H Sumery<sup>1</sup>, Hazwani ZA<sup>1</sup>, Kalsum I<sup>1</sup>, Norliza R<sup>1</sup>, Habibah O<sup>1</sup>, Noorliaza S<sup>1</sup>, N Hidayah Y<sup>1</sup>, AHA Shushami<sup>2,\*</sup>

<sup>1</sup>Pejabat Kesihatan Daerah Barat Daya, Pulau Pinang

<sup>2</sup>Jabatan Perubatan Masyarakat, Pusat Pengajian Sains Perubatan, Universiti Sains Malaysia 16150 Kubang Kerian, Kelantan

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\*Corresponding author Ahmad Hanis Bin Ahmad Shushami E-mail: ahmadhanis@moh.gov.my

# Practitioner seniority as a predictor of pap smear quality in Barat Daya District, Penang

Abstract - The quality of pap smear determined by the specimen adequacy of cervical smears. It plays an important role to detect changes in the cervix particularly the transformation zone (TZ). This study aimed to determine factors associated with poor pap smear quality in Barat Daya District, Penang. This is a cross-sectional study of 276 randomly selected specimens of woman who underwent pap smear test in all government health clinics in Barat Daya District, Penang between January until June 2019. Study proforma was based on cytological report issued by Pathology Department, Penang Hospital and staff records in Nursing Unit, Barat Daya District Health Office. 30.1% has poor smear quality. Women who are menopause are twice the risk to have poor smear guality [Adjusted OR (95% CI): 2.34(1.14, 4.84), p<0.05]. Using conventional method are also had twice the risk of having poor smear quality [Adjusted OR (95% CI): 2.32 (1.14, 4.63), p<0.05], and there were 40% increase in risk of getting poor smear with every increment of 10 years duration of service [Adjusted OR (95%CI): 1.04 (1.0,1.09), P<0.05]. There is a need for credential and privileging for staff nurses to improve smear quality since patient's menopausal status cannot be controlled. Using Liquid-based method is also recommended to improve the quality of pap smear result

*Keywords* — Papanicolaou (pap) smear, transformation zone, endocervical cell, specimen adequacy

## 1 INTRODUCTION

Cervical cancer is a type of cancer that occurs in the cells of the cervix and one of the most common malignancy in the world [1]. Worldwide, its ranked as fourth most frequent cancer in women with an estimated 570,000 new cases in 2018 [2]. Malaysia has a population of 11.55 million women ages 15 years and older who are at risk of developing cervical cancer. It ranks as the third most frequent cancer among women in Malaysia and the second most frequent cancer among women between 15 and 44 years of age [1]. Early diagnosis is proven to reduce mortality due to cervical cancer [3]. The best way to detect cervical cancer is by having regular Papanicolaou tests (pap smear). It is a method of cervical screening used to detect potentially precancerous and cancerous processes in the cervix [4]. A pap smear is performed by opening the vaginal canal with a speculum and collecting cells at the outer opening of the cervix at the transformation zone. The transformation zone is the most common place on the cervix for abnormal cells to develop. Therefore, it is important to retrieve endocervical cells from that area during pap smear [5]. An adequate pap smear should contain two groups of five endocervical cells (EC) and/or squamous metaplastic cells. Transformational zone (TZ) endocervical component was considered an indicator of specimen adequacy. Specimen

adequacy in cervical smears plays an important role to detect any changes in the cervix. Furthermore, the risk of progression to cervical cancer or pre-cancerous lesion is higher in inadequate transformation zone (TZ) component [6]. In Malaysia, pap smear is the main strategy used by Ministry of Health for the detection of precancerous state. Therefore, given the detrimental impact of the absence of endocervical cells is towards screening program, it is important to optimize the quality of this screening tools for the benefit of the public. The percentage of absent endocervical cells in cervical smears for Barat Daya district has increased, from 6.59% in 2018 to 13.05% in 1st half of 2019 [7]. Therefore, factors that contribute towards absence of endocervical cells must be studied to regain higher pap smear quality. Hence, this study was designed to investigate factors associated to poor pap smear quality in Barat Dava District, Penang.

#### 1.1 Materials and methods

This was a cross-sectional study of 276 woman who underwent pap smear test for all clinics in Barat Daya District, Penang. This study uses secondary data obtained from cytological report issued by Pathology Department, Penang Hospital and staff records in Nursing Unit, Barat Daya District Health Office, between January to June 2019. It was approved by the Medical Research & Ethics Committee (MREC), Ministry of Health

Malaysia NMRR-19-3044-50759 (IIR). Duration of the study was from July 2019 until January 2020, conducted in Klinik Kesihatan Bayan Baru, Klinik Kesihatan Bayan Lepas, Klinik Kesihatan Teluk Bahang, and Klinik Kesihatan Ibu dan Anak Air Putih, along with other selected clinics within jurisdiction of Barat Daya district. The reference population were pap smear clients from Barat Daya District, and the source population were results of women who underwent pap smear from all facilities in Barat Daya District. The inclusion criteria were pap smear results of clients taken between January to June 2019 with adequate information, and the pap smear results taken after June 2019 with inadequate information were excluded. The sample size calculation was done in accordance with the objectives, using sample size calculator and the highest number was 276 [8]. The sampling method used was proportionate random sampling. The total 276 samples were segregated proportionately among 16 health facilities in Barat Daya District. The proportion calculated, based on number of pap smear client, who are registered in the health facility as the numerator. The total number of pap smear clients in the district were taken as the denominator. Within the selected facility, cytology reports were reviewed randomly based on record number. An online proforma was designed to assist in the data collection using Google Forms. The results which labelled absent for endocervical cell and/or transformational zone, were considered poor specimen quality. The factors studied were specimen characteristics and the provider factors. The specimen characteristics were age, hormonal status, last menstrual period (LMP), contraception, treatment history, symptoms, and cervix morphology. The provider's factor studied were duration of service and duration of last credential and privileging (C&P).

# 2 RESULTS

## 2.1 Demography

In this study, most people involved were middle aged. The mean (SD) of age was 42.6 (10.4). 209 (75.7%) of study samples were still within reproductive age, and the remaining 67 (24.3%) were already menopaused. Majority were Malays (62.3%), followed by Chinese (26.1%), Indian (8.7%) and foreigner (2.9%). Majority were asymptomatic upon screening, 251 (90.9%), has no previous treatment history, 261 (94.6%) and has normal cervix, 270 (97.8%). Surprisingly, majority of women does not practice any family

planning method, 219 (79.3%). Regarding the specimen result studied, 164 (59.4%) was new case and 112 (40.6%) was recurrent. Majority of sample used Liquid Base Preparation (LBP), 206 (74.6%) (Table 1).

Table 1: Characteristic of pap smear specimen in Barat Daya	I
district (n=276)	

district (n=27	district (n=276)						
Specimen	Characteristic	Ν	(%)				
Type of Screening							
	New Case	164	(59.4)				
	Recurrent	112	(40.6)				
Type of sp	Type of specimen						
	Conventional	70	(25.4)				
Distribution	Liquid Based	206	(74.6)				
Distribution by Health							
	KD Gertak Sanggul	1	(0.4)				
	KD Kampung Perlis	4	(1.4)				
	KD Permatang Damar Laut	23	(8.3)				
	KD Permatang Pasir	5	(1.8)				
	KD Pondok Upeh	14	(5.1)				
	KD Sungai Ara	19	(6.9)				
	KD Sungai Batu	5	(1.8)				
	KD Sungai Burung	4	(1.4)				
	KD Sungai Pinang	8	(2.9)				
	KD Teluk Kumbar	16	(5.8)				
	KK Bayan Baru	52	(18.8)				
	KK Bayan Lepas	85	(30.8)				
	KK Teluk Bahang	8	(2.9)				
	KKIA Air Putih	32	(11.6)				
Race							
	Malay	172	(62.3)				
	Chinese	72	(26.1)				
	Indian	24	(8.7)				
	Foreigner	8	(2.9)				
Treatment	Gynaecological/Chemotherapy		(= .)				
	History	15	(5.4)				
	No Medical History	261	(94.6)				
Presenting Symptoms							
, p	Asymptomatic	251	(90.9)				
	Vaginal Discharge/Bleeding	25	(9.1)				
Cervix Mo	• • •		(- ·)				
	Normal	270	(97.8)				
	Abnormal	6	(2.2)				
Hormonal		-	· /				
	Reproductive Age	209	(75.7)				
	Menopause	67	(24.3)				
Contracep		-	- /				
· ··· • F	Not on Contraception	219	(79.3)				
	IUCD/Hormonal	57	(20.7)				
		01	(2011)				

With regards to the 54 personnel performing the screening, the minimum work experience for service provider was 4 years, and the maximum working experience was 31 years of service. The mean (SD) for working experience was 12 (6) years. This figure shows that majority of personnel who perform the procedures were experienced person. However, half of service provider has last undergone credentialing & privileging (C&P) program for Pap Smear in more than 3 years, 152 (55.1%) (Table 2).

**Table 1**: Characteristics of service provider (n=54)

		(	,			
Characteristic of service Provider	N	(%)	Median (IQR)			
Service Duration (Years)			11.0(8.0)			
Less than 11	142	(51.4)				
More then 11	134	(48.6)				
Duration of Last C&P (Yea		3.4 (4.9)				
Within 3 Years	124	(44.9)				
More Than 3 Years	152	(55.1)				
Table 3: Specimen quality (n=276)						
Specimen Quality		Ν	(%)			
Endocervical Cell/ Transformational Zone Absent		83	3 30.1			
Endocervical Cell/ Transformational Zone Present		19	3 (69.6)			

#### 2.2 Quality of smear

Poor smear quality defined as absent Endocervical Cell/Transformational Zone in the result studied. In this study, 30.1% has poor smear quality (Table 3).

2.22 Factors associated with poor smear quality

All factors studied were analysed using simple logistic regression. The variables that were significant in this univariable analysis were hormonal status, sample type, and service duration. Identification of independent association between the variables were analysed using multiple logistic regression. Variables with p-value of <0.25 all have clinical significance were selected. Forward and backward LR was applied and for final enter method, variables that was included were also hormonal status, sample type, and service duration. There was no interaction found among the three variables and the model was fit.

In multivariable analysis, women who are

Menopause are twice the risk to have inadequate smear, [Adjusted OR (95% CI): 2.67(1.33, 5.35), P<0.05]. This study also found that the method used, using conventional method are also had twice the risk of having poor smear quality [Adjusted OR (95% CI): 2.08 (1.14, 4.63), P<0.05]. Regarding the provider factor, there were 40% increase in risk of getting poor smear with every increment of 10 years duration of service [Adjusted OR (95%CI): 1.04 (1.0,1.09), P<0.05]. The results for simple and multiple logistic regression were summarised in Table 4.

Table 4: Factors associated with poor smear quality (n=276)

Variables	Crude ORª	95% Clª		<i>Аd</i> . В <sup>ь</sup>	<i>Ad</i> . OR⁵	95% Cl <sup>ь</sup>
Hormonal						
Status Repro						
-ductive						
Age	1.00					
Meno		(1.09				(1.33
-pause	2.14	,4.17)	*	0.98	2.67	,5.35)
<b>Symptoms</b> Vaginal Discharge						
/Bleeding	1.00					
Asymp		(0.45				
-tomatic	1.14	,2.83)				
Contraception IUCD						
/Hormonal	1.00	(2.2.2				
No Contra	1.59	(0.86)				
-ception Treatment	1.59	,2.92)				
History						
No						
History	1.00					
Gynaeco		(0.53				
-logical/ Chemo	1.56	,4.54)				
-therapy						
History						
Sample						
Type						
Liquid Base	1.00					
Conven	1.00	(0.97				(1.07
-tional	1.85	,3.50)	*	0.73	2.08	,4.04)
Credential &		,0.00)		0.1.0	2.00	,,
Privileging						
Within						
3 Years	1.00					
<b>Oth</b>		(0.66				
Others	1.11	,1.86)				
Service		(1.00				(1.00
Duration	1.044	,1.08)	*	0.04	1.04	.1.09)
			h.			
Note. a: Simple Logistic Regression, b: Multiple Logistic Regression						

\*: P-value<0.05, CI: Confidence Interval, Adj.: Adjusted

#### 3 DISCUSSION

Thirty percent of this study samples have poor smear quality, and almost seventy percent has good quality smear. This figure is almost similar in few studies in Malaysia and other parts of the world. In another study done in Kelantan, Malaysia 63.5% of the specimens taken were considered good quality [10] and from a study done in North Carolina, USA involving 56,475 samples, 68.5% were reported as good quality [11]. This indicate that the quality of pap smears in this district are still within acceptable range. This study found that the factors associated with poor smear quality are being menopause, using conventional method and duration of service. Evidence showed that for postmenopausal women, satisfactory samples were difficult to get due to conditions such as atrophy, physiological retraction of transformation zone and cervical stenosis [13]. They are also the least likely to be screened [15]. This is supported by findings from few other studies, reported that smears taken from postmenopausal women are more likely to be inadequate [9,13].

Liquid-based cytology has been compared with conventional cytology in many studies; most report a higher proportion of slides that are adequate for assessment [11,12]. This also corresponds to this study's finding, where using conventional method has almost double the risk of aetting poor quality smears, compared with liquid type. Smear taking is a clinical skill that needs to be acquired with experience. However, findings from this study found that smear-taker who works longer prone to get poor smear quality. Interestingly this finding also like another similar study in Kelantan, Malaysia [16]. This could be the impact of lack of training, demonstrated by this study's sample where more than half had training more than three years. This shows that experience and dedication is important, but training were equally important in achieving a good smear [14].

#### 4 CONCLUSION

Quality of pap smear is important for cervical screening, ensuring the high sensitivity of the screening program. Even though the quality of pap smear in Barat Daya District is good, this issue still needs to be addressed to avoid false-negative pap smear result which may cause failure in detection of any changes in the cervical particularly the transformation zone and led to increasing healthcare cost. Currently, the method used for pap smear are slowly shifted to liquid-based type, and menopaused women still need to be screened and must be encouraged to have pap smear.

## 5 RECOMMENDATION

There is a need for better education and practice among staff nurses to improve pap smear quality in the district. Currently, the credentialing and privileging (C&P) system that has been implemented in the district does not require nurses to renew the existing credentialing. Therefore, it is recommended that every nurse to recredential every three years. This includes one day training for sample takers which comprises theoretical learning followed by a period of practical training. This process requires key documents including cytology laboratory statistics, self-assessment tools and manager feedback, which are reviewed by supervising officer.

#### REFERENCES

- [1] Bruni L, Albero G, Serrano B, Mena M, Gómez D, Muñoz J, Bosch FX, de Sanjosé S. ICO/IARC Information Centre on HPV and Cancer (HPV Information Centre). Human Papillomavirus and Related Diseases in Malaysia. Summary Report 17 June 2019. [21/1/2020]
- [2] Ferlay J, Ervik M, Lam F, Colombet M, Mery L, Piñeros M, Znaor A, Soerjomataram I, Bray F (2018). Global Cancer Observatory: Cancer Today. Lyon, France: International Agency for Research on Cancer. Available from: <u>https://gco.iarc.fr/today</u>
- [3] Wright Jr, T. C., Stoler, M. H., Behrens, C. M., Sharma, A., Sharma, K. & Apple, R. (2014). Interlaboratory variation in the performance of liquidbased cytology: Insights from the ATHENA trial. *International Journal of Cancer*, **134(8)**, 1835-1843. doi: 10.1002/ijc.28514
- Pap Smear (Pap Test): Reasons, Procedure & Results. Retrieved from: https://www.healthline.com
   health > pap-smear (Accessed: 19/9/2019)
- [5] Elumir-Tanner, Lizette et al. "Management of Papanicolaou test results that lack endocervical cells." CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne vol. 183,5 (2011): 563-8. doi:10.1503/cmaj.101156
- [6] Zhao, L., Wentzensen, N., Zhang, R.R. (2014). Factors associated with reduced accuracy in Papanicolaou tests for patients with invasive cervical cancer. *Cancer Cytopathol*, 122, 694-701
- [7] Pejabat Kesihatan Daerah Barat Daya (2019).
   Laporan Kejururawatan, Kementerian Kesihatan Malaysia
- [8] Najib, M. (2015). Sample Size Calculator for Estimation of a Single Proportion, Unit of Biostatistics & Research Methodology, School of Medical Sciences, Universiti Sains Malaysia Kubang Kerian Kelantan.
- [9] Mohamed A.M., Paul G.C., Desmond P.B., et. al. (2001). Cervical intraepithelial neoplasia in postmenopausal women: difficulties in cytology,

colposcopy and treatment. The Obstetrician & Gynaecologist, 3(1),8-1

- [10] Noor, N.M. and Sultan, H.M., 2008. Pap Smear Screening in Bachok, Kelantan from January to June 2005. International Medical Journal, 15(3).
- [11] Davey, E., Barratt, A., Irwig, L., Chan, S.F., Macaskill, P., Mannes, P. and Saville, A.M., 2006. Effect of study design and quality on unsatisfactory rates, cytology classifications, and accuracy in liquidbased versus conventional cervical cytology: a systematic review. The Lancet, 367(9505), pp.122-132.
- [12] Castle, P.E., Bulten, J., Confortini, M., Klinkhamer, P., Pellegrini, A., Siebers, A.G., Ronco, G. and Arbyn, M., 2010. Age-specific patterns of unsatisfactory results for conventional Pap smears and liquid-based cytology: data from two randomised clinical trials. BJOG: An International Journal of Obstetrics & Gynaecology, 117(9), pp.1067-1073.
- [13] Demir B, Haberal A, Ozturkoğlu E, Dündar B, Baskan B, Sobacı E, Özgül N. Pap smear screening among the postmenopausal women. Gynecology Obstetrics & Reproductive Medicine. 2010 Dec 11;16(3):168-72.
- [14] Lundberg G.D. (1989b). Quality assurance in cervical cytology. The Papanicolaou smear. *JAMA*, 262, 1672-1679.
- [15] Srikanth J, Upadhya KG, Kumar P. Awareness of cervical and breast cancer among women attending OBG out-patient department of a medical college hospital, Bangalore. Int J Community Med Public Health. 2018 May;5:2104-8.
- [16] Ja'afar SM, Awang H, Ibrahim RMR, Yasin Z, Dollah Z. Absence of Endocervical/Transformation Zone Component in Cervical Papanicolaou Smears in Northeastern Region of Peninsular Malaysia: Prevalence and Risk Factors. International Journal of Human and Health Sciences (IJHHS). 2020;4(3):178-8

[20] 5