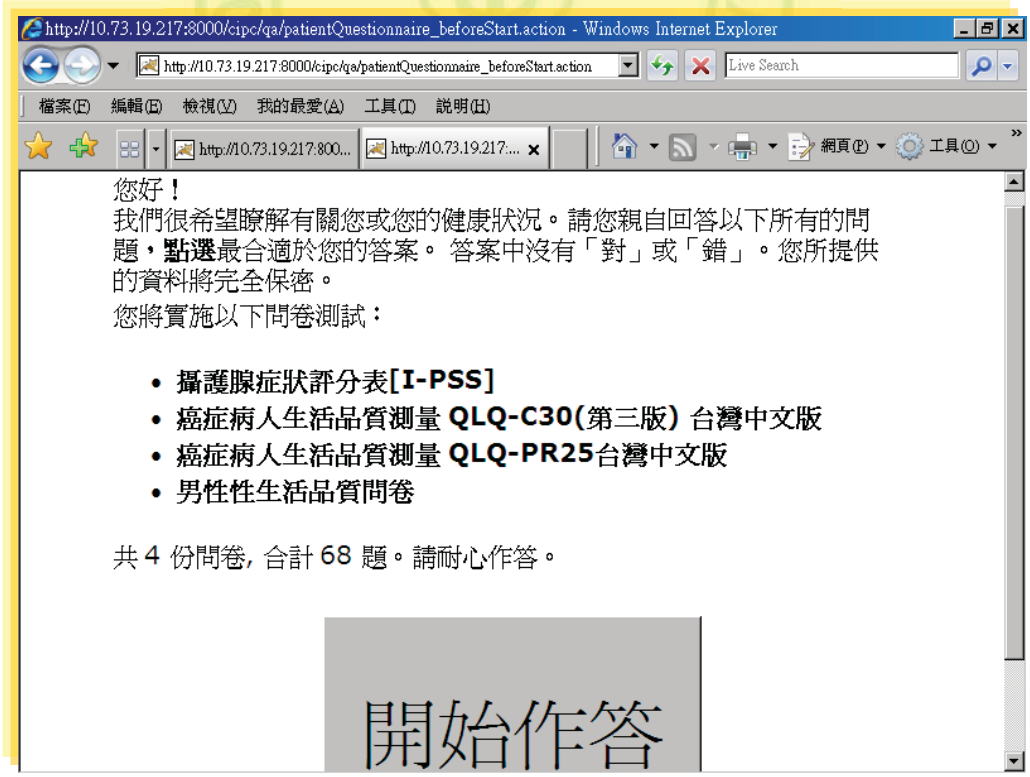
Step5. 開啟 CIPC excel 檔，確認病患編號（注意為 A 組或 B 組），將病患編號填入病患身分證字號，按查詢可用治療編號。



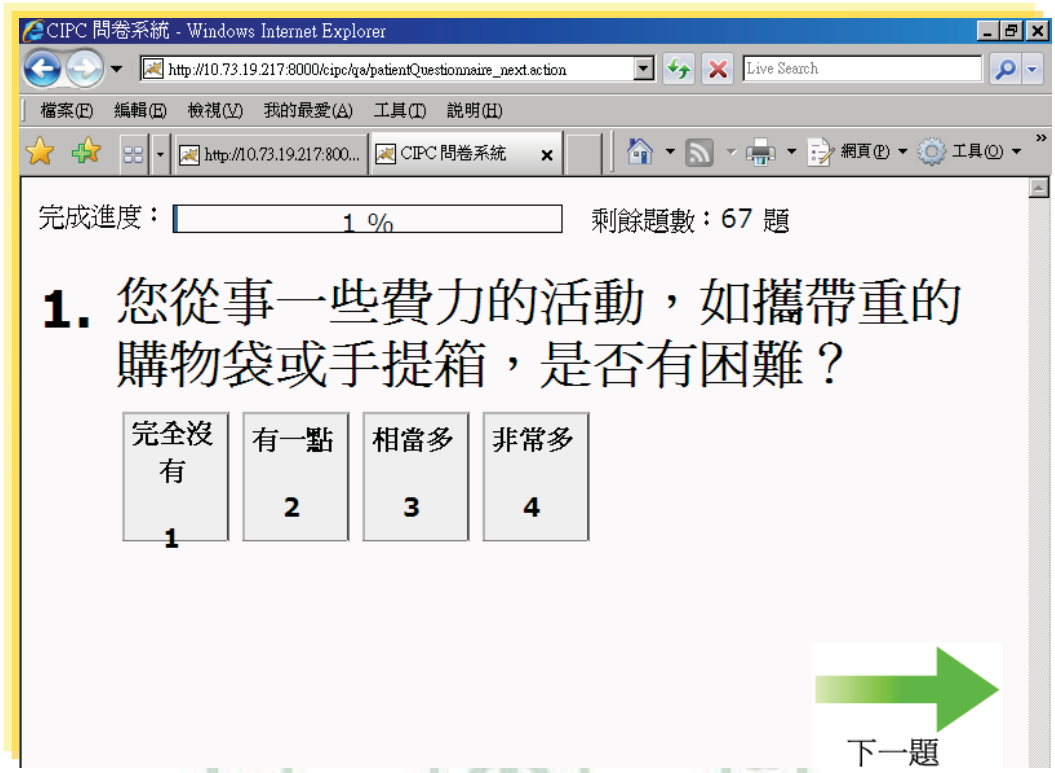
Step6. 按開始作答。

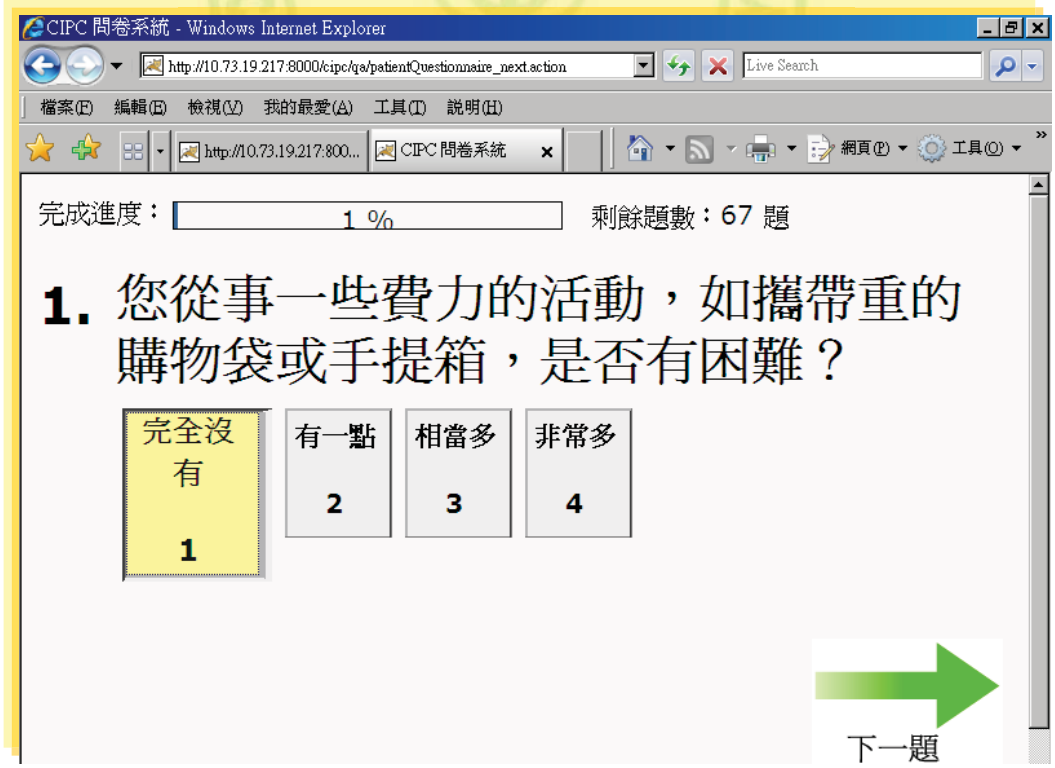


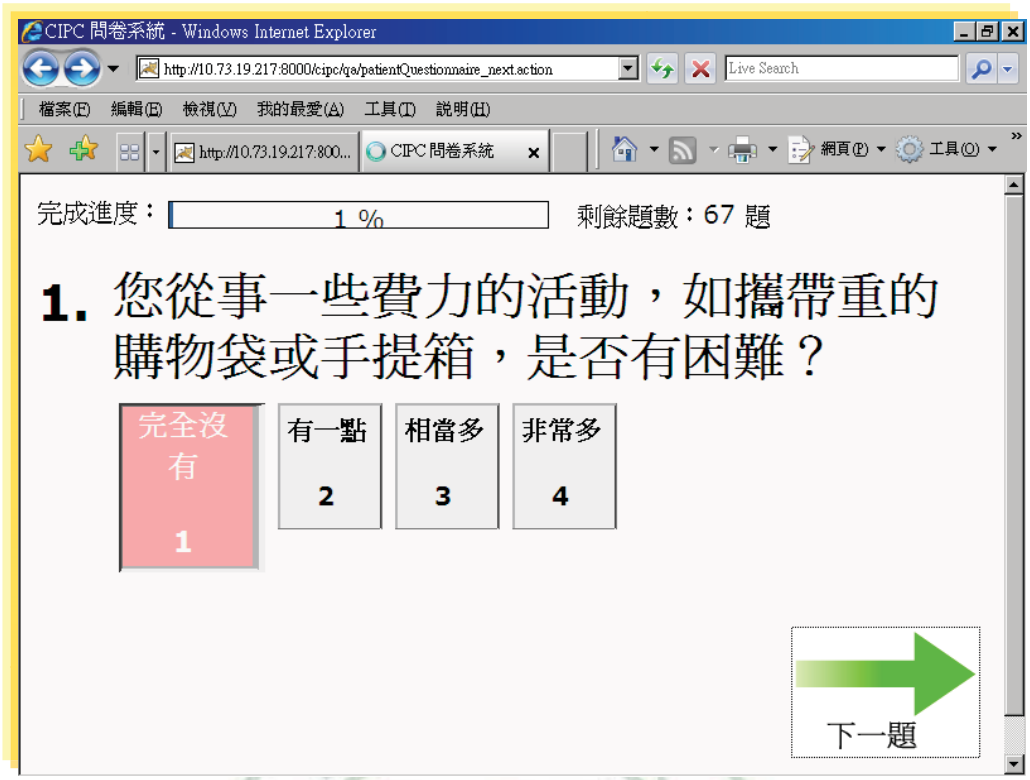
Step6. 告知與紙本問卷題目相同，四份問卷共 68 題，按開始作答。



Step7.訪員講解與示範作答方式，最上面是你完成的進度，再來是題目，回答分這四個程度別，以手指指腹輕觸電腦螢幕上之答案，待答案框框變大，即可按下一題。







Step8.完成進度 100%，結束問卷。
謝謝您耐心作答。

A9. Process of this study