Original Article

Efficiency of the Cancer Care Program's Checklist in Chulabhorn Royal Academy

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Background: The Biorepository Unit was initially established for the storage of specimens from various departments for the main purpose of biomedical research. However, several problems occurred during the management of specimens. Hence, the authors developed the Cancer Care Program's checklist for the standardization of specimen collection.

Objective: To analyze the efficiency of Cancer Care Program's checklist.

Materials and Methods: Data of 370 participants were collected in the Cancer Care Program. Fisher's Exact and Mann-Whitney U Test were applied to analyze data and processing time of specimen collection, respectively.

Results: We obtained higher numbers of informed consent and blood from participants after implementation of the checklist compared with specimen management without the checklist, with a 95% confidence interval. Additionally, the processing time of blood and colorectal tissue collection significantly improved, while other tissues showed no difference after checklist implementation.

Conclusion: This is a preliminary study of checklist development for tissue sample management. After implementation of this checklist, we confirmed a higher number of informed consents and blood collection, with lower processing time of blood and colorectal tissue collection. Nonetheless, further study with more sample sizes is recommended to verify the more efficacy of tissue sample management.

Keywords: Checklist, Cancer care program, Biorepository unit, Chulabhorn royal academy

J Med Assoc Thai 2021;104(Suppl2): S74-8
Website: http://www.jmatonline.com

The Biorepository Unit, HRH Princess Chulabhorn College of Medical Science, Chulabhorn Royal Academy was initially established for the storage of specimens for biomedical research to improve our knowledge and develop new strategies for better prognosis, diagnosis, and treatment for patients[1-4]. We developed the Cancer Care Program to collect and preserve tissues, such as blood, urine and solid tissue, from cancer patients. However, several problems occurred during the management of specimens, such as the loss of participant's information and specimens, lack of standards for specimen collection and processing, low quality of specimens, non-efficient coordination among units and confusion in tissue collection process. To address these issues, the Cancer Care Program's checklist for the standardization of specimen collection was developed[5-7]. However, the efficacy of specimen collection after application of the checklist has never been investigated. Therefore, here we aimed to evaluate the efficiency of the Cancer Care Program's checklist for patients and sample processing from 11th January 2010 to 30th June 2015.

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How to cite this article:

Thitiwanichpiwong P, Sonthi N, Yimyaem M. Efficiency of the Cancer Care Program's Checklist in Chulabhorn Royal Academy. J Med Assoc Thai 2021;104 (Suppl2): S74-8.

doi.org/10.35755/jmedassocthai.2021.S02.12560

Materials and Methods

Ethical approval

This research was approved by the Human Research Ethics Committee, Chulabhorn Research Institute, Bangkok, Thailand (EC No. 020/2558).

Checklist procedure

The checklist in the present study was designed based on the guidelines for biobank management and approved by the Biorepository committee of Chulabhorn Royal Academy. This checklist is designed to provide appropriate guidelines for all units involved in the specimen collection process. The process of specimen management with the checklist is described in Figure 1 and 2[5-7]. In brief, physicians requested informed consent from patients at the Outpatient Department (OPD) or Inpatient Department (IPD). The informed consent form consisted of patient's information, purpose of collection and type, volume and size of sample. Donor information was kept as anonymous[3,4,8-11]. Nurses collected urine and blood from donors at IPD wards and the Operating Room (OR), respectively. After solid tissues

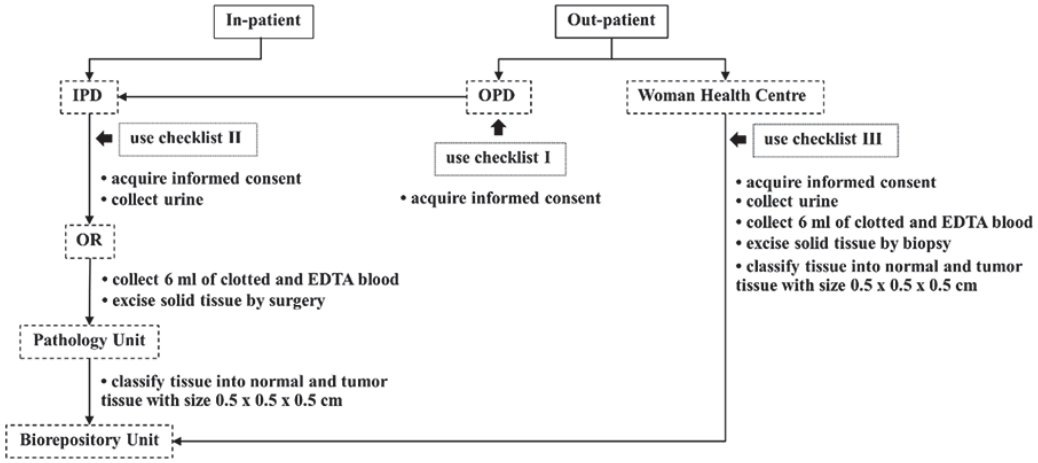

Figure 1. Workflow of specimen collection in the Cancer Care Program (during office hours).

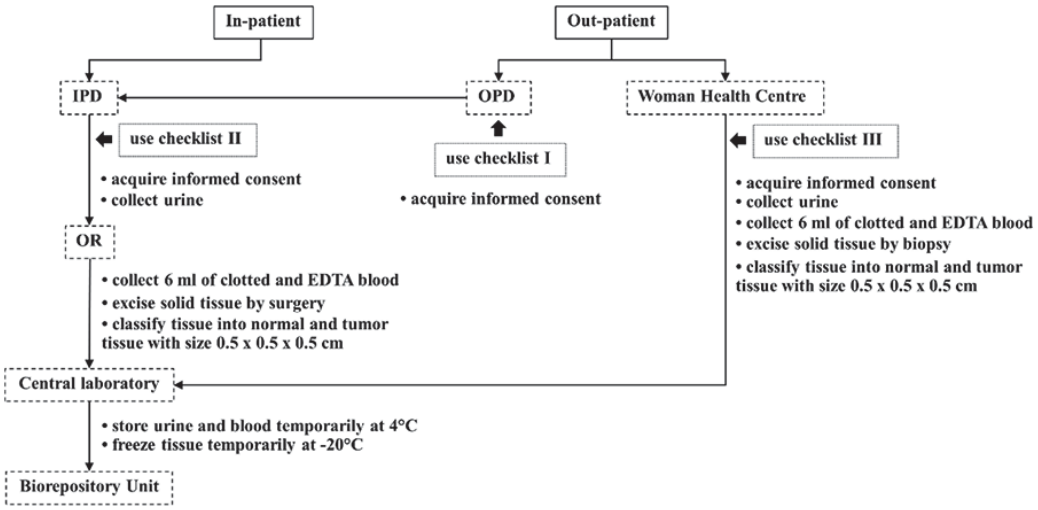

Figure 2. Workflow of specimen collection in the Cancer Care Program (after office hours).

were excised for diagnosis by the surgeon, the fresh tissues were transferred to the Pathology Unit. The pathologist classified tissues into normal and tumor tissues by aseptic technique. All specimens (urine, blood, normal and tumor tissues) were rapidly transferred to the Biorepository Unit for storage (Figure 1). However, some operations may be completed after office hours, with tissue classification by surgeon into normal and tumor tissues. Finally, all specimens were successfully transferred to the Central Laboratory before being forwarded to Biorepository Unit in office hours (Figure 2).

Specimen collection

Each specimen was processed according to the standard procedure that depends on the type of specimen. The reagents and disposable equipment used in the present study, as well as the processes of specimen collection, are described in the following sections.

Urine processing

The authors collected urine in sterile plastic containers with a wide mouth, leak-proof cap and 100 ml capacity. Samples were aliquoted into 1.8 ml labeled cryovials

(Thermo Fisher Scientific, Roskilde, Denmark) and stored at -80°C. This process was completed within 48 h after sample collection[12].

Blood processing

Clotted and EDTA-treated blood were centrifuged (Beckman Coulter, IN, USA) at 2,500 rpm for 10 min at 4°C. Serum, plasma and buffy coat were aliquoted into 1.8 ml labeled cryovials and stored at -80°C. This process was completed within 2 h after sample collection[7,12].

Solid tissue processing

Solid tissues were classified as either normal or tumor tissue. The tissues were excised with a size 0.5×0.5×0.5 cm. The tissues were collected in labeled cryomold (Sakura Finetek, Tokyo, Japan) with Optimal Cutting Temperature compound (Sakura Finetek) and cryovials. Tissues were stored in -80°C. This process was completed within 2 h after sample collection[5-7,12,13].

Data sources

The present study included 370 participants who were registered in the Cancer Care Program of Biorepository Unit, HRH Princess Chulabhorn College of Medical Science, Chulabhorn Royal Academy between January 11th, 2010 and June 30th, 2015. The authors divided the patient information sets into two parts according to implementation of the checklist: the first set of information was before checklist usage (between January 11th, 2010 and March 5th, 2014) and the second set was after the checklist (between March 6th, 2014 and June 30th, 2015). The information examined in the present study included informed consent and collection of specimens (blood, urine and solid tissue), as well as processing time of specimen collection before and after checklist implementation.

Statistical analysis

Statistical analysis was performed by STATA/SE version 12.1 (StataCorp, USA). The number of patients with informed consent and specimen collection before and after checklist implementation were analyzed by Fisher's Exact Test. The processing time of specimen collection before and after checklist implementation were analyzed by Fisher's Exact and Mann-Whitney U Test. A p-value less than 0.05 was considered statistically significant.

Results

Specimen information

This study included 370 participants who were registered at our institution between January 2010 and June 2015. Urine, blood and solid tissue samples of each participant were collected depending on the type of cancer in each participant (Table 1). However, for the ovary, endometrium, uterus tissue, and retroperitoneal mass specimens, we did not obtain adequate information about consent and specimen collection before the checklist; we also did not obtain information on the number of small bowel tissue after the checklist. Therefore, the analysis of these tissues was excluded.

Table 1. Type and number of specimens collected in the Cancer Care Program

Type of specimen	Number of specimens
Urine	154
Blood	331
Colorectal tissue	140
Liver tissue	82
Cervix tissue	41
Lung tissue	14
Ovary tissue	2
Endometrium tissue	1
Uterus tissue	1
Retroperitoneal mass	1
Small bowel tissue	1

Informed consent and specimen collection

We analyzed the differences in these data using Fisher's exact test. The percentage of informed consent and blood collection increased significantly after using the checklist at 95% confidence interval; however, the solid tissue collection showed no difference before or after checklist implementation (Table 2).

Processing time of specimen collection

Comparison of these percentages using Fisher's exact and Mann-Whitney U test showed that the number of blood and colorectal tissue samples with a processing time of no more than 120 min increased significantly after using the checklist at 95% confidence interval, while the processing time of other tissues showed no difference (Table 3).

Discussion

The number of participants who provided informed consent and number of blood collections increased significantly after using the checklist at 95% confidence interval; in contrast, the amount of solid tissue collection did not differ with or without the checklist. When applying the power of test in the solid tissue sample group, the number of less than 0.8 suggested that a higher amount of participants may be required for analyses (Table 2).

Before using the checklist, the management of blood and solid tissues from colorectal, liver, cervix and lung cancer groups required a great deal of time. After development of the checklist, the processing time for the manipulation of blood and solid tissues from the colorectal group was significantly reduced, whereas there was no different time in processing of tissues from the liver, cervix and lung cancer groups. When applying the power of test in liver, cervix and lung tissue sample groups, the number of less than 0.8

Table 2. Specimen collection characteristics before and after checklist usage

Characteristics	Checklist usage				p-value	Power
	No (n=x)		Yes (n=x)			
	n	%	n	%		
Informed consent (all specimens)						
Yes	54	24.5	148	98.0	<0.001	1.000
No	166	75.5	3	2.0		
Blood collection						
Yes	185	84.1	146	97.3	<0.001	0.987
No	35	15.9	4	2.7		
Colorectal tissue collection						
Yes	95	77.9	45	86.5	0.216	0.176
No	27	22.1	7	13.5		
Liver tissue collection						
Yes	59	77.6	23	62.2	0.115	0.328
No	17	22.4	14	37.8		
Cervix tissue collection						
Yes	6	75.0	35	63.6	0.702	0.031
No	2	25.0	20	36.4		
Lung tissue collection						
Yes	10	100.0	4	66.7	0.125	0.242
No	0	0.0	2	33.3		

suggested that a higher number of participants is crucial for analyses (Table 3).

Although we obtained information before and after checklist usage for most specimens, the analysis of data from ovary, endometrium, uterus, retroperitoneal mass and small bowel tissues was not possible due to inadequate data before or after the checklist. Additionally, urine was collected after using the checklist, and thus we could not analyze data from urine.

Conclusion

The Cancer Care Program's checklist was developed for the management of specimens from participants, such as urine, blood and solid tissues. This checklist allows us to obtain informed consent and participant's data, as well as calculate the processing time in sample collection. This checklist is the first step to improve the management of clinical specimens for quality and quantity standards. However, some groups showed no difference in the duration of collection and amount of specimens before and after the checklist application, which may result from an insufficient amount of specimens. Improvement of the checklist with a longer study duration may allow for acquiring reliable data to develop a standard protocol for specimen management to be applied by other units or institutions.

What is already known on this topic?

Previous studies have shown that protocols for specimen collection, processing, and storage can be the best practice for quality improvement of samples such as urine, serum, plasma, buffy coat and solid tissue in a biorepository[5-7,12,13].

What this study adds?

We developed the Cancer Care Program's checklist based on the standardization for sample collection from other tissue banks. Here we analyzed the efficacy of our checklist at Chulabhorn Royal Academy. After implementation of the checklist, we observed a higher number of informed consent and blood collection, with shorter processing time for blood and colorectal tissue collection.

Acknowledgements

This research was supported by Chulabhorn Royal Academy.

Potential conflicts of interest

The authors declare no conflict of interest.

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Table 3. Processing time of specimen management before and after checklist usage

Processing time of specimen collection (min)	Checklist usage				p-value	Power
	No (n=x)		Yes (n=x)			
	n	%	n	%		
Blood						
≤120	96	55.2	137	93.8	<0.001	1.000
>120	78	44.8	9	6.2		
Median (range)	105.5 (28 to 5,698)		53 (18 to 5,721)		<0.001	
Colorectal tissue						
≤120	23	25.6	23	51.1	0.004	0.784
>120	67	74.4	22	48.9		
Median (range)	154.5 (35 to 4,890)		115 (23 to 3,902)		<0.001	
Liver tissue						
≤120	8	50.0	11	47.8	1.000	0.038
>120	8	50.0	12	52.2		
Median (range)	115.5 (15 to 3468)		121 (42 to 3,723)		0.416	
Cervix tissue						
≤120	6	100.0	31	88.6	1.000	0.000
>120	0	0.0	4	11.4		
Median (range)	60 (26 to 95)		55 (18 to 1,386)		0.782	
Lung tissue						
≤120	0	0.0	3	75.0	0.400	0.000
>120	1	100.0	1	25.0		
Median (range)	3,853		93 (40 to 3,837)		0.157	

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