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Resource Use and Cost of Treating Human Papillomavirus–Related Lesions in Japanese Women

Akiko Mizukami^{1,*}, Toshihiko Kaise, PhD², Georges Van Kriekinge³

¹Vaccines Health outcomes Department, Development and Medical Affairs Division, GSK, Tokyo, Japan; ²Health outcomes Department, Development and Medical Affairs Division, GSK, Tokyo, Japan; ³Health Economics, Vaccines Value and Health Science, GSK, Wavre, Belgium

ABSTRACT

Background: Human papillomavirus (HPV) infection is established as a necessary causal factor in several pathologies including cervical cancer (CC), which recorded over 11,000 new cases in 2011 in Japan. Nevertheless, cost burden data of human papillomavirus–related diseases in Japan are lacking. **Objectives:** To evaluate resource use and costs in women with HPV-related lesions. **Methods:** A retrospective study using insurance claims databases was performed to assess the annual medical cost for suspected cervical intra-epithelial neoplasia (CIN)/CC, genital warts (GWs), CIN (all grades), and CC. Information on the treatment of GWs was obtained from the Claims Database developed by Japan Medical Data Center Co., Ltd. Information on CIN and CC was obtained from the Evidence-Based Medicine provider database developed by Medical Data Vision Co., Ltd. Databases cover about 1% of the Japanese population. Total annual cost in Japanese yen (¥) per patient in 2011 was calculated on the basis of

resource used and unit costs from Japan medical insurance tariffs. **Results:** Average annual costs were as follows: GWs, ¥34,424; suspected CIN/CC, ¥6,240; CIN 1, ¥17,484; CIN 2, ¥46,583; CIN 3, ¥166,227; and CC, ¥474,756. **Conclusions:** To our knowledge, this is the first observational study to estimate the annual medical costs of HPV-related diseases in Japan using real-world data collected in routine clinical practice. It could provide help in estimating the economic burden of HPV-related lesions in Japanese women.

Keywords: cervical cancer, cervical epithelial neoplasia, cost, genital warts, human papillomavirus, Japan.

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Introduction

Human papillomavirus (HPV) infection is established as a necessary causal factor in cervical cancer (CC) [1] and is also the cause of cervical intra-epithelial neoplasia (CIN) and nonlethal genital warts (GWs). HPV has also been identified as an etiological agent in other cancers in women such as vulvar (43% attributable to HPV infection), vaginal (70% attributable), anal (88% attributable), and oropharyngeal (52% attributable in Japan) cancers [2]. CC is associated with a considerable global health burden, with an estimated 528,000 new cases and 266,000 deaths worldwide in 2012 [3]. In Japan, CC was the ninth leading cancer reported among women of all ages, with 11,378 cases recorded in 2011 (17.3 per 100,000 population) [4], which is high compared with a CC crude rate of between 5.2 and 13.0 per 100,000 population in other industrialized countries [3]. GWs in Japan have been reported with an incidence rate of 32.5 per 100,000 women [5], whereas a recent systematic literature review has reported on a GW incidence rate between 76 and 191 per 100,000 population [6].

Screening programs can reduce morbidity and mortality from CC by detecting precancerous lesions, that is, before they develop into cancer [7,8]. Cervical screening by cytology test has a long history in Japan where a national screening program was enacted in 1982/1983 and further expanded to include women 20 years and older to be screened every 2 years in later years, which has reduced the incidence and mortality of CC [9,10]. Nevertheless, recent estimates of the uptake of screening in Japan have been low, estimated at 24% in 2010 and at 31% in 2013 [11]. Low CC screening rates in Japan may be influenced by several factors such as not being covered by health insurance, low motivation to participate, and lack of awareness [12–14]. HPV prevalence in women with normal cytology indicates that it is the highest in women younger than 25 years (23.8%), followed by women aged 25 to 34 years (12.3%) and much lower later in life (6.4%–8.6%) [15].

A structured review of the scientific literature combining search terms related to cost of illness, health expenditures, country name (Japan), and cervical disease on May 3, 2017, identified 17 articles of which none reported on cost estimates of

Conflicts of interest: All the authors are employees of the GSK group of companies. T. Kaise holds shares in the GSK group of companies as part of his employee remuneration.

* Address correspondence to: Akiko Mizukami, Vaccines Health outcomes Department, Development and Medical Affairs Division, GSK, GSK Building 4-6-15, Sendagaya, Shibuya-ku, Tokyo 151-8566, Japan.

E-mail: akiko.mizukami@gsk.com

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cervical disease or GWs on the basis of health care consumption. Accurate costs of illness data are a customary element of economic evaluations in each disease area as well as a necessary part for future decisions on the options for HPV disease management in Japan and are a crucial component of mathematical models [16].

The objective of this study was to evaluate the average annual medical resource use and cost of treatment of CC, CIN, and GWs on the basis of observed data, as well as the total annual cost burden in Japan.

Methods

Databases

This was a retrospective study using data from two commercially available databases. Information on the treatment of GWs was obtained from the Claims Database (CDB) developed by Japan Medical Data Center Co., Ltd. (JMDC-CDB) [17]. Information on CIN and CC was obtained from the Evidence-Based Medicine (EBM) provider database developed by Medical Data Vision Co., Ltd. (MDV-EBM provider database).

JMDC-CDB is a health insurance claims database containing data (birth year, sex, type of claim and monthly claims data on disease name, medical practice, and drug prescription) on inpatient, outpatient, and pharmacy expenditure for employees and their family members in contracted health insurance societies, which can allow follow-up of patients over time for the duration over which the employee remains in the company. The database covers about 1% of the Japanese population but elderly patients aged 65 years or older are under-represented in the database because the data come from employee health insurance claims. This database was chosen as the data source for GWs because it covers clinics and hospitals and GWs are treated in both settings, and because the incidence of GWs in Japan peaks in young women (late teens to early twenties) and then decreases with age [5].

The MDV-EBM provider database is a hospital-based database containing medical accounting data (inpatient and outpatient) and diagnosis procedure combination (DPC) information (detailed inpatient information) of patients of all ages in about 120 (8%) DPC-applied hospitals, which represent approximately 4.2 million subjects. The database does not include university or national hospitals. The DPC system is a comprehensive payment system based on a medical fee point schedule of DPC on medical care for acute phase hospitalization in Japan. The MDV-EBM provider database has been shown to have the same age distribution as a large governmental patient survey [18]. The database provides data on age, consultation date, sex, inpatient/outpatient flag, disease name, and daily accounting data on medical practice and drug prescription. This database was selected for CIN and CC data because these conditions are typically treated in hospitals and because CC incidence in Japan increases between the age of 20 and 40 years and remains elevated thereafter [19].

It was assumed that the extracted data were representative of the Japanese population.

Inclusion Criteria

Inclusion criteria are presented in Table 1. Data for female patients aged 15 years or older receiving treatment for GWs between January 1 and December 31, 2011, were collected on the basis of the *International Classification of Diseases, Tenth Revision* (ICD-10) code A63.0 (anogenital [venereal] warts). An additional inclusion criterion was the eligibility period of insurance (gained before 2011 and lost after 2011).

Data for patients aged 15 years or older receiving treatment for CIN 1, CIN 2/3, or CC between January 1 and December 31,

Table 1 – Inclusion criteria.

Criterion	GWs	Suspected CIN or CC	CIN 1	CIN 2	CIN 3	CC
Data source	JMDC	MDV	MDV	MDV	MDV	MDV
ICD-10 codes	A63.0	N87.0, N87.1, N87.2, N87.9, D06, and C53.9	N87.0	N87.1	N87.2 and D06	C53
Procedures	No definition	N004: Cytology test	No definition	No definition	No definition	No definition
Diagnosis	Confirmed	Suspicious	Confirmed	Confirmed	Confirmed	Confirmed
Gender	Female	Female	Female	Female	Female	Female
Age	15 years or older	15 years or older	15 years or older	15 years or older	15 years or older	15 years or older
Treatment period	In 2011	In 2011	In 2011	In 2011	In 2011	In 2011
Diagnosed date	No definition	In 2011	In 2010 and 2011	In 2010 and 2011	In 2010 and 2011	From 2007 to 2011
Consultation department	All	OB, GYN, or OBGYN	OB, GYN, or OBGYN	OB, GYN, or OBGYN	OB, GYN, or OBGYN	OB, GYN, or OBGYN

Note. ICD-10 codes—A63.0: Anogenital (venereal) warts; C53: Malignant neoplasm of cervix uteri; C53.9: Cervix uteri, unspecified; D06: Carcinoma in situ of cervix uteri; N87.0: Mild cervical dysplasia; N87.1: Moderate cervical dysplasia; N87.2: Severe cervical dysplasia; N87.9: Dysplasia of cervix uteri, unspecified. Procedure code—N004: Cytology test. CC, cervical cancer; CIN, cervical intraepithelial neoplasia; GW, genital wart; GYN, Gynecology; JMDC, Japan Medical Data Center; MDV, Medical Data Vision; OB, Obstetrics; OBGYN: Obstetrics and gynecology.

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