MEFANET @ AKUTNĚ.CZ

From Reliable Data to Informed Decisions

Evidence for Patient Education



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CHOICE BREAST CANCER LITERACY | Co-funded by the European Union

#healthydata | iba Institute of Biostatistics and Analyses

The woman's priorities belong in the decision



Education should help her understand the options and express what matters to her.

Three sources for educational design

SURVEY

407 women

246 in Arm A
161 in Arm B

INFORMATION ENVIRONMENT

External information

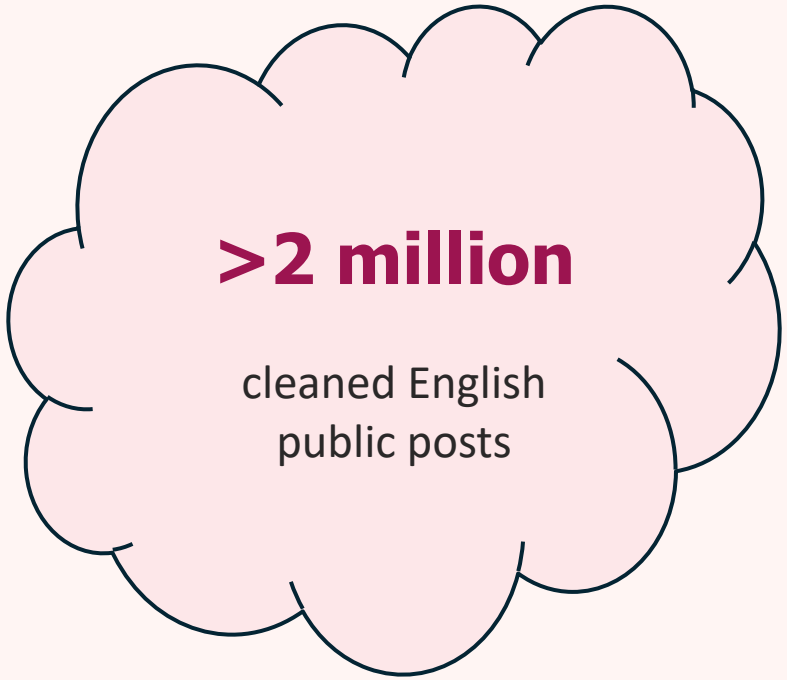
Public online posts

STAKEHOLDERS

Experience of care

Contextual observations

External evidence: information environment



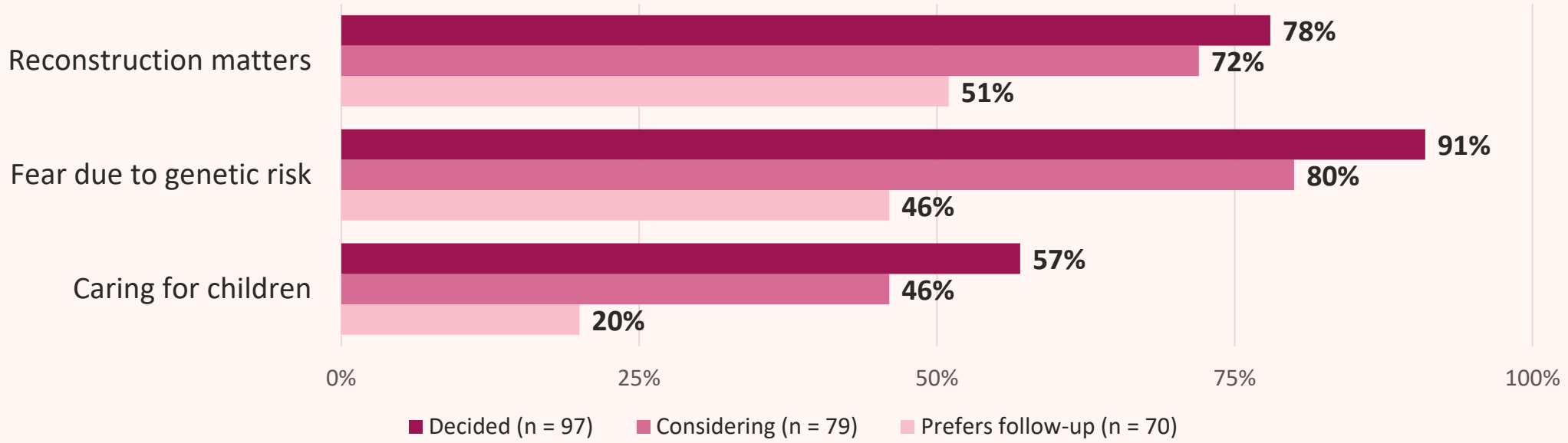
Resource mapping

Information exists across organisations,
with limited integration into decision support.

Online engagement alone does not measure understanding or decision quality.

Women weigh the same issues differently

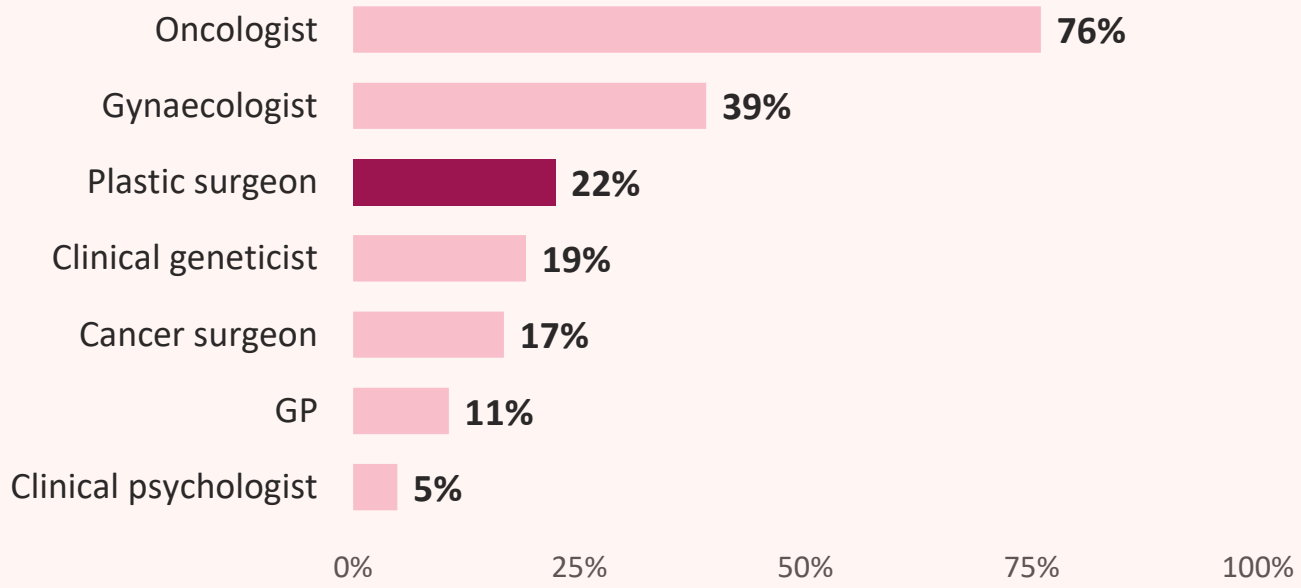
Agreement with selected statements, by attitude to preventive mastectomy

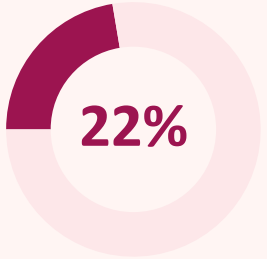


Reconstruction matters to 51% of women who prefer follow-up.

Specialist contact is uneven

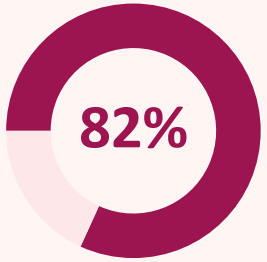
Reported consultations about preventive mastectomy, among all 246 women in Arm A





consulted a plastic surgeon

55 of 246 women



of these women reported an influence

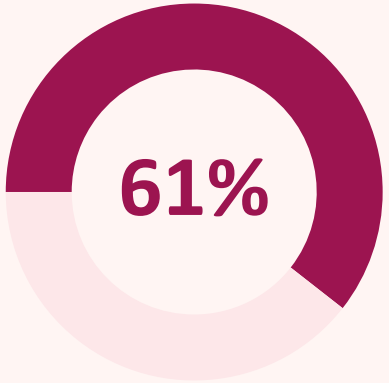
45 of 55 women

The answers describe perceived influence, not a measured effect of the consultation.

Personal contact is the preferred support

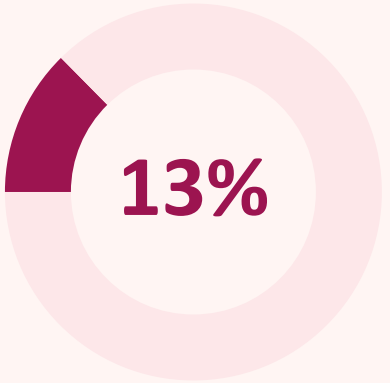
Which type of support would be most suitable when making the decision?

Meeting in person



149 of 246 women

A brochure or website



31 of 246 women

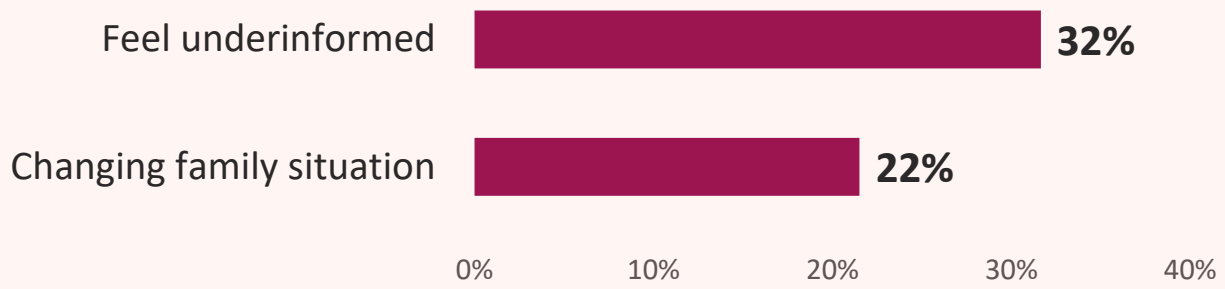
Materials can prepare, guide and extend a conversation.

Reasons for hesitation and preferred support

79 undecided women answered two separate questions

Reasons for hesitation

Why have I not decided yet?



25 of 79 feel underinformed
17 of 79 cite their family situation

Desired support

What would help me most?

25%

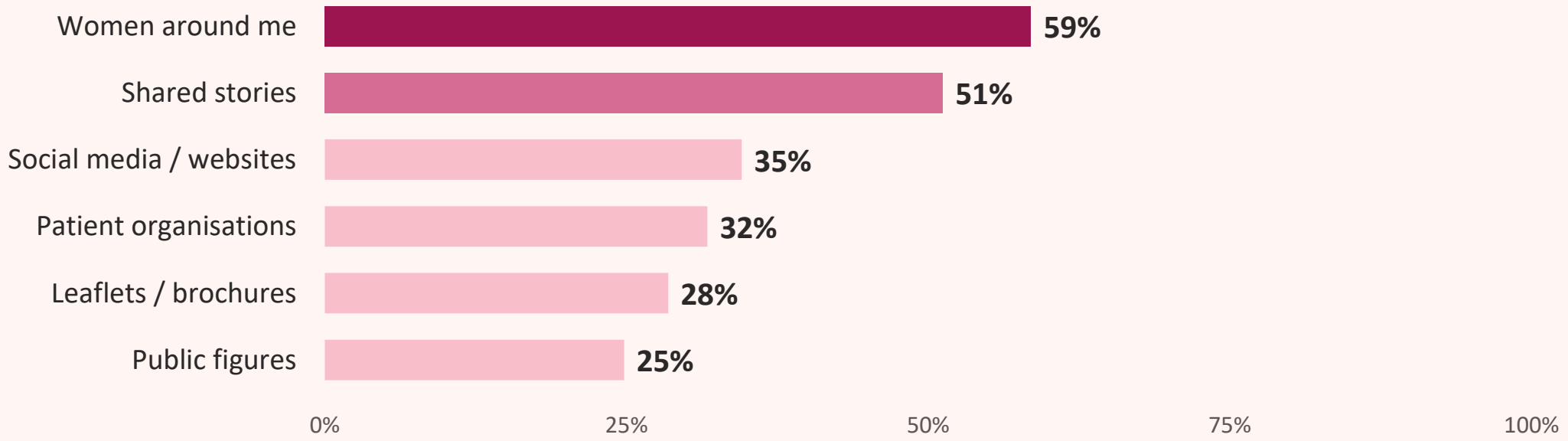
20 of 79 women

A conversation with a woman who has gone through it

Identify what each woman needs from the conversation.

Other women's experiences feature in decisions

Agreement that each source significantly influences the decision, among 246 women



Peer experience needs a place alongside individual clinical advice.

CLADE-IS® within IBA's quality system

Technology developed and used in IBA's ECRIN and EHDEN certification work

ISO 9001

Quality management
and continual improvement

ISO/IEC
27001
27017
27018

Information security
27017 / 27018 for cloud

ECRIN

Clinical data management
and IT

EHDEN

OMOP data mapping
and harmonisation

CLADE-IS® brings these working practices to CHOICE data collection.

CLADE-IS® and IBA data management

A documented path from the questionnaire to an interpretable analysis

Specify

Versioned questions
Language versions
Defined variables

→

Collect

Role-based access
Format checks
Within-form checks

→

Review

Form status
Data review
Documented changes

→

Export

Data dictionary
Analysis cutoff
Defined population

Audit trail:

- A history of data and form-status changes stays linked to the record.
- Impressive vs. reproducible result

Arm B brought an earlier decision into view

The study expanded from prevention choices to the genetic-testing pathway

Arm A

246 women

Confirmed BRCA1/2/PALB2

Risk-reducing mastectomy, reconstruction and personal priorities

Arm B

161 women

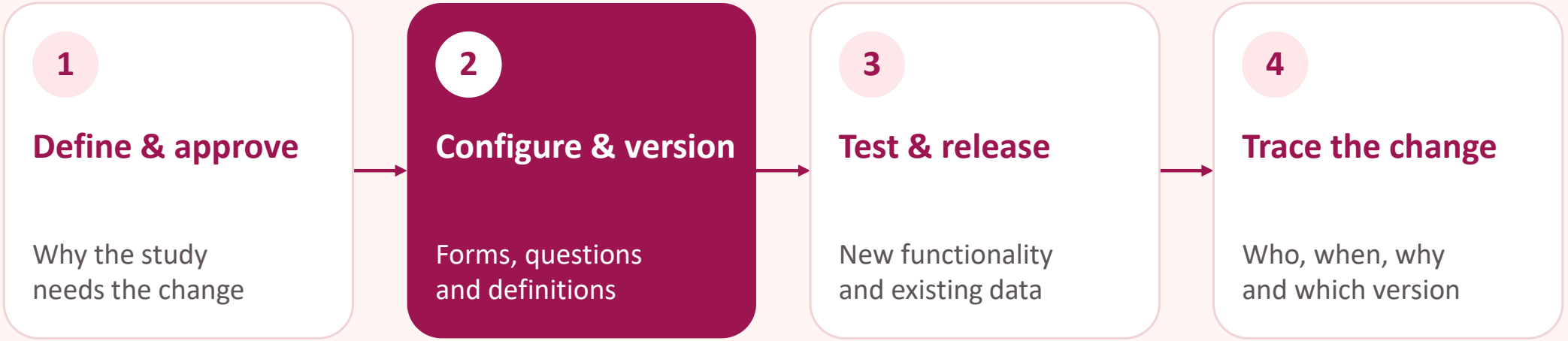
Before a confirmed result

Information, access and the decision about genetic testing

The platform adapted while the two decision questions stayed distinct.

Flexibility through controlled change

The Arm B expansion illustrates why a configurable platform needs a documented process

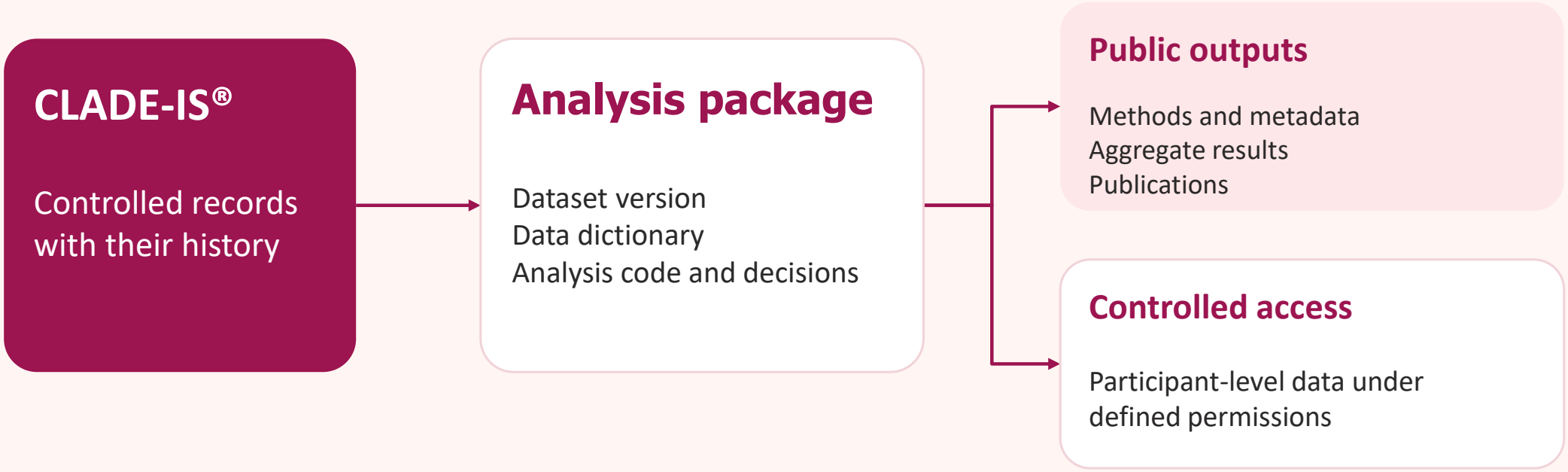


GCP principles keep adaptation accountable and protect data integrity.

- CHOICE DMP §3.11: F88 modification request and F89 eCRF Tracker. ICH E6(R3) §4.3.4: risk-based validation of changes.

Reproducible evidence and responsible sharing

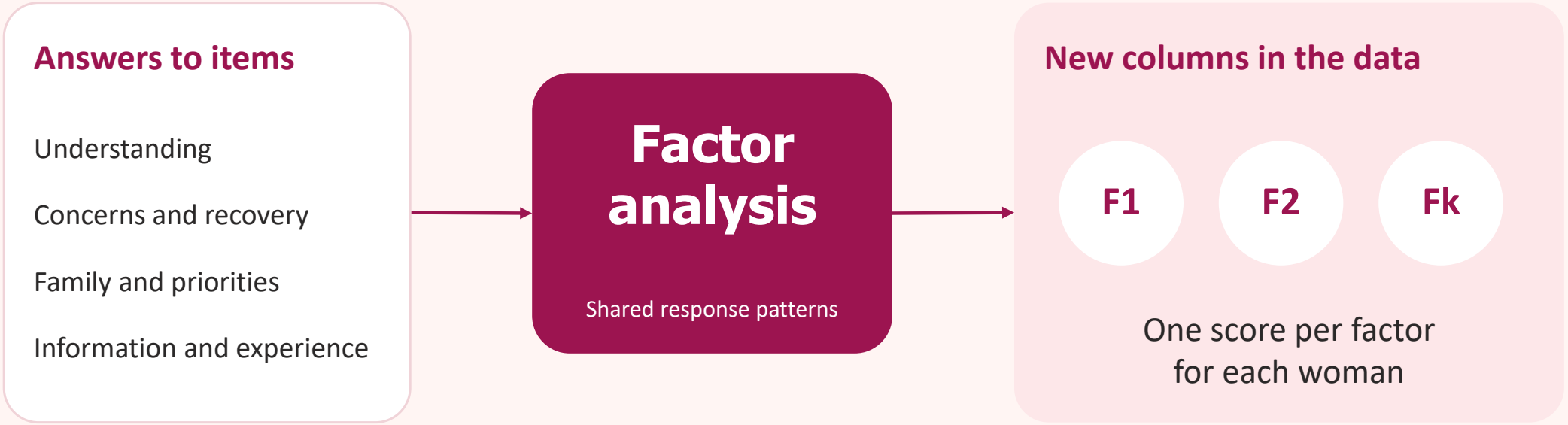
Open science builds on documented data, methods and access conditions



FAIR: findable outputs, clear access rules, shared definitions and reusable methods.

Factor analysis creates new variables

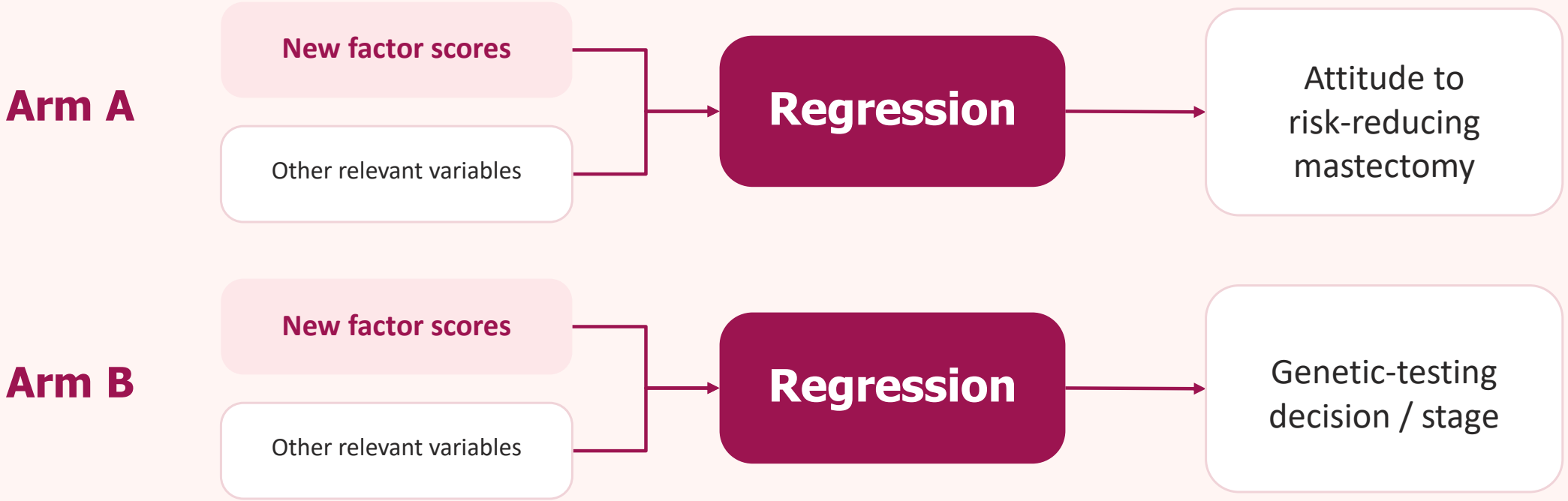
43 common Likert items in Arm A provide the initial pool; Arm B has its own item set



The new variables summarize shared variation across the original answers.

Factor scores and other variables enter regression

Each arm has its own factors, covariates and decision outcome



Which factors are associated with the decision?

- Work in progress.
- Estimated scores carry uncertainty.
- Regression estimates adjusted associations, not causal effects.

Materials should support each role

Learning tasks informed by data evidence and stakeholder observations

The woman

What matters to me?

Prepare questions
Describe priorities
Identify practical needs

The clinician

What advice fits her?

Explain individual trade-offs
Elicit priorities
Offer relevant specialists

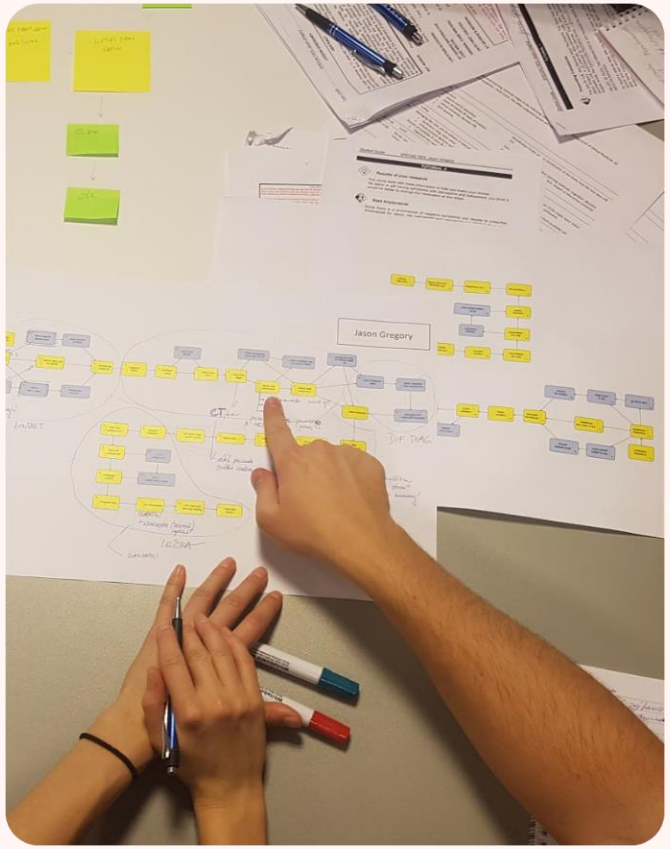
The peer supporter

What can my experience offer?

Describe lived experience
Acknowledge differences
Refer clinical questions

Question prompts, consultation guides and balanced peer stories.

Rehearsing a conversation with a virtual patient



Breaking bad news

AKUTNĚ.CZ®

Assoc. Prof. Vojtěch Peřina, MD, PhD, Simon Trnka, MSc, Barbora Pecková, Sabina Šindlářová

Play the virtual scenario | Česky | Test your knowledge

Situations in which it is necessary to deliver bad news to a patient or their relatives usually expose doctors or other healthcare professionals to increased emotional stress. In clinical practice, healthcare professionals of any specialty may face the need to communicate serious issues with patients or their families at varying degrees of intensity. Standardized procedures, particularly the SPIKES protocol, have been developed to help manage these difficult situations effectively. This algorithm outlines the individual steps of the SPIKES protocol.

2026 | Bad news | SPIKES protocol | Emotions | Support | Published at: 28.8.2026

What should improve in the next consultation?

- Can the woman explain her options and say what matters to her?
- Can the clinician recognize her priorities and connect her with the right expertise?



Reliable data guide the content.
Evaluation shows whether the education helps.

- NZIP and the tools presented next can carry content built around these learning goals.

Reference: analysis populations

Different subsets need explicit denominators

Population	N	Use
Arm A, all countries, BRCA1/2/PALB2	246	Main descriptive results
Arm A, BRCA1/2 subset	212	BRCA1/2-only analyses
Arm A, Czechia, all variants	202	Subset of the main sample
Arm B, all / analysis subset	161 / 147	Definitions must accompany models
Earlier HADEA Czech sample	139	Earlier descriptive snapshot

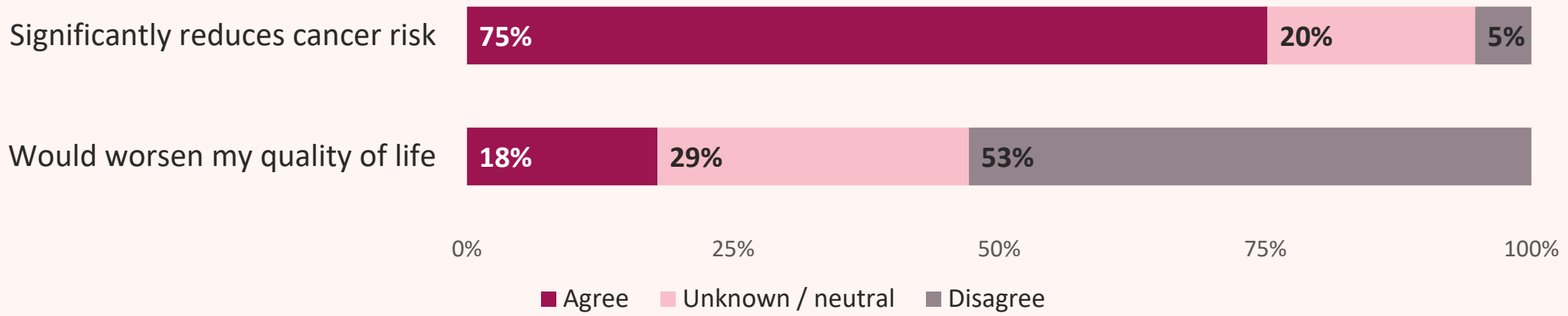
Country and clinical-history composition differ. The earlier HADEA sample is not a matched follow-up cohort.

Reference: choices in the modelling plan

Measurement	Ordinal coding, unknown / neutral answers, applicability, factor stability and reliability.
Outcome	Define the decision categories separately within each arm.
Complexity	Use a justified predictor set. Avoid duplicating factors with all their source items.
Interpretation	Report uncertainty, missingness and stability. Consider confounding and timing.

Reference: beliefs about benefit and quality of life

Two separate statements, among all 246 women in Arm A



Risk reduction: 185 agree, 48 unknown / neutral, 13 disagree.
Quality of life: 44 agree, 72 unknown / neutral, 130 disagree.

WP2, Table 3.21. Counts determine percentages. Unknown and neutral are combined in the questionnaire and cannot be separated here.

Sources and acknowledgements

WP2	IBA descriptive report, export 2 Nov 2026 CHOICE questionnaire, eCRF, DMP and Data Entry Manual Likert plots
WP3	Brno WP3 Insights (NOVA IMS) and Midterm Results Report D3.1 Mapping Report
Frameworks	ICH E6(R3), IBA certification sources Open-science and factor-score methodology

Co-funded by the European Union. Views and opinions expressed are those of the author(s) only and do not necessarily reflect those of the European Union or HaDEA. Neither the European Union nor the granting authority can be held responsible for them.

Different needs among undecided women

79 women were collecting information and had not yet decided

32%

25 of 79

A stated reason for hesitation

Feel underinformed

25%

20 of 79

The help they would value most

Want a peer conversation

22%

17 of 79

A stated reason for hesitation

Changing family situation

Identify what each woman needs from the conversation.

WP2, Table 3.28. Percentages recalculated within n = 79. The first and third values concern hesitation; the middle value concerns desired help.