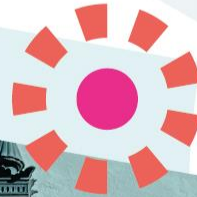


.cáncer. XII FORO
DE **ovario**
Y OTROS TUMORES
GINECOLÓGICOS

Control de síntomas en cáncer ginecológico

Ainhoa Madariaga

Hospital Universitario 12 de Octubre



Conflicts of interest

- **Speaker:** AZ, GSK, Clovis, PharmaMar
- **Advisory:** AZ, GSK

Overview

- Symptom control in gynecologic malignancies
- Patient reported outcomes in clinical trials
- Patient reported outcomes in usual care



Symptom control in gynecologic cancers

Toxicity management in gynecologic malignancies

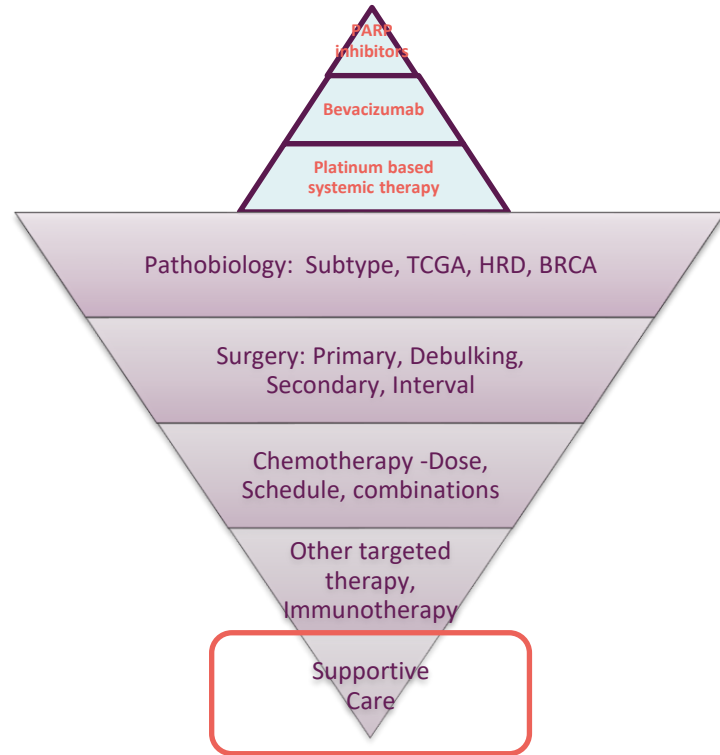
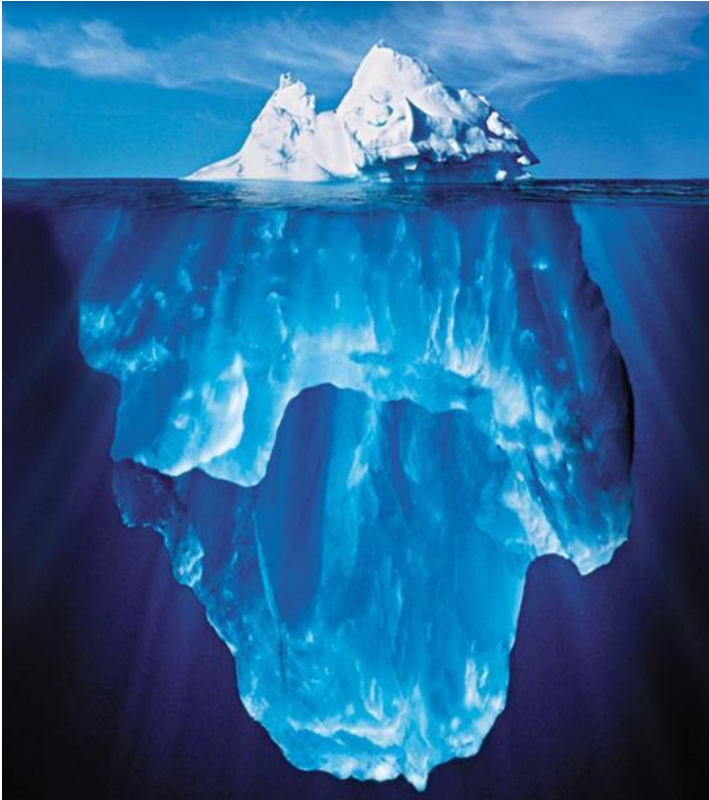


What is Important?

1. Effectiveness
2. Toxicity
3. QoL
4. Convenience
5. Cost

Symptom control in gynecologic cancers

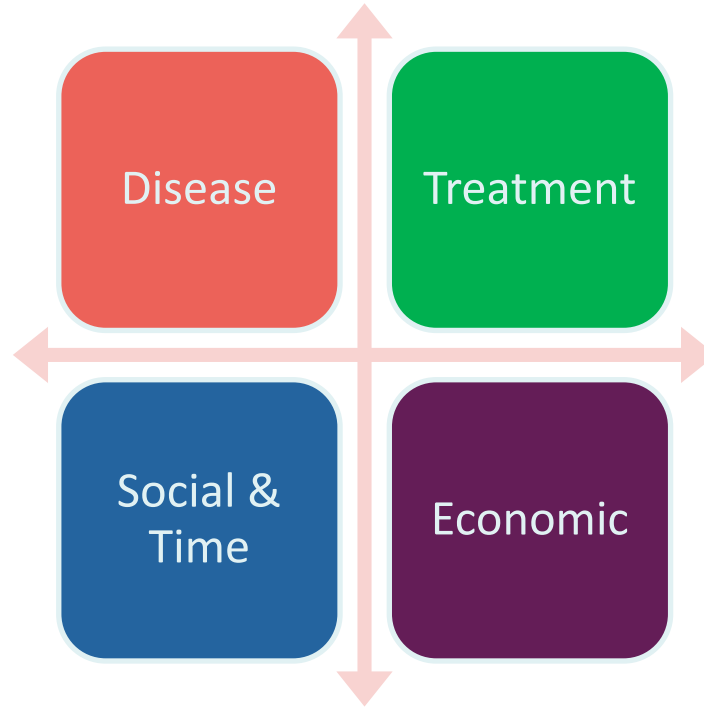
Toxicity management in gynecologic malignancies



Symptom control in gynecologic cancers

Toxicity management in gynecologic malignancies

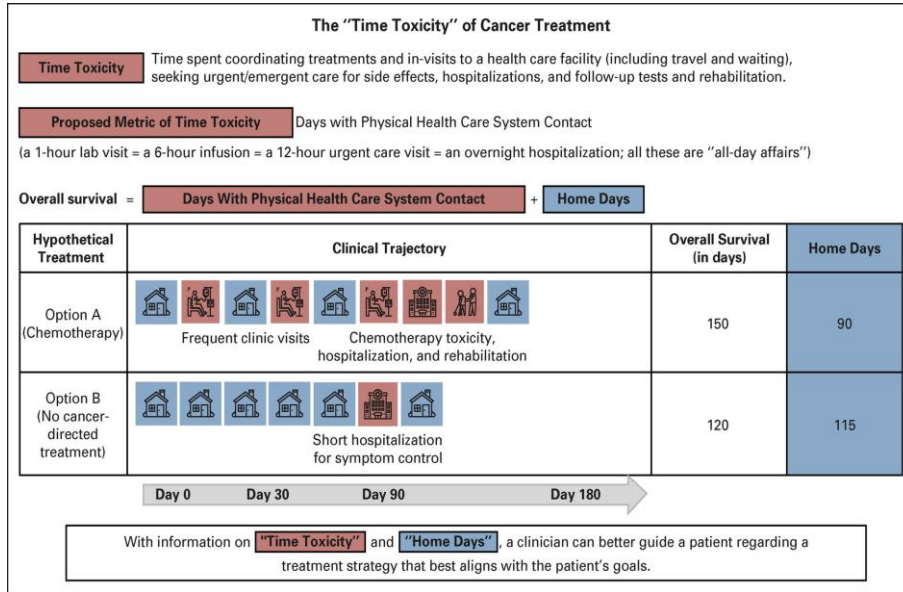
- Ovarian
- Endometrial
- Cervical
- Vagina, vulva
- Other



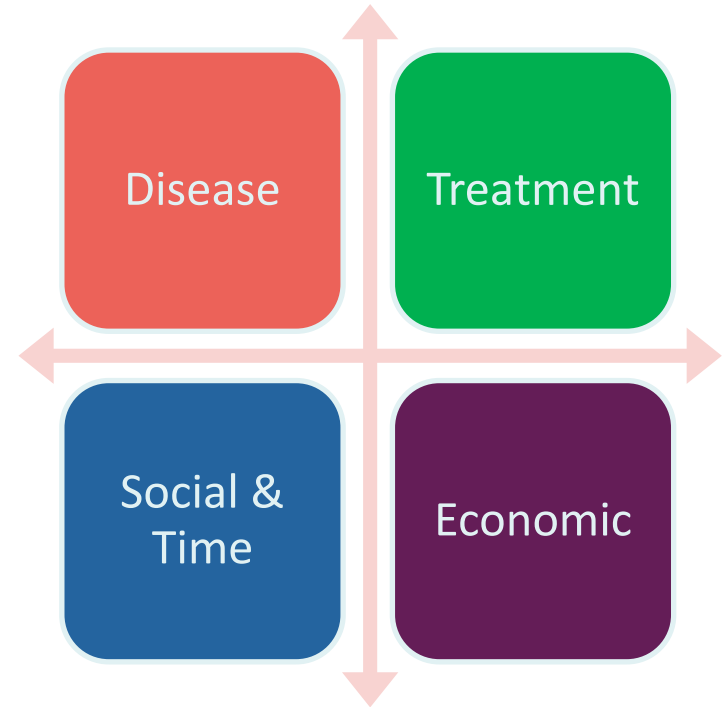
- Treatment vs maintenance
- Type of therapy
 - Chemotherapy
 - ADCs
 - Targeted therapy
 - Immunotherapy
 - Novel combos

Symptom control in gynecologic cancers

Toxicity management in gynecologic malignancies



SGO endometrial cancer (n=70) → 15% time on health care



Patient reported outcomes in clinical trials

Toxicity recording in clinical trials

Clinician reported

Common Terminology Criteria for Adverse Events (CTCAE)

Version 5.0

Published: November 27, 2017

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Patient reported

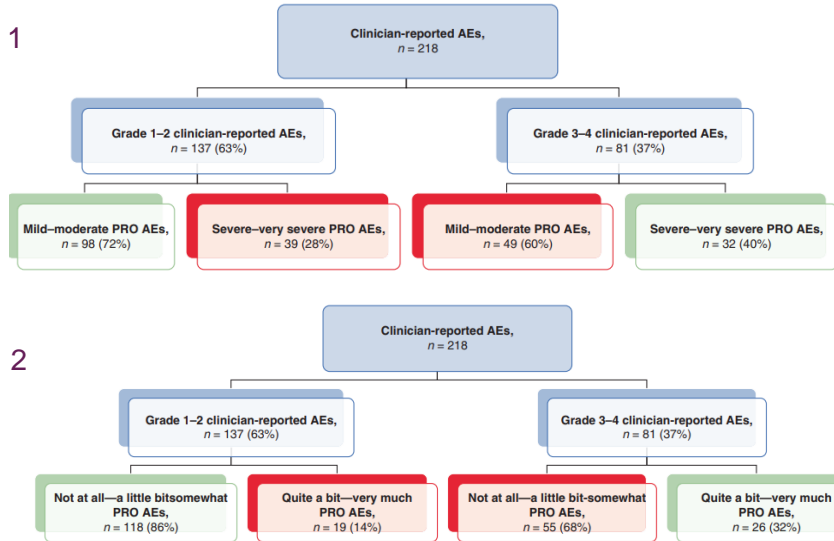
- PRO-CTCAE
 - Severity, Frequency, Interference
- Generic HRQoL (no pathology specific)
- HRQL specific per pathology
 - All cancers: EORTC QLQ-C30, FACT-G
 - Specific per type of cancer: ovary, lung, other
- Specific for symptoms or domains
 - HADS (anxiety & depression), Brief Pain Inventory (BPI)
- Utility domains (EQ-5D)
- Other

Duration → Longitudinal analysis

Patient reported outcomes in clinical trials

Correlation between physician and patient reported toxicity

Early phase trials



Clinician-reported AEs (blue) and associated PRO-CTCAE severity (1) and interference (2) scores

Phase III trials

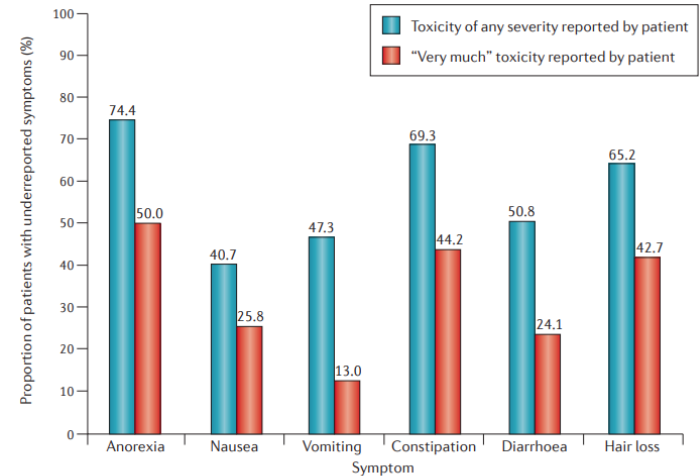


Figure 1 | Underreporting of treatment-related toxicities by physicians, relative to patients with either advanced-stage lung cancer, or early-stage breast cancer. Underreporting of

Agreement low (Cohen's-k coefficient 0.15 - 0.45)

She looks GREAT!

How my care team and others perceive I feel

Trouble with word retrieval/Focusing

Foggy Brain

Severe dry eye

Anxiety/Depression

Mouth Sores/change in taste

Dental problems

paronychia

Dry mouth

Chest wall pain

Rash

SOB – loss of lung function

Numbness/pain surgical sites

Fatigue

Diarrhea/nausea

Joint pain/muscle aches

Acid Reflux

Dry Cracked Skin

Loss of Muscle Mass

Numbness/tingling

Sensitive skin

Lacerations on heels

Random loss of toenails

How I actually feel

Tolerable is Relative!

Patient reported outcomes in clinical trials

Clinical trials - PROs in gynecologic malignancies

Ovarian Cancer Consensus

Statements on crucial elements in future trial design

Patient reported outcomes (PROs) and quality-of-life measures (33 of 33 groups approved)

- 1 Incorporation of self-reported toxicity assessment (eg, PRO-CTCAE) should be considered
- 2 Predefined PRO endpoints should be included in the statistical analysis plan in randomised trials, particularly when there is a difference in equipoise between arms, such as extended maintenance therapy or additional agents; if feasible, such PROs should continue past disease progression and continue until initiation of next intervention
- 3 If progression-free survival is the primary endpoint, consideration could be given to including PROs as an additional primary endpoint
- 4 Inclusion and reporting of PRO endpoints in protocols should follow the published guidelines (eg, ISOQOL, CONSORT-PRO)
- 5 All clinical trials that include PROs should incorporate strategies to avoid and address missing data

Patient reported outcomes in clinical trials

PROs in gynecologic malignancies

Most phase III randomized clinical trials include HRQoL endpoints

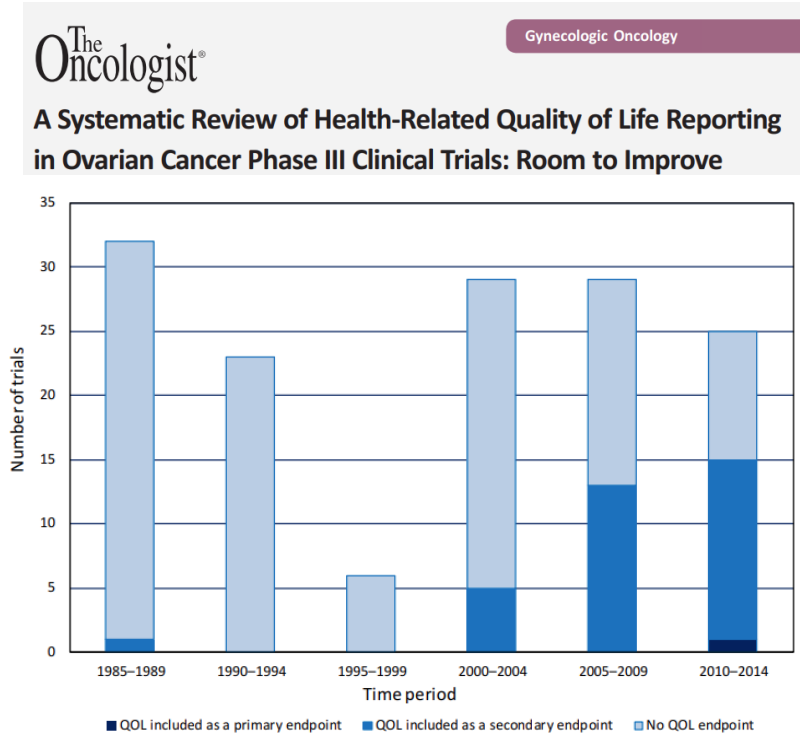
↑ use in gynecology clinical trials:

- 2% (1980s) → 62% (2010+)

Mostly secondary or exploratory

HRQoL reporting:

- Compliance 74%
- Missing data dealing 37%
- No studies post-PD data



Patient reported outcomes in clinical trials

PROs in gynecologic malignancies - Phase III trials

- **PARPi in ovarian cancer – No changes in primary PRO measures**
 - Maintenance after response to chemotherapy
 - Time with no / little disease related symptoms

Contemporary exploratory PRO outcomes

TWIST: time without significant symptoms of toxicity (i.e. nausea, vomiting, fatigue ≥ 2)

Q-TWIST: Quality-adjusted time without symptoms or toxicity

QAPFS: Quality-adjusted PFS

Patient reported outcomes in usual care

Toxicity management: Real time PRO assessment

Real-time PRO assessment

- Phase III randomized trial at MSKCC
- Multi-tumour
- 12 symptom monitoring
- Alerts generated for symptoms considered:
 - Severe
 - Worsened

ABSTRACTS & PRESENTATIONS

2023 ASCO Annual Meeting - Poster Session

Proactive assessment of patient reported outcomes in patients with ovarian cancer.

Abstract: 5567 | Poster Bd #: 262

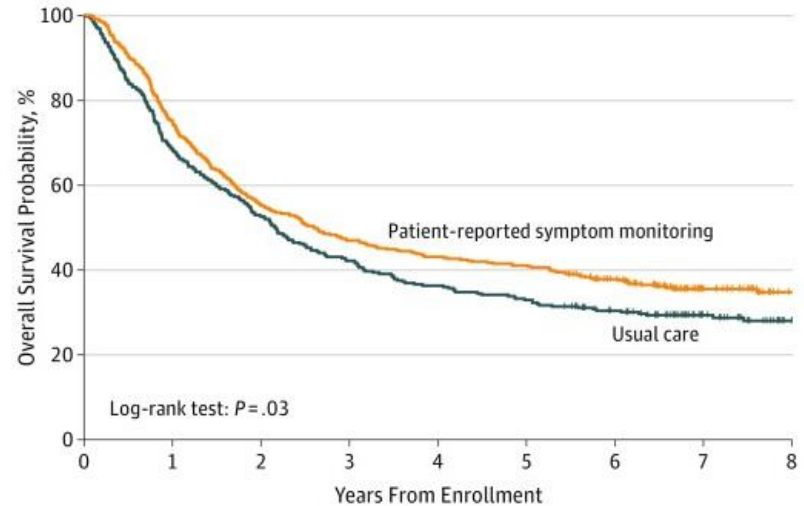


Presenter:
Ainhoa Madariaga MD



Hospital 12 de Octubre

**OS: PRO 31.2 m (24.5-39.6)
vs usual care 26.0 m (22.1-30.9), $p=0.03$**



Patient reported outcomes in usual care

Toxicity management: malignant bowel obstruction



Patient reported outcomes in usual care

Toxicity management: malignant bowel obstruction

Retrospective single-centre analysis:

Patients with advanced gynecologic cancer admitted due to MBO

- Pre-MBO (2014-2016): n=106
- MBO program (2016-2018): n=63

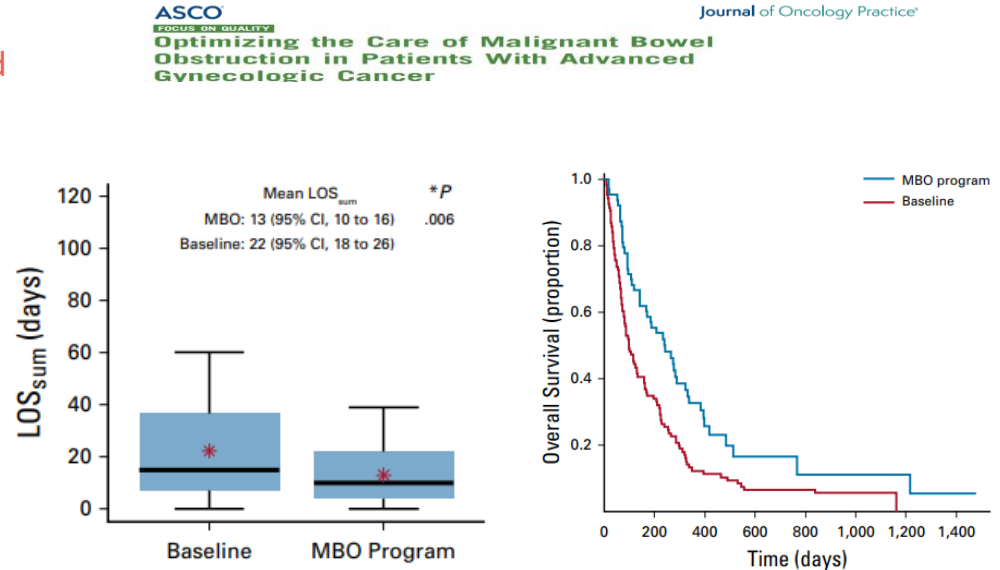
Median OS: 243 v 99 days (p= 0.002)

Cumulative hospital length of stay

- 13 v 22 days, p= 0.006

Cost per hospital admission

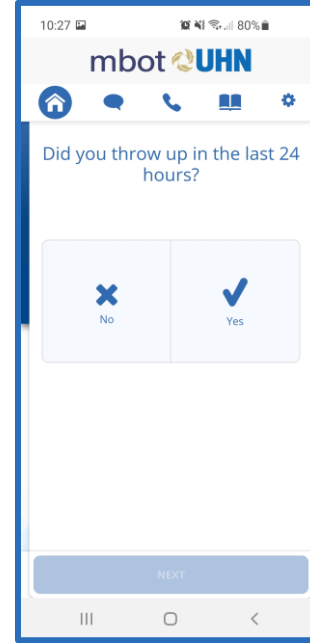
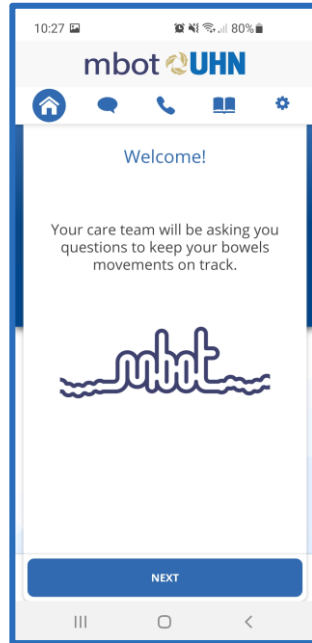
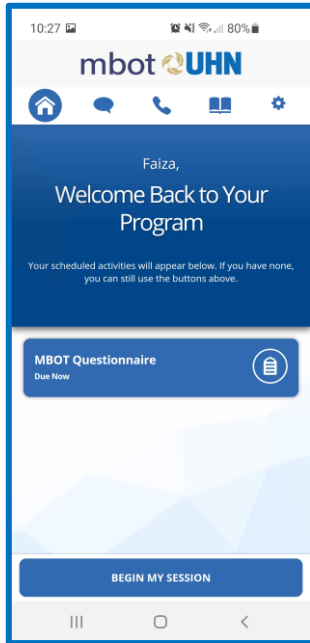
- MBO program: mean \$12,284
- Baseline group: mean \$18,934



Patient reported outcomes in usual care

Toxicity management: malignant bowel obstruction

MBOT: My Bowels On Track



Conclusions



Listen, explore & report potential AEs



Educate about what to expect



Build a support system



Role of remote monitoring & AI

Proactive assessment of patient reported outcomes improves overall survival in patients with advanced cancer.

Thanks!



Our Patients
Nurses
Physicians
Trials Team
Research Team
Grant Agencies

SEOM
Sociedad Española
de Oncología Médica

CONQUER CANCER®
THE ASCO FOUNDATION



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