

BARCELONA
2024

ESMO

congress

Waste reduction through redispensing unused oral anticancer drugs

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DECLARATION OF INTERESTS

Non

Cancer drug waste jeopardizes sustainability



**Climate
change**



Pollution



Costs



Shortages



Redispensing unused oral anticancer drugs (ROAD)

From the patient at home back to the
pharmacy



ZonMw

Projectno. 848018008

2014 - 2018

Feasibility research
PhD dissertation



2020

National grant
Waiver Ministry of
Health

2021

ROAD1.0 trial in 4
hospitals



2022

Trial finished with
>1,000 patients

2023

NVZA Guideline
JAMA Oncology



2023-2024

Waiver Ministry of
Health
ROAD2.0 trial in 14
hospitals

How to deal with legal issues

Falsified Medicines Directive

Prohibits redispensing unused drugs by patients within the supply chain

- Sealed packaging (light, humidity, authenticity)

Formal waiver

By Dutch Ministry of Health for a trial



ROAD study

Multicenter trial in 4 Dutch hospitals

Enclosed in sealed packaging with temperature indicator

Study population

Adult patients using an oral anticancer drug with a clinical diagnosis of (blood)cancer

- Recruitment by the outpatient pharmacy

Effect

Cost savings

Environmental impact



ROAD intervention



Dispensed medication

Enclosed in sealed packaging with temperature indicator



Returning unused medication

Patients are requested to return unused drugs



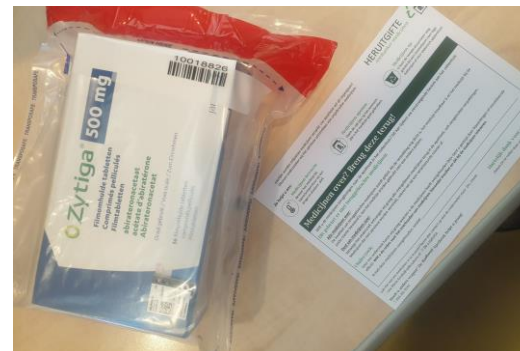
Assuring drug quality

- Unopened seal (light, humidity, authenticity)
- Remaining shelf-life ≥ 6 months (integrity)
- Storage according to SmPC (integrity)

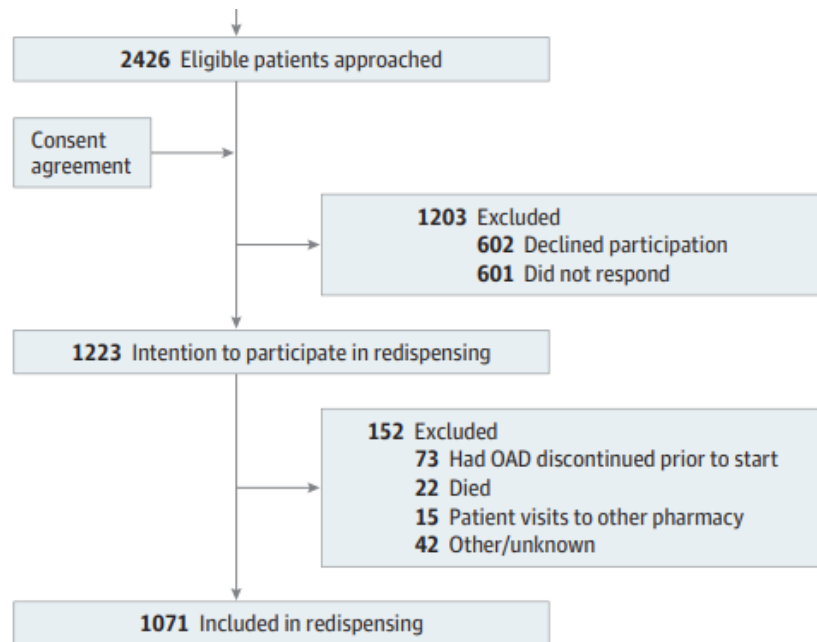


Redispensing medication of verified quality

Reimbursing the price paid by the original payer



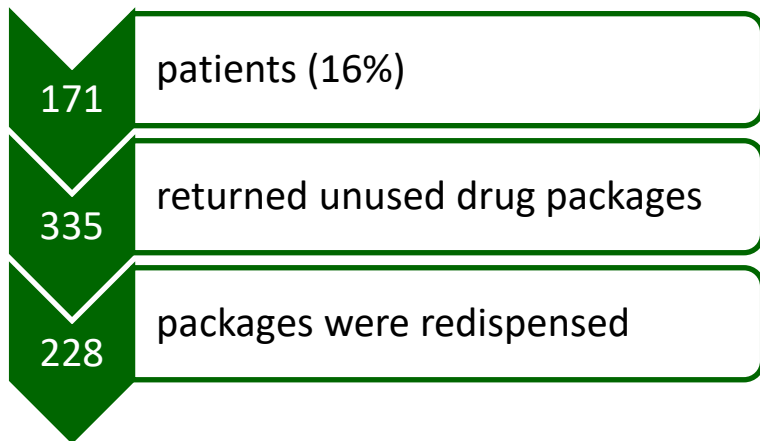
ROAD participants



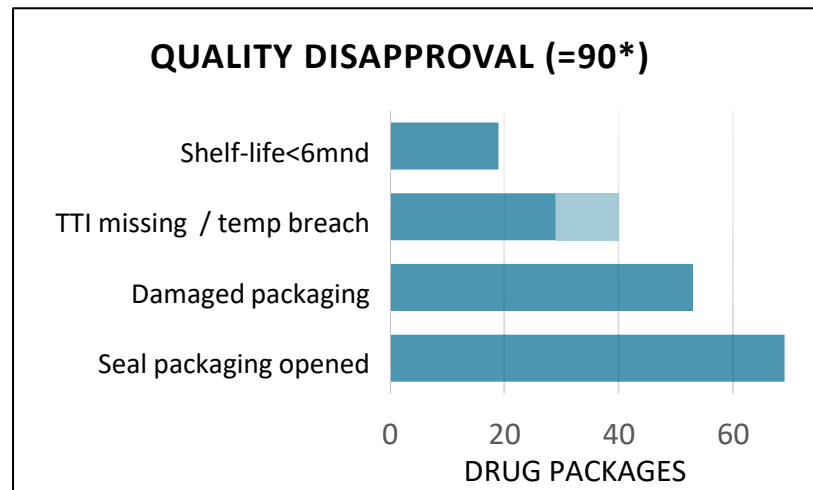
OAD: oral anticancer drug

n = 1,071	
Gender [no. (%)]	
Male	622 (58.1)
Female	449 (41.9)
Age [years]	
Median (IQR)	70 (62 – 75)
Center [no. (%)]	
Academatic centers	655 (61.2)
Teaching centers	416 (38.8)
Indication [no. (%)]	
Solid cancers	548 (51)
Hematological cancers	523 (49)
OAD [no. (%)]	
Targeted therapies	655 (61)
Cytotoxic agents	255 (24)
Endocrine therapy	152 (14)
Immunosuppressants	91 (8)
OAD onset [no. (%)]	
≤ 6 months	347 (32)
7 – 24 months	338 (32)
> 24 months	386 (36)
Participation duration [months]	
Median (IQR)	12 (7 – 12)

ROAD study results



68% waste reduction



* Multiple criteria could apply per package

ROAD cost savings

Table 2. Mean Net Annual Cost Savings Attained Per Patient Associated With Redispensing Oral Anticancer Drugs vs Standard Practice (eg, Disposal of Unused Drugs) and Influence of Quality Assurance Procedure

Quality procedure	Redispensed OADs		Patients with redispensed OAD(s)		Annual mean per patient vs standard practice, (95% CI) ^a		
	No.	% (95% CI)	No.	% (95% CI)	Costs; €	Benefits; €	Net cost savings; €
Base case ^b	228	1.7 (1.6-1.9)	128	12.0 (11.0-12.9)	37 (35-38)	613 (481-746)	576 (444-709)
Single-use TTI ^c	228	1.7 (1.6-1.9)	128	12.0 (11.0-12.9)	70 (67-73)	613 (481-746)	543 (411-676)
Optimized quality procedure ^d	250	1.9 (1.8-2.0)	141	13.2 (12.1-14.2)	9 (8-9)	663 (527-800)	655 (518-791)
Visual check only ^e	335	2.6 (2.4-2.7)	171	16.0 (14.8-17.1)	1 (1-1)	816 (664-968)	814 (663-967)

Research

JAMA Oncology | Original Investigation

Cost Savings and Waste Reduction Through Redispensing Unused Oral Anticancer Drugs The ROAD Study

Elisabeth M. Smale, PharmD; Bart J. F. van den Bernt, PharmD, PhD; Eibert R. Heerdink, MS, PhD; Ingrid M. E. Desar, MD, PhD; Toine C. G. Egberts, PharmD, PhD; Charlotte L. Bekker, MS, PhD; for the ROAD Study Group

ROAD

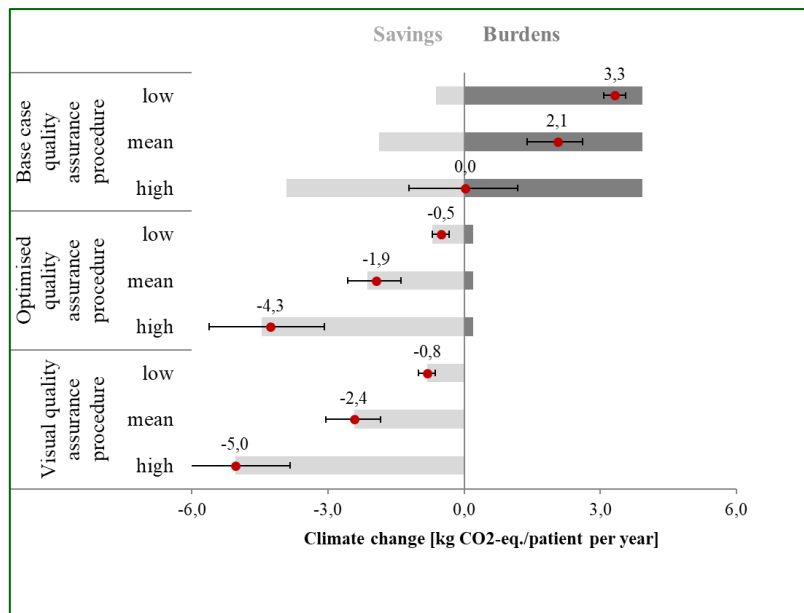
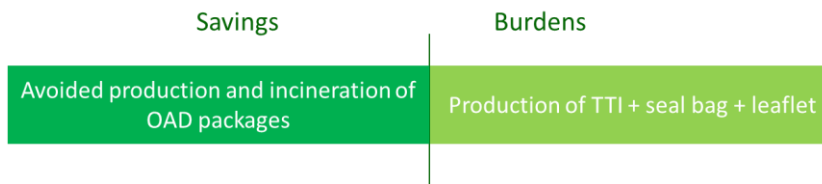
environmental impact

Cradle-to-grave Life cycle Assessment

Environmental benefits are obtained

Particularly if verification materials are
selectively used

Per 1,000 patients: 100 trees for 1 year



ROAD 2.0 ongoing



13/14
hospitals
open

>6,000
patients
invited



>2,600
patients
consented



Dutch guideline on redispensing

- Redispensing receives multidisciplinary support
- Dutch Association of Hospital Pharmacists (NVZA) developed **multidisciplinary** guideline

Position Paper Redispensing of oral oncolytics

“rely on approved quality process and manage accountability”



A screenshot of the 'Richtlijnen database' website. The header includes the logo for 'Federatie Medisch Specialisten' and the title 'Richtlijnen database'. A navigation menu contains links for 'RICHTLIJNEN', 'Q ZOEK', 'NIEUWS', 'INSTRUCTIES', 'WERKWIJZE', 'OVER', 'CONTACT', and 'APP'. There are also links for 'LOG IN' and 'COVID-19'. Below the navigation, a breadcrumb trail reads '← Terug naar zoekresultaten'. The main heading is 'Standpunt Heruitgifte van orale oncolytics', with a '+ VOLGEN' button to its right. Below the heading, it says 'Initiatief: NVZA' and 'Aantal modules: 2', with a 'Download richtlijn' button. A search bar is visible at the bottom left with the text 'Zoeken binnen deze richtlijn'. On the right, there is a section titled 'Startpagina - Standpunt Heruitgifte van orale oncolytics' with a date 'Beoordeeld: 27-09-2023'.



Next steps

Ultimate goal

Redispensing as standard practice in 2025

- Legislation
- EU partnership

ROAD international symposium

November 14-15, Nijmegen, the Netherlands

Join and bring your oncology pharmacist

Free registration



Thank you

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