Implementation of public health genetic interventions

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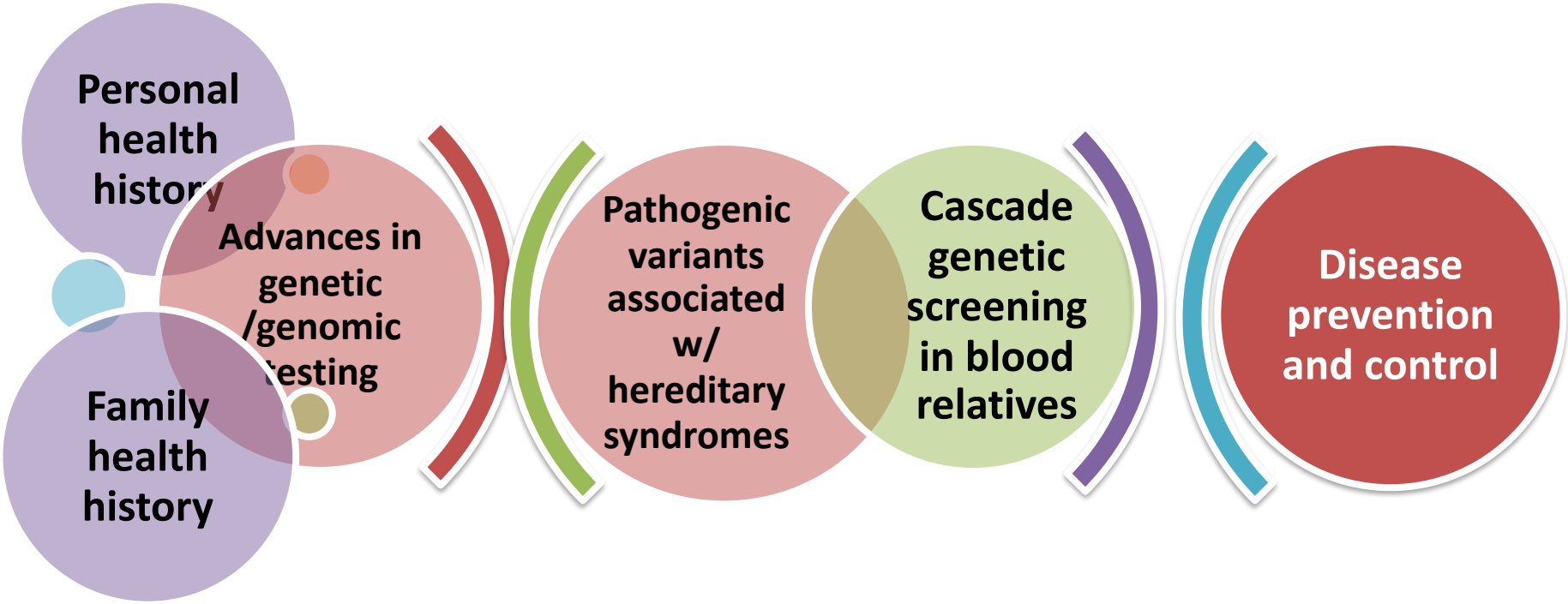
Personal and Family History, and Genetic Testing - Tools for Disease Prevention and Control



Personal and Family History and Genetic Testing - Tools for **Cancer** Prevention and Control

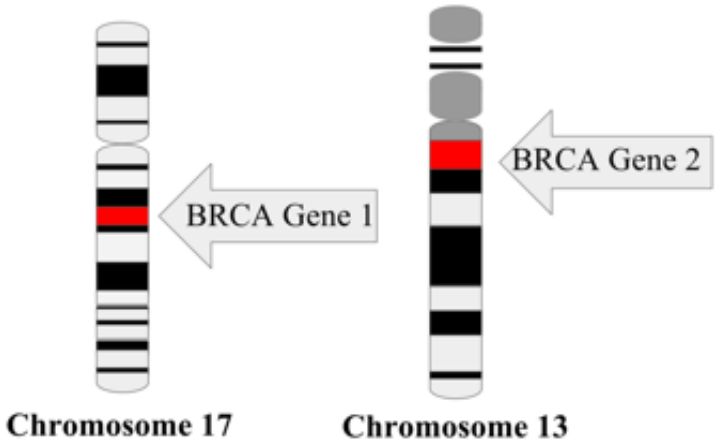
About 2%-15% of breast, colorectal, endometrial, ovarian cancer cases are due to inherited syndromes

Approximately 1,800 new cases per year in Switzerland

- Very high probability for >1 cancer
- Early age onset <45 → consequences for life trajectory / finances
- Biological impact on blood relatives (FDR, SDR, First Cousins)

  (12.5% - 50% probability for inheriting the pathogenic variant)

Hereditary Breast/Ovarian Cancer - HBOC



Monogenic disorder - autosomal dominant germline mutations

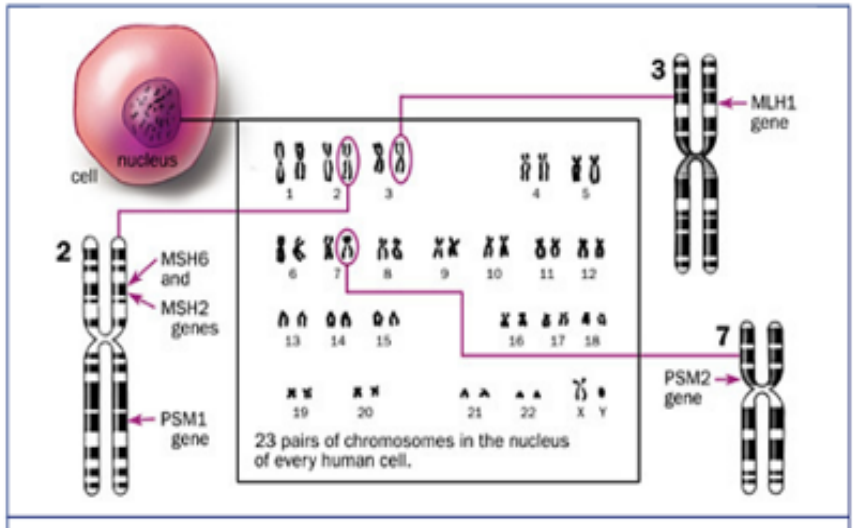
Primarily *BRCA1*, *BRCA2*, *PALB2*

Cancer Type	General Population Risk	Mutation Risk BRCA1	Mutation Risk BRCA2
Breast	12%	50%-80%	40%-70%
Second primary breast	3.5% within 5 years Up to 11%	27% within 5 yrs	12% within 5 yrs 40%-50% at 20 yrs
Ovarian	1%-2%	24%-40%	11%-18%
Male breast	0.1%	1%-2%	5%-10%
Prostate	15% (N. European origin) 18% (African Americans)	<30%	<39%
Pancreatic	0.50%	1%-3%	2%-7%

Tumor suppressor genes

Produce proteins that repair damaged DNA. Mutations in these genes lead to the accumulation of genetic defects that allow cells to grow and divide uncontrollable.

Lynch Syndrome



Carcinoma	Lynch syndrome, %	General population, %
CRC – males	54–74	5
CRC – females	30–52	5
Endometrial cancer	28–60	2
Ovarian cancer	6–7	1
Gastric cancer	6–9	<1
Cancer of the small bowel	3–4	<1
Pancreatic cancer	<1–4	1
Cancer of the hepatobiliary tract	1	rare
Cancer of the urogenital tract	3–8	rare
Brain cancer	2–3	<1
Sebaceous skin tumor/keratoacanthoma	1–9	rare

Monogenic disorder – autosomal dominant germline mutations in DNA mismatch repair (MMR) genes:

- *MLH1* (MutL homolog 1), Chromosome 3p21
- *MSH2* (MutS homolog 2), Chromosome 2p16

} Up to 90%

- *MSH6* (MutS homolog 6), Chromosome 2p16 → ~ 10%
- *PMS2* (postmeiotic segregation 2), Chromosome 7p22

1 in **30** patients with colorectal cancer has Lynch Syndrome

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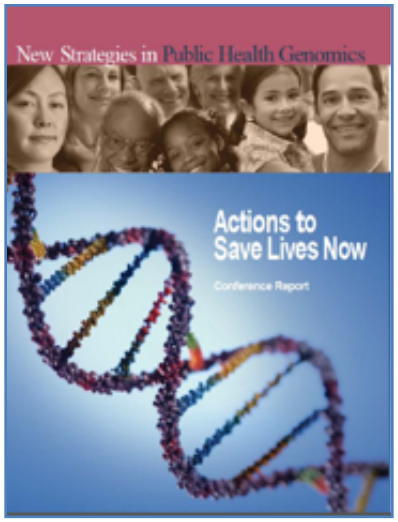
Recommendations for Genetic Screening:
US Preventive Services Task Force and Centers for Disease Control and Prevention

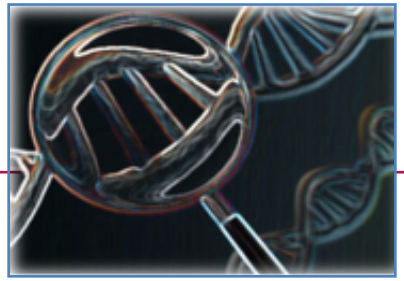
Tier 1 Cancer Genetic Syndromes HBOC, LS

positive impact on public health - evidence-based guidelines

Easily detectable, acceptable, actionable

- Systematic screen personal and family history for HBOC, LS
- If positive, genetic counseling and genetic testing
- If testing positive, counseling for risk management
- **Systematic cascade genetic screening of asymptomatic at-risk blood relatives**





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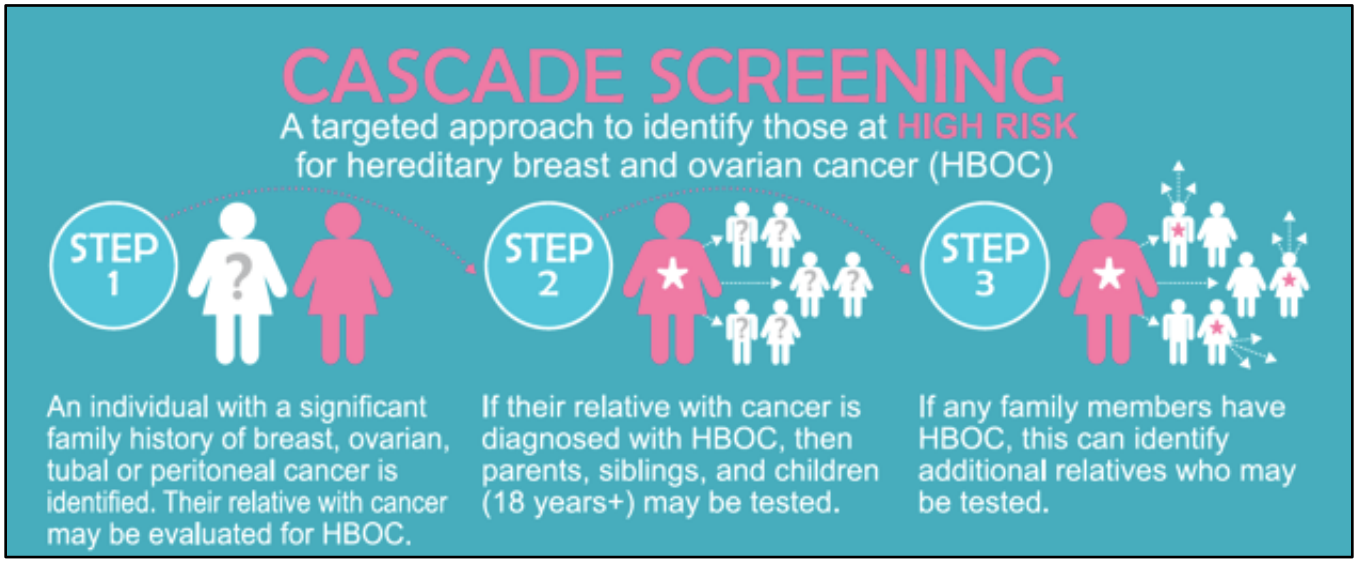
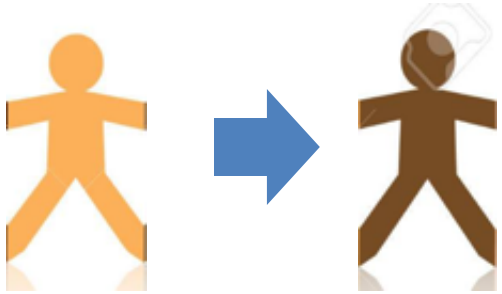
NELSON ET AL. *ANN INTERN MED* 2013; KHOURY MJ, EVANS JP. *JAMA* 2015



- Identify individuals carrying a germline pathogenic variant associated with HBOC or LS
- Extend genetic testing to his/her asymptomatic blood relatives
- Offer risk management options to positive cases and exclude true negatives from increased surveillance



Due to privacy laws, communication of genetic test results to at-risk relatives can be ONLY through the mutation carrier

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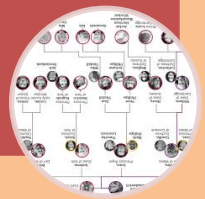
https://www.cancer.gov/publications/dictionaries/genetics-dictionary/def/cascade-screening

Barriers to Cancer Predisposition Cascade Genetic Screening

- SES
- Decision making
- Screening/ disease management
- Family support and communication

Individual - Family



- Lack of genetic/ genomic education
- Clinical management skills

Healthcare providers

- Availability, accessibility, acceptability
- Coordination of services
- Continuation of care
- Legislation, HTA
- Public health awareness

Healthcare – Insurance system

Micro – Meso- Macro- level

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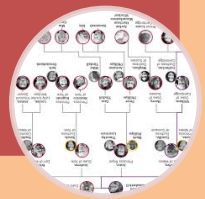

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Screening and Genetic Testing in Young Breast Cancer Survivors and Relatives

Funding: Centers for Disease Control and Prevention (PI: Katapodi, 2011)

University of Michigan and

Michigan Cancer Genomics Program

Community outreach to increase genetic testing and cancer surveillance in women with breast cancer < 45 y.o. and blood relatives

- ✓ Recruitment from Michigan cancer registry
- ✓ Random sample female breast cancer < 45 y.o.
- ✓ Purposeful sample 1-2 relatives (FDR or SDR)/ patient
- ✓ Randomized unit: Family
- ✓ Targeted (generic) vs. Tailored (person-specific) messages

Outcomes for YBCS [a] Tailored n=398 Targeted n=403	Baseline		Follow-up [b]		Tailored vs. Targeted p value [c] (95% CI)	Change from Baseline to Follow-up p value [d] (95% CI)	
	Tailored	Targeted	Tailored	Targeted		Tailored	Targeted
Had Genetic Testing	79 (19.85%)	107 (26.55%)	99 (24.87%)	127 (31.52%)	1.00 (-0.030 - 0.031)	≤0.001[e] (0.031 - 0.077)	<0.001[e] (0.031 - 0.076)
Had CBE according to NCCN [a] Guidelines	342 (85.92%)	333 (82.63%)	361 (90.70%)	356 (88.33%)	0.66 (-0.040 - 0.023)	<0.001[e] (0.029 - 0.074)	<0.001[e] (0.037 - 0.084)
Had mammography according to NCCN [a] Guidelines[f]	298 (87.64%)	292 (87.16%)	315 (92.65%)	302 (90.15%)	0.17 (-0.009 - 0.033)	<0.001[e] (0.029 - 0.079)	0.002[e] (0.014 - 0.074)

Outcomes for Relatives Tailored n=239 Targeted n=192	Baseline		Follow-up [b]		Tailored vs. Targeted p value [c] (95% CI)	Change from Baseline to Follow-up p value [d] (95% CI)	
	Tailored	Targeted	Tailored	Targeted		Tailored	Targeted
Had Genetic Testing	9 (0.04%)	4 (0.02%)	17 (0.07%)	5 (0.03%)	0.08[f] (-0.001 - 0.038)	0.005[e] (0.013 - 0.065)	1[e] (0.000 - 0.029)
Had CBE according to NCCN [a] Guidelines	179 (74.89%)	146 (76.04%)	204 (85.36%)	161 (83.85%)	0.44 (-0.032 - 0.002)	<0.001 (0.069 - 0.151)	<0.001[e] (0.044 - 0.325)
Had mammography according to NCCN [a] Guidelines[f]	109 (69.87%)	87 (71.31%)	126 (80.77%)	96 (78.69%)	0.43 (-0.039 - 0.110)	<0.001[e] (0.065 - 0.348)	0.004[e] (0.014 - 0.133)

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Cancer Genetic Services in Switzerland

- **11% of all Swiss breast cancer patients have genetic testing**
- **25% of breast cancer patients with a strong family history**
- **Lower numbers for Lynch syndrome**

FERLAY J ET AL. *INT J CANCER* 2015; ALLEMANI C ET AL. *LANCET* 2015; SCHOUMACHER F ET AL. *SWISS MED WKLY* 2001; BOUCHARDY, C. *SCHWEIZER KREBSBULLETIN* 2015;

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FNSNF
Swiss National Science Foundation

krebsforschung schweiz
recherche suisse contre le cancer
ricerca svizzera contro il cancro
swiss cancer research

CASCADE

- **CASCADE Consortium (est. 2016)** - working association researchers, clinicians, community professionals, educators, students
- **Goals** are to:
  - ✓ Support research related to cancer predisposition genetic screening and care continuum
  - ✓ Foster collaboration among health - community professionals
  - ✓ Disseminate scientific advancements - scientists, practitioners, patients, families, healthcare institutions, and involved stakeholders
  - ✓ Foster the development of researchers and clinicians through mentorship, access to data, and collaborative studies

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CASCADE

Settings

Basel

Bern

Delemont

Geneva

Lugano

St. Gallen

Biostatistics
Epidemiology
Health Services Research
Public Health

Gastroenterology
Genetic Medicine
Gynecology
Obstetrics
Oncology

Anthropology
Health Communication
Nursing
Psychology
Sociology

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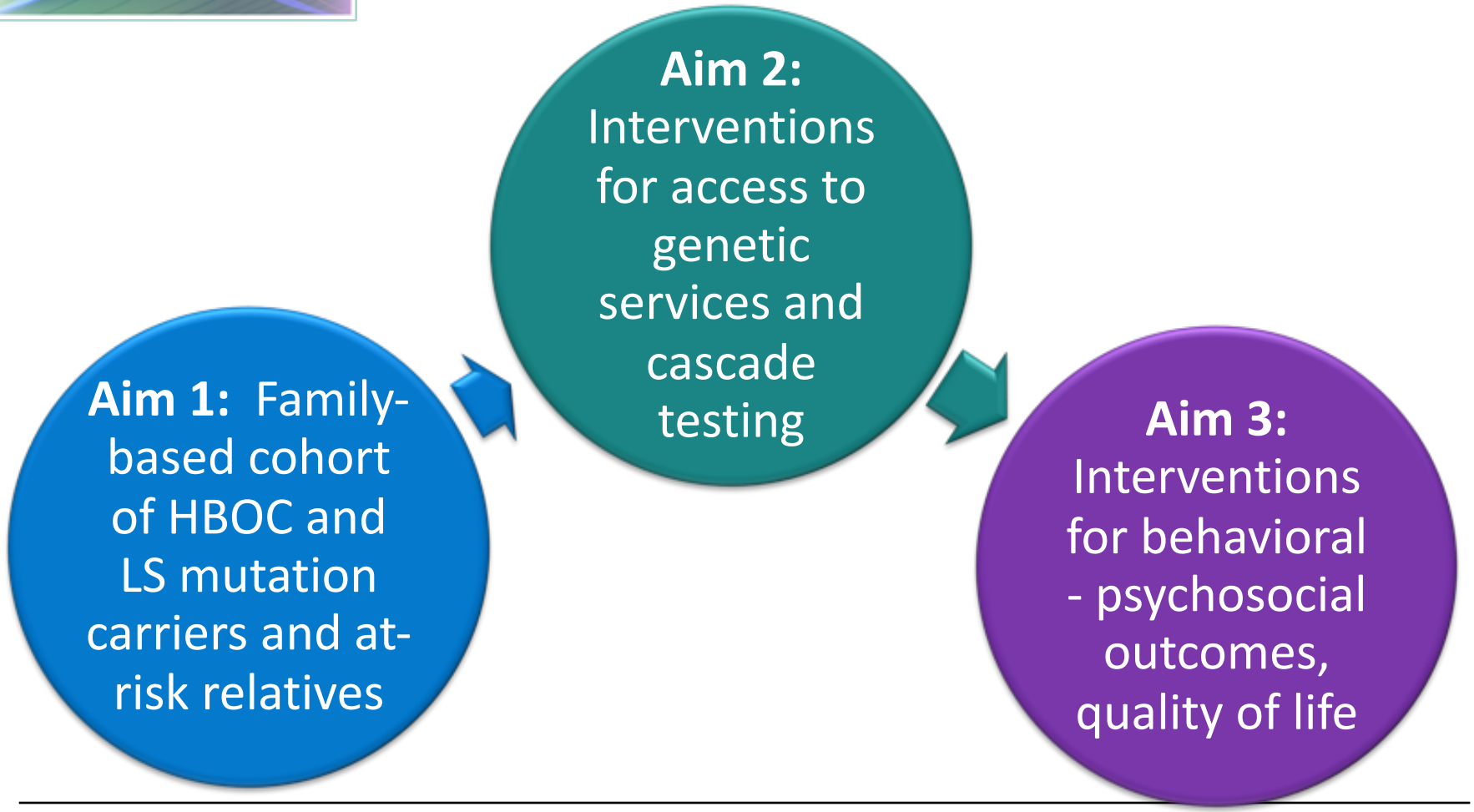
CASCADE

Cancer Predisposition Cascade Genetic Screening in Switzerland
Hereditary Breast/Ovarian Cancer & Lynch Syndromes



Katapodi, MC et al. *JMIR – Res Protocols* 2017

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swiss cancer research

CASCADE

Cancer Predisposition Cascade Genetic Screening in Switzerland
Hereditary Breast/Ovarian Cancer & Lynch Syndromes

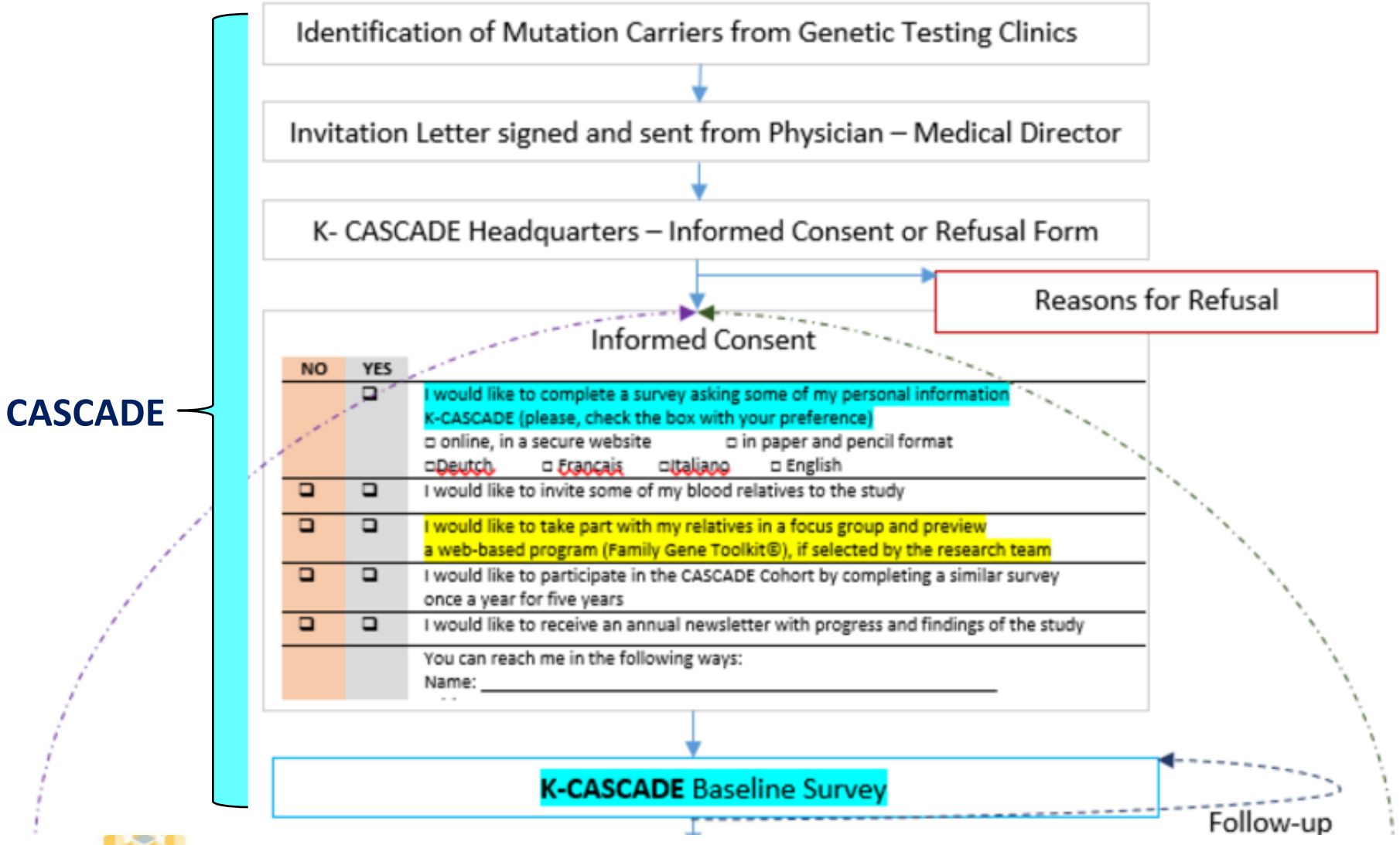
Aim 1: Family-based cohort of HBOC and LS mutation carriers and at-risk relatives

(confirmed mutation carriers, untested relatives, true negatives)

Benefits of family-based cohort:

- enriched for hereditary cancer risk
- captures risk associated with family history in distant relatives and age of cancer onset
- study gene-environment interactions at heterogeneous levels of risk
- behavioral and psychosocial outcomes
- practices related to cancer screening and risk reduction
- facilitate translation of research findings into clinical practice

Flow of Assessments



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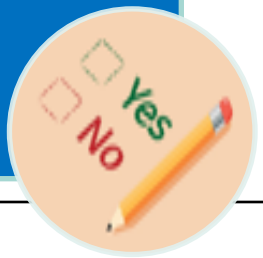
CASCADE

Cancer Predisposition Cascade Genetic Screening in Switzerland
Hereditary Breast/Ovarian Cancer & Lynch Syndromes

Aim 1: Family-based cohort of HBOC and LS mutation carriers and at-risk relatives

- Demographics
- Clinical characteristics
- Cancer status
- Surveillance
- Access - barriers to services
- Decision making
- Family engagement
- Quality of life

Surveys



- Perceptions about providers' role and communication of genetic cancer risk
- Disclosure of genetic risk to at-risk relatives
- German, French, Italian

Focus groups - Interviews

Characteristics of Participants (April 2020)

	HBOC n=243	Lynch Syndrome n=50
Female	202 (83%)	30 (60%)
Caucasian	200 (82%)	40 (80%)
Cancer Diagnosis	121 (50%)	38 (76%)
Breast	77 (64%)	2 (5%)
Ovarian	26 (22%)	4 (11%)
Pancreatic		1 (2%)
Colorectal	2 (2%)	24 (63%)
Had genetic testing	(85%)	49 (98%)
Pathogenic variant	189 (92%)	44 (90%)
FDR (survey data)	1238	
Willing to invite	767 (62%)	
Willing to invite and eligible	702 (57%)	
Accept participation	351 (46%)	

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First Findings (April 2020)

- 65% of mutation carriers shared test results with some relatives
- 40% of mutation carriers do no remember receiving a recommendation for cascade genetic testing of relatives

and

Interviews n=20

- Providers address communication to relatives in a quick and non-detailed way; lack of continuity
- Family communication is complex and selective. It is subject to certain logics (e.g. “protection”) that overshadow the responsibility to communicate
- Females and those with greater genetic literacy are more likely to discuss with closer relatives
- In case of illness, the weight given to family communication is relative due to other concerns and priorities related to own health or to health of closest family members

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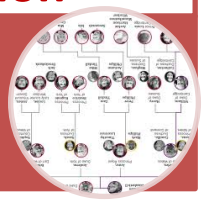
Cascade Genetic Testing

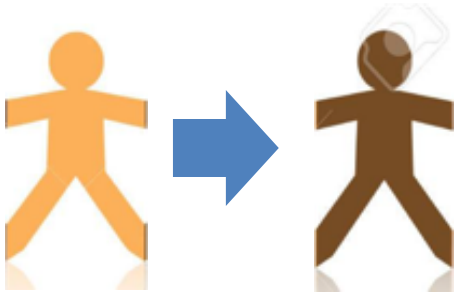
Aim 2: Interventions for access to genetic services and cascade testing

Access to services is a multifactorial problem –
Micro- Meso- Macro- Levels

- SES
- Decision making
- Screening/ disease management
- **Family support and communication**

Individual - Family





Due to privacy laws, communication of genetic test results to at-risk relatives can be ONLY through the mutation carrier

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The DIALOGUE Study:
Using digital health to improve care for families with predisposition to hereditary cancer

SNSF-NRF Innovation Funding Program – Swiss-Korean Bilateral Collaboration

Web-based platform based on the Family Gene Toolkit

M 1: Knowledge of cancer genetics
M 2: Decisional support for genetic testing
M 3: Active coping with challenges
M 4: Skills-building communication training
M 5: Cancer risk management

Dose, duration: self-paced, within 4 weeks

Device agnostic (accessible via PC, mobile, tablet etc.)

Active comparator: www.kintalk.org

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Original Paper

Development of a Web-based Family Intervention for BRCA Carriers and Their Biological Relatives: Acceptability, Feasibility, and Usability Study

Maria C Katapodi[1,2], RN, PhD, FAAN; Miyeon Jung[3], RN, MSc, PhD; Ann M Schafenacker[2], BSN, MSN; Kara J Milliron[4], MSc, CGC; Kari E Mendelsohn-Victor[2], MPH; Sofia D Merajver[5,6], MD, PhD; Laurel L Northouse[2], RN, PhD, FAAN

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Abstract

Background: Carriers of breast cancer gene (*BRCA*) mutations are asked to communicate genetic test results to their biological relatives to increase awareness of cancer risk and promote use of genetic services. This process is highly variable from family to family. Interventions that support communication of genetic test results, coping, and offer decision support in families harboring a pathogenic variant may contribute to effective management of hereditary cancer.

The DIALOGUE Study: Adaptation of the Family Gene Toolkit

Focus groups basis for adaptation and tailoring of Family Gene Toolkit

Expert clinicians n = 6-10

HBOC carriers (n=10 -12) and at-risk relatives (n=10 -12)

Usability testing (n = 5-6): “Think aloud” method

Acceptability testing (n= 5-10): Clarity, appropriate length, level of detail, relevance, interest, satisfaction

1-7 Likert scale

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The DIALOGUE Study:
Message Tailoring

Targeted (generic) messages

- Limited variability in predictors

Tailored (person-specific) messages

- Variability in predictors
  - Identify predictors based on theory of stress and coping and family adaptation in genetic illness
  - Select predictors for tailoring based on variability of responses from focus groups and surveys

Strategy	Sample message (tailored elements in **bold**)
Personalization	
Cancer type	When someone has **ovarian cancer**, it affects the whole family, especially her **underage children**
Mutation	***BRCA2*** mutations can be passed on to **sons** and **daughters**
Feedback	
Active coping	When you face difficult situations, you often **try to find more information**
Passive coping	When you face difficult situations, you often **like to withdraw and not discuss about the problem**

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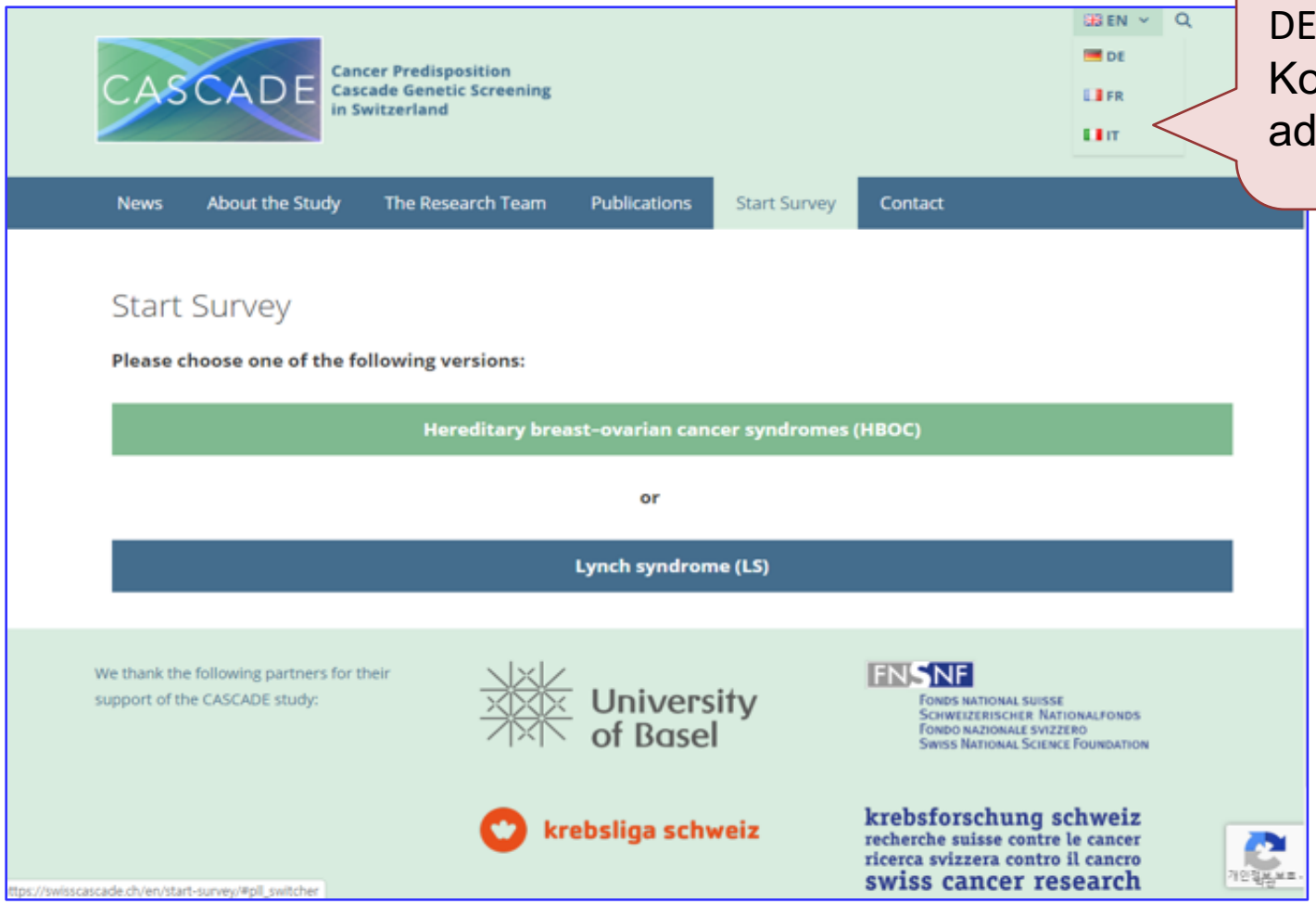
https://swisscascade.ch or https://k-cascade.kr

Four languages
DE, FR, IT, EN
Korean to be added



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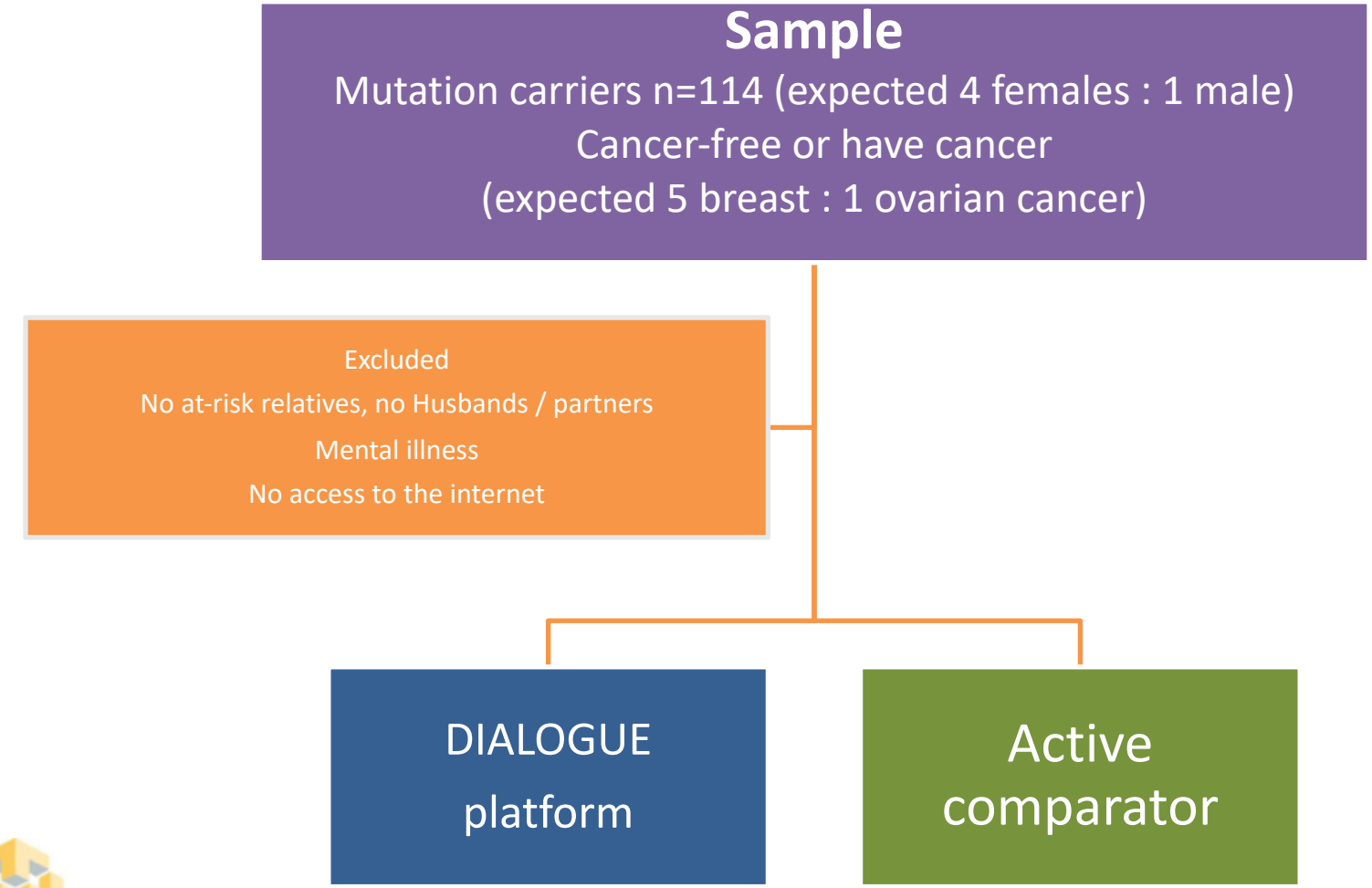
The DIALOGUE Study:

Cluster RCT for efficacy of adapted DIALOGUE platform

Randomization at the family level



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The DIALOGUE Study:

Primary and secondary outcomes at 2 and 6 months

Concepts	Instruments	Cronbach's alpha	Test- Retest Reliability	Assessment	
				Baseline	Follow Up
PRIMARY OUTOMES					
Psychological distress	Profile of Mood States (POMS-SF) (103) 37 items, 7-point Likert scale	0.82-0.91	-	√	√
Proportion of informed relatives	Self-Report	N/A	N/A	√	√
Intention to inform relatives	Informing Relatives Inventory (102) 68 items, 7-point Likert scale	0.82-0.92	-	√	√
Intention to have genetic testing (applicable for untested relatives)	1 item, 7-point Likert scale	N/A	N/A	√	√
SECONDARY OUTCOMES					
Knowledge of breast cancer risk factors and genetics	Risk Factor Knowledge Index (38) 17 items, True, False, Don't Know	0.89	0.85	√	√
	Breast Cancer Genetics Index (104) 12 items, True, False, Don't Know	0.82	0.81	√	√
Coping with stressful events	Brief Cope (105) 25 items, 7-point Likert scale	0.71-0.90	0.71-0.85	√	√
Decision making	Decisional Conflict Scale – Genetic Testing (106) (for untested individuals) 16 items, 7-point Likert scale	0.96	-	√	√
	Decisional Regret – Genetic Testing (107) (for individuals that had genetic testing 5 items, 7-point Likert scale	0.87	-	√	√
Quality of Life	SF-12 summary score (subdomains will be assessed purely exploratory) (108) 12 items, multiple point Likert scale	0.83	-	√	√
INTERVENTION EVALUATION					
Evaluation of intervention acceptability	Intervention acceptability, interest, usefulness, level of detail, relevance, and satisfaction (92) 15 items, 7-point Likert scale	-	-		√

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The DIALOGUE Study:

Theory-based tailoring variables

Concepts	Instruments	Cronbach's alpha	Test- Retest Reliability	Assessment	
				Baseline	Follow Up
DEMOGRAPHICS					
Demographics, Personal, Family Cancer History	Self-Report (114)	-	-	√	
TAILORING VARIABLES					
Type of relationship - proband and relative(s)	Self-Report	N/A	N/A	√	
Perceived risk	Perceived Cancer Risk (69) 1 item, 10 numerical points w/ verbal anchors	N/A	N/A	√	
Fear of cancer recurrence (for cancer patients)	Concerns About Recurrence Scale (CARS) (109) 4 items, 7-point Likert scale	0.93	0.91	√	
Self-efficacy dealing with cancer (for cancer patients)	Self-Efficacy – Breast Cancer (110) 14 items, 7-point Likert scale	0.80	0.71	√	
Self-efficacy using genetic services (for cancer patients)	Self-efficacy using genetic services 1 item, 7-point Likert scale	N/A	N/A		
Family support	Family Support in Illness (111) 10 items, 7-point Likert scale	0.86	0.83	√	
Family hardiness	Family Hardiness Index (112) 20 items, 7-point Likert scale	0.90	0.78 - 0.86	√	
Satisfaction with genetic counseling (for tested individuals)	Multidimensional Impact of Cancer Risk Assessment (MICRA)(113) 19 items, 7-point Likert scale	0.75 – 0.86	-	√	
Barriers and facilitators for genetic services	Barriers and facilitators for genetic services (37) 11 items, multiple choice	N/A	N/A		

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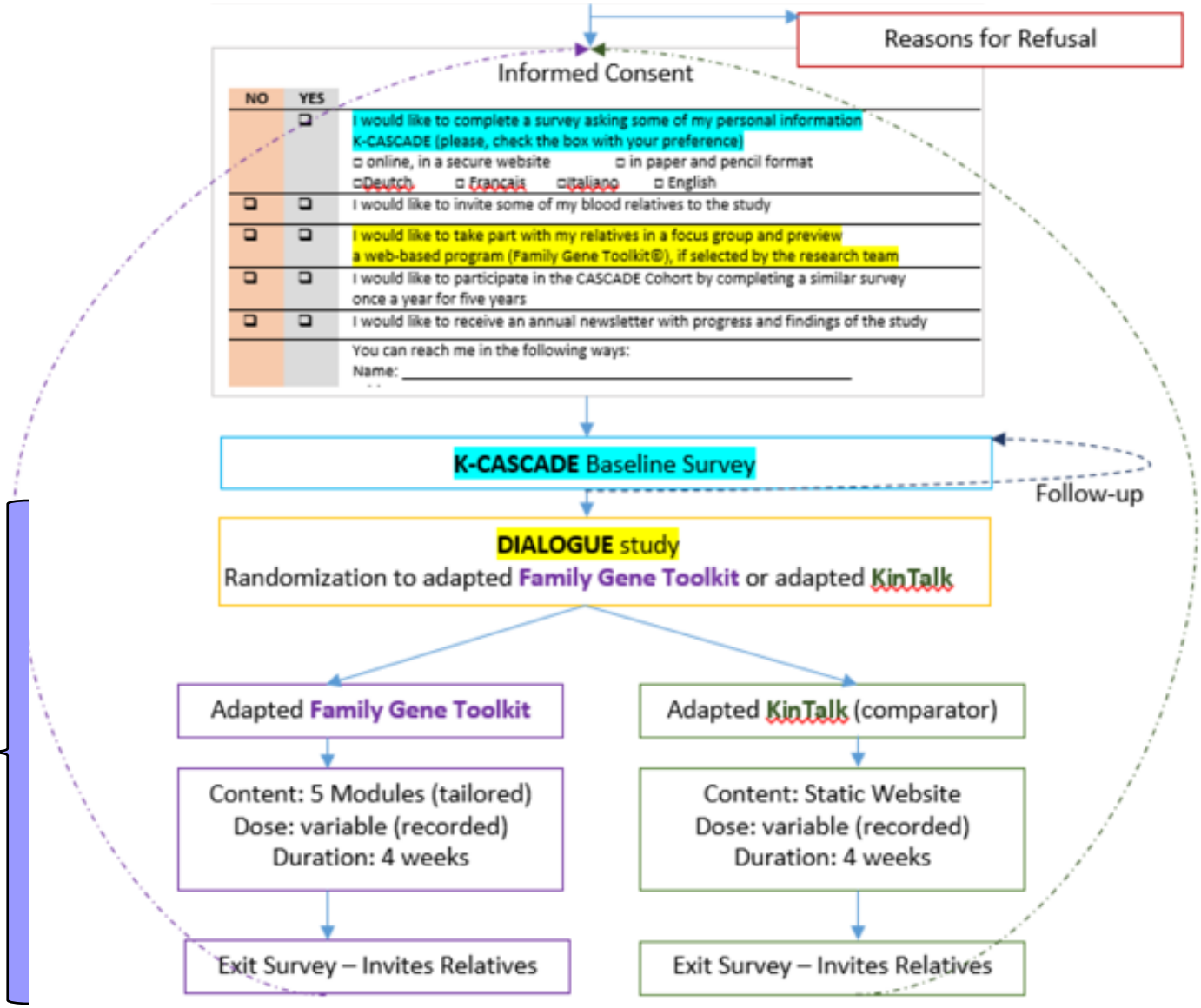
Flow of Assessments



DIALOGUE

The DIALOGUE Study:

Implementation and dissemination of DIALOGUE platform

RE-AIM Framework www.re-aim.org

Maintenance

Individual - Organization

Adoption - Implementation

Organization level

Reach - Effectiveness

Individual level

SSPH+ SWISS SCHOOL OF PUBLIC HEALTH

ETH zürich

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RE-AIM dimension	Definition	Outcomes to be measured throughout the study	Strategies to be implemented to enhance future dissemination and implementation
Reach (individual level)	The absolute number, proportion, and representativeness of individuals willing to participate	• Response rate of mutation carriers • Number of relatives accessing the website(s) • Demographic, linguistic characteristics, region • Response rate to K-CASCADE	• Assess reasons for refusals (refusal form) • Mini-interview with those who decline participation • Help individuals set up free email accounts (Gmail etc.) • Post study advertisers to clinical settings
Effectiveness (individual level)	The impact of the intervention on outcomes, including negative effects, quality of life, economic outcomes, subgroup effects	• Assess times participants accessed each module • Assess number of "relative invites" initiated through the website • Evaluate acceptability, interest, usefulness, level of detail, relevance, and satisfaction at the follow up survey • Evaluate for potentially negative outcomes in the follow up survey (open-ended question) • Assess quality of life for calculating QALYs in future cost-effectiveness analysis	• Individual tailoring and linguistic tailoring • Ongoing technical support to participants • Optimal maintenance of the online platform without interruptions
Adoption (setting, staff, or organization level)	The absolute number, proportion, and representativeness of settings and intervention agents who are willing to participate	• Number of clinicians and clinical settings willing to participate in the study • Diversity (geographic, linguistic, etc.) in participating settings	• Develop recruitment materials for clinical settings outlining the FGT benefits and K-CASCADE • Advertise the program within the SAKK network for Switzerland and the KOHBRA network for Korea • Conduct mini-interviews with participating and non-participating clinical settings and assess the need for further customization
Implementation (setting, staff, or organization level)	The intervention agents "fidelity" to the key elements of an intervention. This includes consistency of delivery as intended, adaptations made, and the time and cost of the intervention.	• Monitor referrals of mutation carriers from different clinical sites • Evaluate the cost for adapting modules for other hereditary cancer syndromes e.g., Lynch syndrome	• Provide demonstrations of the program to clinical settings
Maintenance (individual and setting levels)	The extent to which a program or policy becomes institutionalized or part of the routine organizational practices and policies. At the	• Assess resources needed to maintain the website • Assess number of visits per month/year	• Incorporate HBOC support groups in each country • Seek feedback from clinical settings about rates of cascade genetic testing

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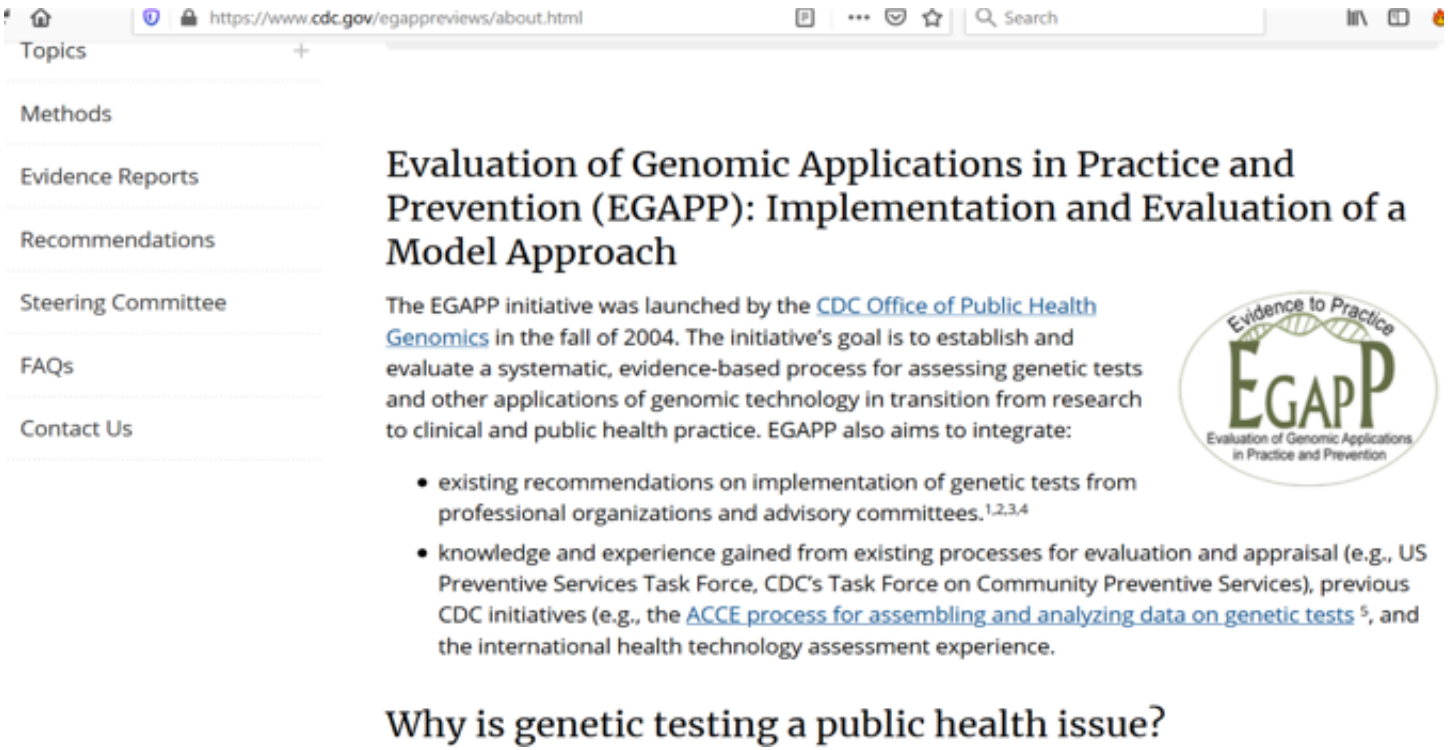
Access to Cascade Genetic Screening in Switzerland

- Biological impact on blood relatives (FDR, SDR, TDR)
  (12.5% - 50% probability for inheriting the pathogenic variant)
- Cost of full sequence genetic testing ~ 3,500 CHF
- Cost of targeted genetic testing ~ 450 CHF
- No insurance coverage for SDR and TDR (50% missed relatives)

- Availability, accessibility, acceptability
- Coordination of services
- Continuation of care
- **Legislation, HTA**
- Public health awareness

Healthcare – Insurance system

Access to Cascade Genetic Screening in Switzerland

- Two studies currently examine the cost-effectiveness of cascade genetic testing for HBOC and LS in Switzerland
- 

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