

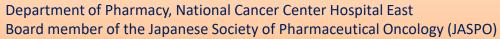




Evolution of oral anticancer agents management in Japan



Shinya Suzuki, RPh, PhD



30, January 2022

Conflict of Interest disclosure slide

Research fund	□scientific research fund □contract □do □other () ☑ N/A	nation		Sponsor	n/a
Name of lead presenter	Shinya Suzuki			Institution or company/position	National Cancer Center Hospital East / Chief Pharmacist
		No	If yes, please sp	pecify the name of company and/	or organization, your status.
employee of company and	or profit-making organization	M			
adviser of company and/or	r profit-making organization	M			
profit of stock		М			
lecturer fees		М			
manuscript fees		M			
Contributions		М			
research expenses		M			
fees of testimony, judgme	ent, comment, etc.	М			
representative of organiza expenses from company	tion for clinical study receiving research	М			
presents or any payment		М			

30 June to 2 July 2022



I came from far east Japan to see you face to face in real life!!!





- Overseas travel is still difficult in Japan.
 - It took about one month to get permission from my hospital.
- Limited number of international flight: so far, No Lufthansa from Japan!!!
 - EXPENSIVE flight fee...
 - Cancel flight Frequently occurs...
 - Alaska and Arctic route... long flight...
- Missing/delaying suitcases...
 European Conference of Onco





Gratitude messages from JASPO's presidents



"Let's continue to work together to ensure that many cancer patients continue to receive excellent treatment. I look forward to seeing you in Japan."

- Kazushi Endo (2011-2018 president)

"Approximately 5,000 members work in hospitals, pharmacies, companies, and universities, and are engaged in the pharmaceutical care of cancer patients, collaborating with each other on a daily basis. We hope that our mutual exchange of ideas will lead to the happiness of tomorrow's cancer patients. I pray that the relationship between ESOP and JASPO will deepen further in the future."

Hiroyoshi Kato (2018-2021 president)





"JASPO's one of the main activities is "collaboration and exchange with domestic and international organizations related to cancer pharmacotherapy". We look forward to continuing to work together as a good partner."

Naoki Kondo (current president)



30 June to 2 July 2022

ESOP/JASPO symposium in the JASPO2022





30 June to 2 July 2022

European Conference of Oncology Pharmacy



We have common issues, so Japanese always have learned many from Europe and US.



"Oral anticancer agents management" in Japan **Problems**

- · Shift from inpatient (hospital) care to outpatient care/community healthcare
 - Unfortunately, community pharmacists are not playing a sufficient role in community healthcare
- Difficult to manage adverse drug reactions that occur at home
 - Difficult to determine what to do when side effects occur
 - Majority of patients are elderly
- Simply..., "New drugs are difficult!!!"
 - (even pharmacists do not understand them)
 - Various molecular targeted drugs

30 June to 2 July 2022

about the JASPO 10 years anniversary celebration

Newspaper

Hey, do you know newly marketed oral anticancer drug "Selpercatinib"?

???? I don't know... I cannot even pronounce it!!!



Community Pharmacist





Pharmacists working for the Japanese government



"Oral anticancer agents management" in Japan Problems & Measures

- Shift from inpatient (hospital) care to outpatient care/community healthcare
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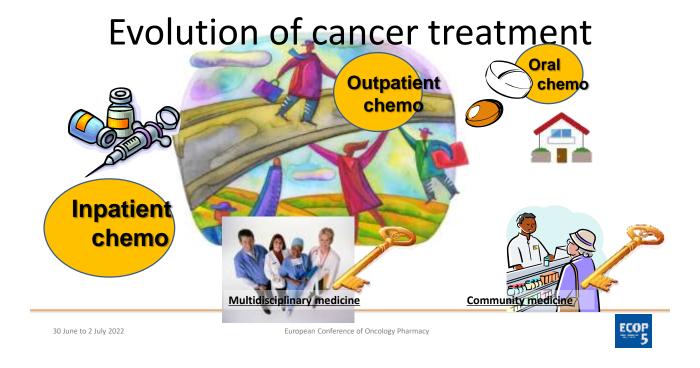
"Oral anticancer agents management" in Japan Problems & Measures

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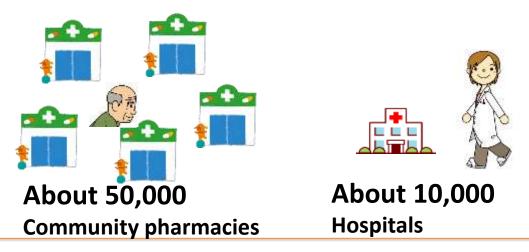




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Number of pharmacists



30 June to 2 July 2022



Community pharmacists do not work well????







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Not enough knowledge, education and information.

		Japan ¹⁾	Canada ²⁾
		N=583	N=352
ved adeq	uate oncology education in undergraduate	e degree	
	Yes	39 (6)	48 (13)
	No	544 (93)	209 (59)
	No response	0	95 (27)
ved adeq	uate oral chemotherapy education in unde	ergraduate degree**	
	Yes	59 (10)	n.a.
	No	524 (90)	n.a.
	No response	0	n.a.
ved adeq	No response	, ,	cation events or community
	Yes	373 (64)	19 (5)
	No	210 (36)	238 (67)
	No response	0	95 (27)

1) Suzuki S, Abbott R, et al., Jpn J Clin Oncol, 2017. 2) Abbott R, et al., J Oncol Pharm Pract, 2014.



30 June to 2 July 2022

Number of oral anticancer drugs approved in Europe

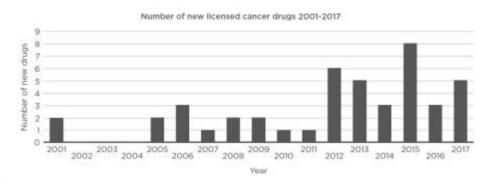


Figure 1: Graph showing the year that different oral anticancer agents were licensed in Europe. Courtesy of Klaus Meier.

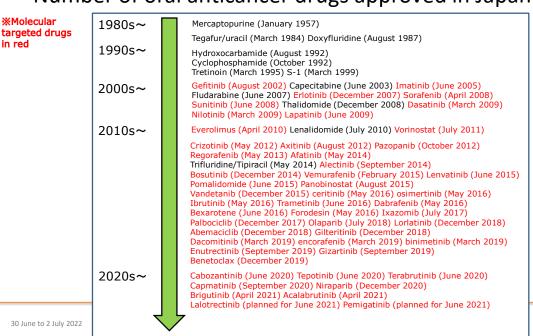
2001: capecitabin, imatinib; 2005: anagrelide, erlotinib; 2006: dasatinib, sorafenib, sunitinib; 2007: lenalidomide; 2008: lapatinib, nilotinib; 2009: gefitinib, thalidomide; 2010: pazopenib; 2011: abiraterone; 2012: axitinib, crizotinib, nuxolitinib, tegafur-kombi, vandetanib, vernurafenib; 2013: afatinib, datorefenib, enzalutamide, regorafenib; vismodegib; 2014: cabozantinib, ibrutinib, idelalisib; 2015: carfilizomib, ceritinib, cobimetinib, lenvatinib, nintedanib, olaparib, panobinostat, trametinib; 2016: osimertinib, palbociclib, tipiracil; 2017: alectinib, ixazomib, ribociclib, tivozanib, venetoclax.

30 June to 2 July 2...

Meier K, Bergsbaken J, Suzuki S, EMJ 2018;3(2):60-68

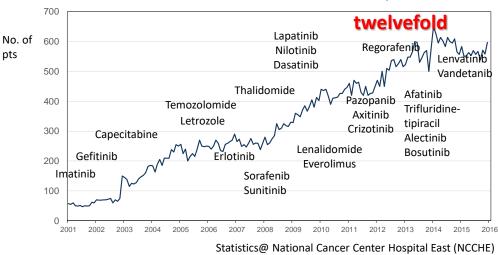


Number of oral anticancer drugs approved in Japan



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Number of oral anticancer drug use patients @National Cancer Center Hospital East



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With the increasing number of difficult treatments, doctors, nurses, pharmacists, and other medical staff in hospitals have raised their own level of professionalism.

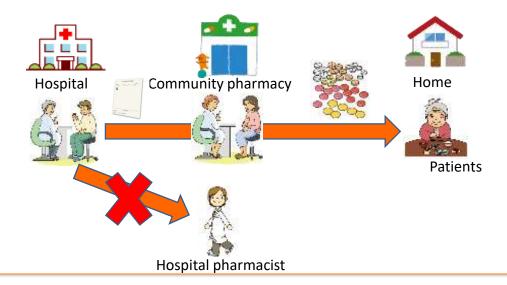




Pharmacists had started clinical services @outpatient injection treatment center



Oncologists directly give a prescription to patient.



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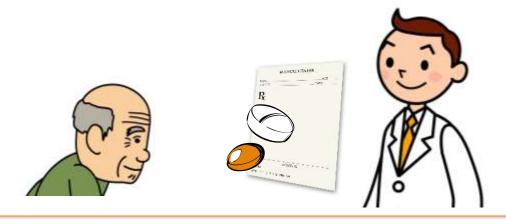
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	Variable	No. (%) patients		p
		DHs ⁶ n = 274 (%)	GHs ^b n = 428 (%)	
Table 2 Backgrou		216 (79)	91 (21)	< 0.001
characteristics of l	hospitals ≥10 chemotherapy patients per day	246 (90)	109 (26)	100.00
	Professional qualifications	240 (20)	100 (20)	-0.001
Hospital pharmacists	JSHP-certified Oncology Pharmacist ⁶	214 (78)	111 (26)	< 0.001
cannot check	JSPHCS-certified Oncology Pharmacist ^d	66 (24)	25 (6)	< 0.001
outpatient oral	JSPHCS-certified Senior Oncology ^d Pharmacist	78 (29)	20 (5)	< 0.001
chemotherapy	JSMO-certificated Oncologist ⁶	128 (47)	39 (9)	< 0.001
prescriptions (<20%)	Chemotherapy regimen check	49.87	250	
1 1 ()	Inputient chemotherapy			
	Injection chemotherapy	270 (99)	423 (99)	0.73
	Oral chemotherapy	153 (56)	284 (66)	< 0.01
(· ·)	Outpatient chemotherapy			
	Injection chemotherapy	272 (99)	418 (98)	0.1
()	Oral chemotherapy	30(11)	73 (17)	< 0.05
M C	Contents of chemotherapy regimen check			
	Dose of anticancer agents	273 (100)	424 (99)	0.38
· · · · · · · · · · · · · · · · · · ·	Interval of chemotherapy	268 (98)	405 (95)	< 0.05
	Premedication and supportive medicine	223 (81)	343 (80)	0.68
	Administration rates	217 (79)	345 (81)	0.64
	Laboratory data	181 (66)	266 (62)	0.29
	Medical history	147 (54)	208 (49)	0.19
30 June to 2 July 2022	Concurrent medication Suzuki S, Sakui	rai H, et al., Int	J Clin Pharm,	2016.

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Community pharmacists do not work well????

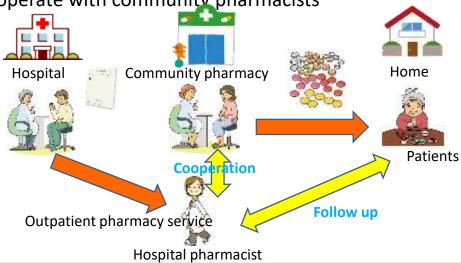


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Hospital pharmacists provide outpatient service to cooperate with community pharmacists



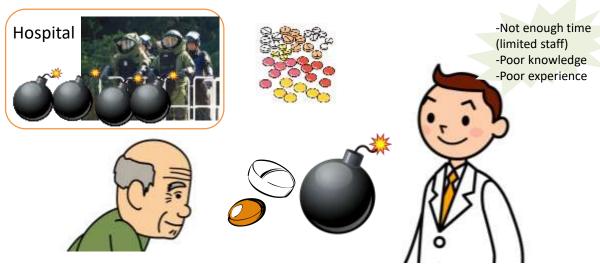
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My community pharmacist days...



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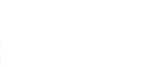


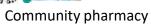
What are ways to bridge this gap?













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Healthcare reimbursement fee



30 June to 2 July 2022



"Oral anticancer agents management" in Japan Problems and Measures

- Shift from inpatient (hospital) care to outpatient care/community healthcare
 - Unfortunately, community pharmacists are not playing a sufficient role in community healthcare

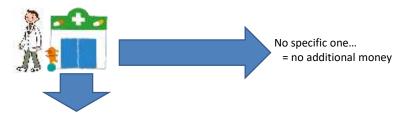




- ✓ Contribution to community healthcare by community pharmacies through the family pharmacist system: Revenue ↑
- ✓ Communication with hospitals through adverse drug reactions: Revenue ↑
- ✓ Cooperation between hospitals and community pharmacies (information sharing, study program): Revenue ↑
- ✓ Advanced medical function pharmacies by pharmacists with oncology qualifications

^{30 June t}the future: Revenue 个

New Japanese National Policy (2021) Accreditation of Community Pharmacies with Specific Functions





Community Collaboration Pharmacies

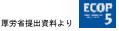
✓ provide centralized and continuous support in cooperation with local community
pharmacies for information collaboration with medical institutions.

Specialty medical institution-linked community pharmacies

✓ provide specialized pharmacy management for cancer and other diseases in cooperation with medical facilities.

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Healthcare reimbursement fee for community pharmacy

"Family pharmacy fee"

- Since the FY 2016 revision of reimbursement of medical fee, the government promote the family pharmacy which has advance pharmacy management function.
- Requirement: Certified pharmacist, three years pharmacist experience, <u>24 hours consultation</u>, etc.







24hours business!!!
Please call me
freely!!!

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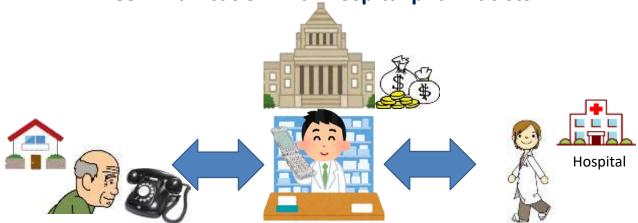




Healthcare reimbursement fee for community pharmacy

"Telephone follow-up for patients"

"Communication with hospital pharmacists"



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Telephone follow-up contributed to sorafenib or lenvatinib oral treatment

Sorafenib	N=48	1	
		n	%
Nonadherence patients		17	35
Total nonadherence events self-judgement mistakes		31 18 13	58 42
Timing of the findings outpatient telephone follow up		16 15	52 48

Telephone follow- up interventions (N=156)	No event, n = 28 (17.9%)	Observed drug-related problems and managed them using developed flowchart, n = 69 (44.2%)	Distincted problems with an oncologist and decided to continu observation with no medical intervention, n=18 (11.5%)	Oncologists decided to temporarily interrupt lematinib after report of adverse drug reactions from formacists, n=41 (26.2%)
Hand-foot syndrome		6	0	15
Hypertension		31	10	6
Angrexia		5	0	5
Distrites		1	0	4
Drug mistake		4	2	3
Drug consultation		6	0	3
Pain		5	1	2
Fatigue		5	2	65
Thrombosis		0	0	(3)
Proteinaria.		0	.0	US
Rash		2	3	0
Dehydration		2	0	0
Bleeding		1	0	0
Constipation		10	0	0

Suzuki S, et al. JJPHCS. 2014

Suzuki S, et al. SAGE Opn Med. 2020

(in Japanese)

<u>(in Japanes</u>



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30 June to 2 July 2022



Healthcare reimbursement fee for hospital pharmacy

"Disclosure of treatment methods (chemo regimens) on the HP"

What is a Cancer Chemotherapy Regimen? About the regimen approved as an in-hospital regimen, the contents are disclosed for use to insurance phermiscots and offermiscots. This document is previously for the propose of proper adventisation management of patients undergoing cancer treatment at the National Cancer Center trainplate bast, and is not intended for any other purpose. The delarge and administration schedule may change depending on the patient's constition. List of cancer chemotherapy regimens by clinical department • Respiratory Medicine • Non-small cell largicancer (PDF: 129KB) • Small Del Lario Cancer (PDF: 129KB) • Hand and Hack (manual Medicine) • Gestronhestinal internal medicine

- Colorectal Centre (PDF: 13682)
- Gestric cancor (POF, 363XB)
 Escribered cancer (PDF: 149XB)
- · Distribution (State | Line | Co.
- Oncology
- Britist Concer Trestuminal, Combination Regimen (PDE: 12468)
- Breast Cancer Perfurament + Trasturument Combination Renimes (PDF: 131KB)
- · Breest conser Others (PDF; 180KB)
- Heruffchillery and Pangwells: Internal Hedicine (PDF: 19868)
- Hematology Occology
- Others (PDE: 36KB)

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Healthcare reimbursement fee for hospital pharmacy

"Cooperation with community pharmacists on the HP"

Regarding reception of tracing reports and establishment of consultation desk

Reception of tracing report (reception fax number) 04-7135-5452

Timpet]

L. Side effects of anti-cancer drug treatment Grade 2 or higher symptoms (providing information for the next medical examination without urgency)

 In addition, information provision to the hospital side for the patient (information provision for the next consultation)

If there is an urgent need, please contact the doctor or the patient should contact the autpatient chemotherapy holline. If you have any doubts or prescription suggestions, please contact your doctor directly.

<Outpatient Chemotherapy Hotline> Reception hours 8:30 to 17:15 on weekdays:

Phone number 04-7130-0500

* Other than the above hours, use the following phone number Phone number 04-7133-1111 (representative) 30 June to 2 July 2022 | European ConEstablished a consultation desk for anti-cancer treatment (for insurance pharmacles)

We answer simple questions about chemotherapy such as unknown regimen and side iffect treatment.

fowever, we cannot accept prescription questions or individual patient response methods.

Yease feel free to contact us:

rakuzai-di@east.ncc.go.jp





Healthcare reimbursement fee for hospital pharmacy

"Regular meeting with hospital pharmacists"

Before COVID-19











Quoted from a TV news report about our pharmacy







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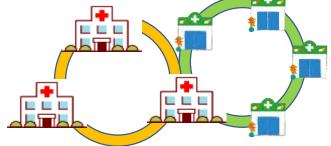
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Technology?

Share patient information using technology





- ➤ In some special areas, hospitals and community pharmacies share electric patient records using IT technology...
- ➤ However, it costs money and privacy issue is problem to make it. Therefore, it is still not common in Japan.

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"Oral anticancer agents management" in Japan Problems & Measures

Shift from inpatient (hospital) care to outpatient care/community healthcare

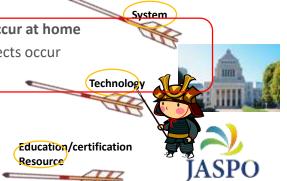
 Unfortunately, community pharmacists are not playing a sufficient role in community healthcare

Difficult to manage adverse drug reactions that occur at home

Difficult to determine what to do when side effects occur

Majority of patients are elderly

- Simply..., "New drugs are difficult!!!"
 - (even pharmacists do not understand them)
 - Various molecular targeted drugs



ECC

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Technology?

We have...

Smart phone apps

- -Record Medical history
- -Record OTC medicines
- -Medicine scheduler (alarm, record)



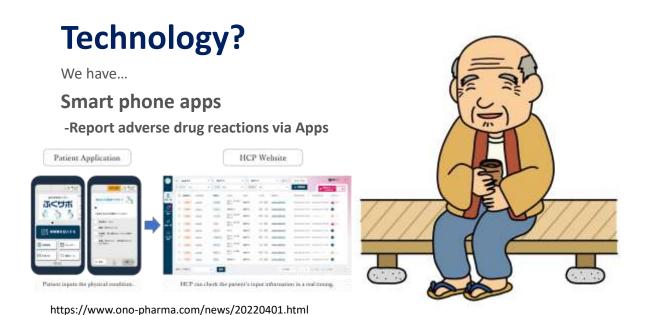




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https://www.nichiyaku.or.jp/e-okusuri/ (In Japanse)





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Most patients (elderly patients) use...



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Technology?

We have...

Online system

-Mainly for COVID-19 infection, not for oral anticancer medicine...





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Technology?

I believe that in 20 years when the current digital generation turns 60, there will be a variety of technologies to combat oral anti-cancer drugs...



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Technology?

Actually, we use analog tools...

Paper documents

Medicine notebook

and ask questions...





of Oncology Pharmacy



Technology?

Actually, we use analog tools...

Telephone consultation
Telephone follow up
FAX (facsimile) tracing report







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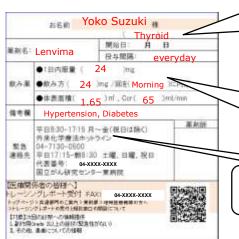




Tools to share information between hospitals and community pharmacies







Drug name, treatment schedule, starting date of administration, and other items required for prescription audit

Information related to dosage, such as body surface area and organ function

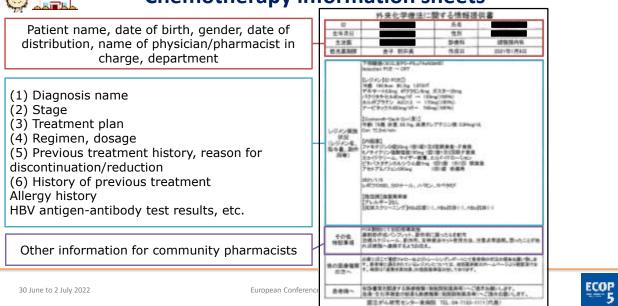
Contact information in case of illness or emergency

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Tools to share information between hospitals and community pharmacies





Tools to share information between hospitals and community pharmacies

Provide clinical laboratory data values on outpatient prescriptions

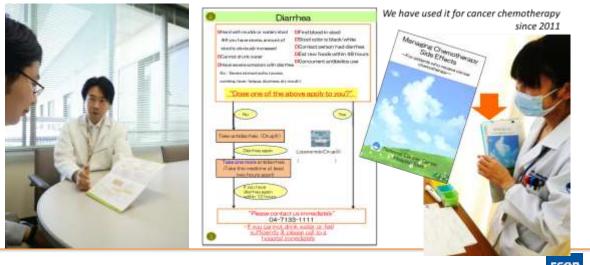


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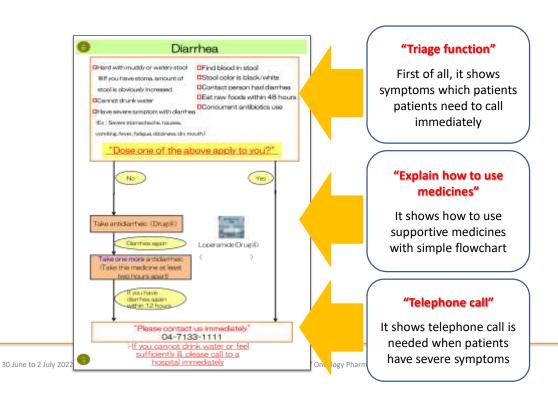
Flowchart type leaflet

@National Cancer Center Hospital East, Japan



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Flowchart type leaflet

@National Cancer Center Hospital East, Japan

Table 3. Emergency hospital admissions and telephone calls.

	FCL	Non-FCL	p-value*
	139 cycles/49 pts	163 cycles/60 pts	
Emergency hospital admissions, n (%)	1 (1)	16 (10)	0.0015
Emergency hospital visits, n (%)	4 (3)	17 (10)	0.01
Nonadherence (inpatients), n (%)	17 (12)	31 (19)	1.0
Nonadherence (outpatients), n (%)	5 (4)	23 (14)	0.002
Telephone calls, n (%)	22 (16)	11 (7)	0.01
Total calls	30	11	
Calls according to pharmacists' instruction	24 (80)	5 (45)	
Calls before emergency admissions	1 (100)	6 (37)	
Calls before emergency visits	4 (100)	6 (37)	

FCL: flowchart-type leafler; cycles: number of chemotherapy cycles; pts: number of patients.

Emergency admissions rate was lower in FCL group than in non-FCL group and medication adherence and phone calls were higher in FCL group than in non-FCL group

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Education based on board certification system



- ✓ It has been about ten years since Japanese original BCOP certification system started.
- ✓ The Japanese BCOP and JSMO, Japanese Society
 of Medical Oncology, certified oncologist certification
 showed positive effect to adequate chemotherapy
 implementation.
- ✓ BUT, the oncology pharmacy certification did not exist in community pharmacists...



- The JASPO have started the Accredited Pharmacist of Ambulatory Cancer Chemotherapy (APACC) and Board-Certified Pharmacist of Ambulatory Cancer Chemotherapy [BPACC]that focus on not only hospital pharmacists but also community pharmacists.
 - Now, the certification is one of the requirements to achieve healthcare reimbursement fee.

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Specialized oncology credentials for physicians or pharmacists in hospitals contribute to proper treatment

Compliance for adequate cancer chemotherapy

Characteristic	Odds ratio	95 % CI ^a	p
Designated hospital	1.08	[0.68-1.69]	0.73
>400 beds	0.86	[0.56-1.32]	0.50
≥10 chemotherapy patients per day	1.13	[0.71-1.79]	0.60
Professional qualifications			
JSHP ^b -certified Oncology Pharmacist	0.76	[0.52-1.12]	0.17
JSPHCS ^c -certified Oncology Pharmacist	1.56	[0.74-3.28]	0.23
JSPHCS ^c -certified Senior Oncology Pharmacist	0.29	[0.13-0.76]	< 0.01
JSMO ^d -certificated Oncologist	0.48	[0.31-0.76]	< 0.01

Suzuki S, Sakurai H, et al., Int J Clin Pharm, 2016.



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Education program increases confidence in educating patients





Table 5. Factors for confidence in educating patients about oral chemotherapy

Parameter	Odds ratio	95% confidence interval	P value
Age	1.05	0.79-1.05	0.69
Number of years of experience	1.01	0.98-1.05	0.37
Number of oral chemotherapy prescriptions/week	1.01	0.92-1.12	0.70
Number of continuing education events attended	1.67	1.35-2.08	< 0.001
An understanding of chemotherapy cycles and doses	4.89	2.53-9.45	< 0.001

In a multivariate analysis, confidence in educating patients about oral chemotherapy was associated with an understanding of chemotherapy cycles and doses (odds ratio = 4.89, 95% confidence interval [2.53-9.45]) and the number of continuing education events they had attended (odds ratio = 1.67, 95% confidence interval [1.35-2.08]).

Suzuki S, Abbott R, et al., Jpn J Clin Oncol, 2017.

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If you use it frequently, you have confidence to use it. Stock medicine at a pharmacy and community pharmacist's confidence of oral medicines for different types of oral chemotherapy drug

	Stock is avail	able, N=583	Confidence of ph	armacists
Drug	Yes, n	(%)	Comfortable, n	(%)
Regorafenib	154	(27)	73	(47)
Temazolomide	195	(34)	108	(55)
Sunitinib	206	(36)	101	(49)
Sorafenib	267	(46)	141	(52)
Erlotinib	298	(52)	164	(55)
Imatinib	330	(57)	224	(67)
Gefitinib	382	(66)	244	(63)
Exemestane	420	(72)	352	(83)
Capecitabine	443	(76)	318	(71)
Tamoxifen	504	(87)	428	(84)
1: tegafur/oteracil/gimeracil	539	(93)	433	(80)

30 June to 2 July 2022

European Conference of Crusiose Pharmaco Suzuki S, Abbott R, et al., Jpn J Clin Oncol, 2017.



Education based on board certification system



Education based on board certification system



Needs based JASPO activities

2016 **2000**members

About the Society

The society established in 2012

Members were consisted of hospital pharmacists and community pharmacists

Number of the members was about 2,000

Prior color revers fragated pharmacists, community pharmacist, pharmacists companies and lawyer by artificial companies on the work practice.

The furnishment design revers a single for every publishment.

2018 **3000**members



International relation committee in JASPO.
 The JASPO recently published multidisciplinary guideline for handling of hazardous drugs.

2022 **5000** members

(20% is community pharmacist)





30 June to 2 July 2022

European Conference of Oncology Pharmacy



JASPO's publications in response to the needs



Occupational Exposure Control Guidelines for Cancer Pharmacotherapy 2019



Guidance for Community Pharmacists and Hospital Pharmacists on Outpatient Anticancer Drugs



Guidance for family pharmacists and pharmacies on cancer drug therapy (Just published 2022)

ECOP

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JASPO's textbooks in response to the needs



Regimen handbook 7th edition



A Beginner's Guide to Oral Anticancer Drugs



Clinical Oncology Pharmacy

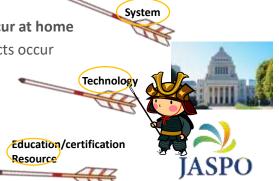
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"Oral anticancer agents management" in Japan Problems & Measures

- Shift from inpatient (hospital) care to outpatient care/community healthcare
 - Unfortunately, community pharmacists are not playing a sufficient role in community healthcare
- · Difficult to manage adverse drug reactions that occur at home
 - Difficult to determine what to do when side effects occur
 - Majority of patients are elderly
- Simply..., "New drugs are difficult!!!"
 - (even pharmacists do not understand them)
 - Various molecular targeted drugs



ECOP

30 June to 2 July 2022

Thank you for your continued cooperation!

European Conference of Oncology Pharmacy





"I would like to <u>make friends</u> to **improve** oncology pharmacy !!!"



ssuzuki.ncc@facebook.com

https://www.linkedin.com/pub/shinya-

suzuki/87/a/a9b

HAR

e-mail: ssuzuki@east.ncc.go.jp

