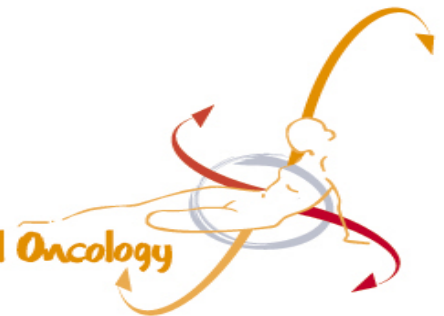


Patients' Perspectives Against COVID-19 Pandemic: Impact on Guidelines

The largest survey, that captures the views, fears and perspectives of patients with gynaecological cancer in Europe

Name: Murat Gultekin



CAREFULL DECISION: CASE BY CASE

- **Elective surgeries during incubation period of COVID-19**

- 34 Asymptomatic Patients
- Median Age: 55
- 100% of the Patients Developed Pneumonia
- 44% Needed ICU
- 21% has died Due to ARDS, Cardiac Arrhythmia etc.

Research Paper

Clinical characteristics and outcomes of patients undergoing surgeries during the incubation period of COVID-19 infection

Shaoqing Lei^a, Fang Jiang^{b,c}, Wating Su^a, Chang Chen^d, Jingli Chen^e, Wei Mei^f, Li-Ying Zhan^g, Yifan Jia^h, Liangqing Zhang^g, Danyong Liu^g, Zhong-Yuan Xia^{h,i}, Zhengyuan Xia^{h,i,j,k}

- **NIHR Global Surgery Unit, Birmingham Study : COVIDSurg-Cancer (Lancet)**

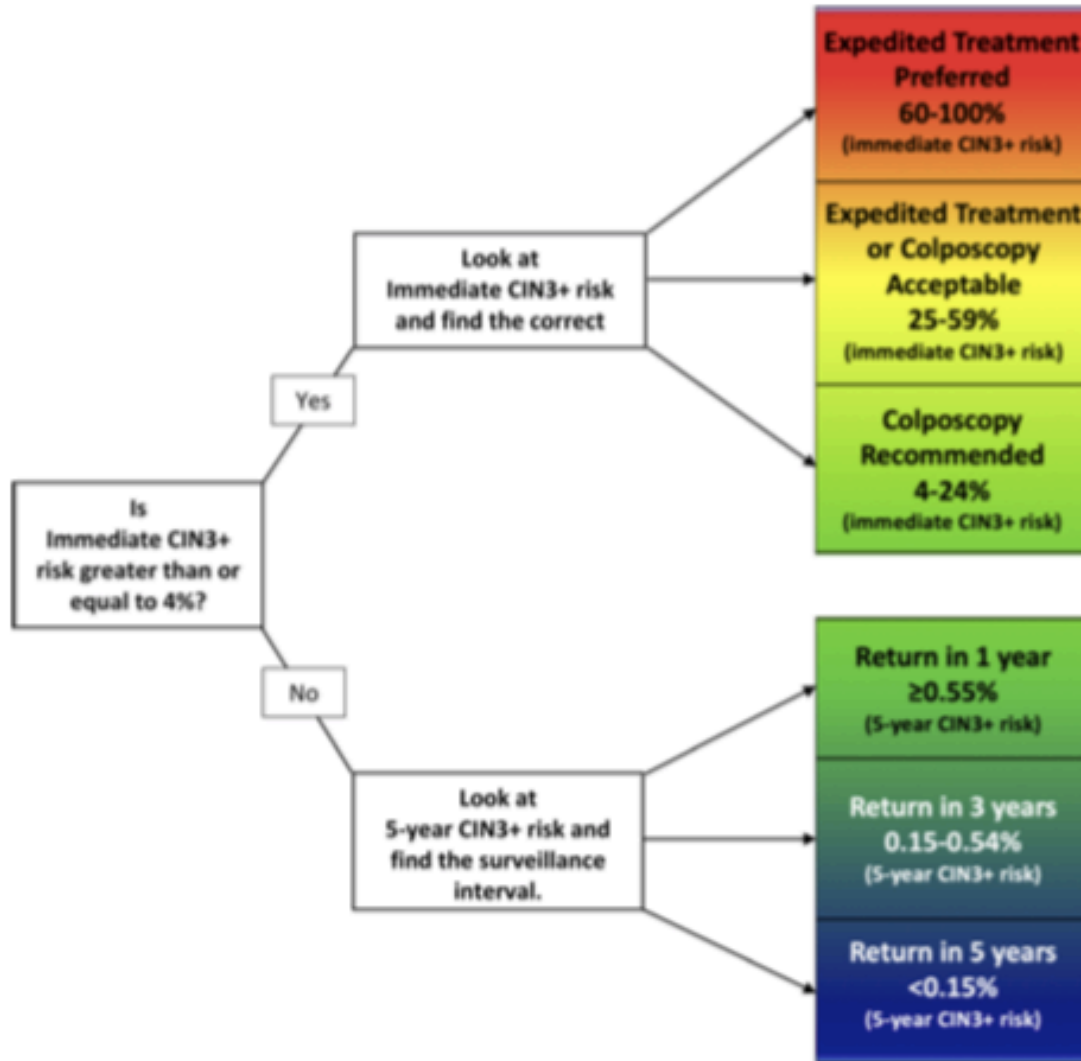
- N= 400 General Surgery Operations, 70% Emergency
 - Post-op 30 Day Mortality: 25%
 - No mortality under age of 50
- COVIDSurg-Gynae

Effect of Covid-19 Pandemic on Prevention

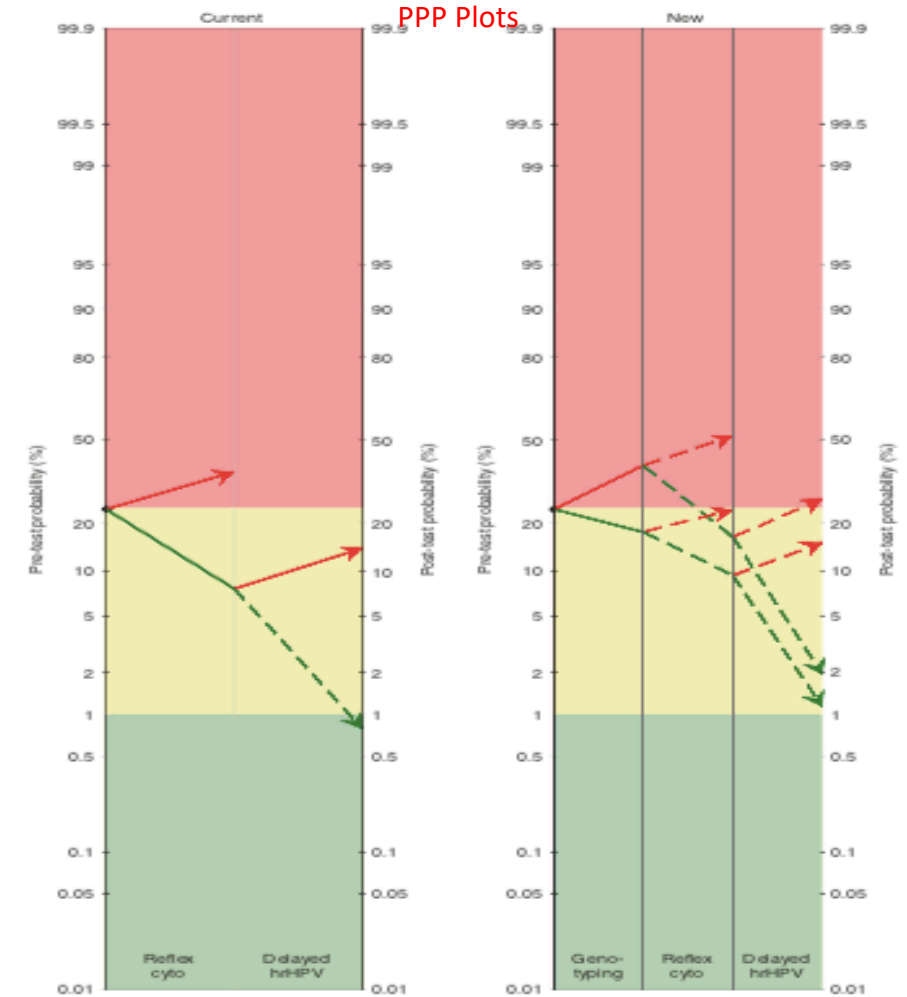
- Great majority of the cases can be post-poned
 - Define a new treshold for colposcopy and treatment treshold
 - This depends on the local conditions in your country and in your hospital
 - Avoid unnecessary visits for screening and vaccination
 - Safety of the patients and medical workers is the first priority
- Real effect will be seen at post-covid period
 - Screening stoped
 - Post-Covid Tsunami
 - Self Tests for prolonged pandemics
 - Economic: Only real cost effective interventions
 - Research Fundings will be limited
 - WHO Cervical Cancer Elimination Program

	Follow Up (mo)	Rates (%)			
		Regression	Persistence	Progression	Complete Remission
CIN I	10	59	27	14	59
CIN 2	7	45	6	19	35
CIN3	7	34	64	2	23
Meta-Analysis, Nekos C,2018, Scientific Reports; 8:6383					

New Risk Stratified Cancer Screening in USA and in Europe : Colposcopy Referral Tresholds: 5%, 10%, 20% Immediate Risk for CIN3+



Norway: Old and New HPV Screening Algorithms



Published Statements : Also Protect Yourself From Malpractice in Long Term

- **American College of Surgeons** : Cervical conization or Loop Electro-Excision Procedure to exclude cancer (Class 3) can be delayed for a few weeks
- **ASCCP** :
 - Individuals with suspected invasive disease should have contact attempted **within 2 weeks** and evaluation within 2 of that contact (4 weeks from the initial report or referral).
 - Individuals with high-grade cervical disease without suspected invasive disease should have documented attempts to contact and procedures scheduled **within 3 months**.
- **BSCCP**: Only women who have had a recent cervical smear suggesting high grade lesions, abnormal cells in endocervical cells or possible glandular neoplasia, or suspicion of invasive disease should be seen for colposcopy.
- **SGO**:
 - SEMI-URGENT (TIER 3A/3B): 1-4 WEEKS
 - Adenocarcinoma In Situ, Suspicious Invasive Cancer with Inadequate Colposcopic Exam

ESGO-EFC Recommendation

- **Vaccine**
 - Countries that decide to suspend the vaccination program will have to implement **additional recall and awareness strategies**, with the aim of not reducing vaccination coverage in the near future.
 - Regarding women who have already started the vaccination schedule, the administration of the subsequent dose could be postponed, provided that the **schedule is completed within 12-15** months from the first dose.

Ciavattini A, Delli Carpini G, Giannella L, Arbyn M, Kyrgiou M, Joura EA, Sehouli J, Carcopino X, Redman CW, Nieminen P, Cruickshank M, Gultekin M. European Federation for Colposcopy (EFC) and European Society of Gynaecological Oncology (ESGO) joint considerations about human papillomavirus (HPV) vaccination, screening programs, colposcopy, and surgery during and after the COVID-19 pandemic. Int J Gynecol Cancer. 2020 Aug;30(8):1097-1100.

ESGO-EFC Recommendations

- **Screening**

- During the suspension period, an accurate list of women who have not been screened should be prepared and continuously updated by each screening center.
 - Virtual consultations
 - Common Statements from National Societies
 - HPV Self-Sampling
 - Telecolposcopy or digital colposcopy
- In patients with a positive high-risk HPV test result; continue with a reflex cytology or recall for cervical cytology
 - According to ESGO meta-analysis on triage:¹
 - The risk of CIN3+ among hrHPV+ women who are HPV16+ is 16% and among those who are HPV16/18+ is 15%, that may need a scheduled reflex cytology within 2 weeks
 - Gultekin et al. 4 Million HPV Screening ²
 - HPV 16+ Risk of CIN2+ 32%
 - HPV (+) with ASC-H, HSIL cytology ; risk varies between 30-40%

- **Colposcopy and Treatment**

- 2 Weeks, 3 Months, 6-12 Months

¹ Eurogin December, 2019, Arbyn M. Et al

² Gyn Oncol, April 2020, Article in Press

ESGO-EFC Recommendations Coming Soon

2-4 WEEKS

- Patients with a cervical cytology result of **“squamous cell carcinoma,” “atypical glandular cells, favor neoplastic (AGC-FN),” “endo-cervical adenocarcinoma in situ,” or “adenocarcinoma”**.
- Patients with histopathological diagnosis of suspected invasive disease from cervical or vaginal biopsy who need excisional treatment to confirm the diagnosis.

3 MONTHS

- Patients with **“high-grade squamous intraepithelial lesion (HSIL),” “atypical squamous cells that cannot exclude HSIL (ASC-H),” or “atypical glandular cells not otherwise specified (AGS-NOS)”** at cervical cytology.
- Patients with a histopathological diagnosis of high-grade intraepithelial lesion without suspicion of invasion from a cervical biopsy (HSIL, CIN2–3), vaginal biopsy (HSIL, VAIN2–3), or a vulvar biopsy/ excision (vulvar HSIL or differentiated VIN)

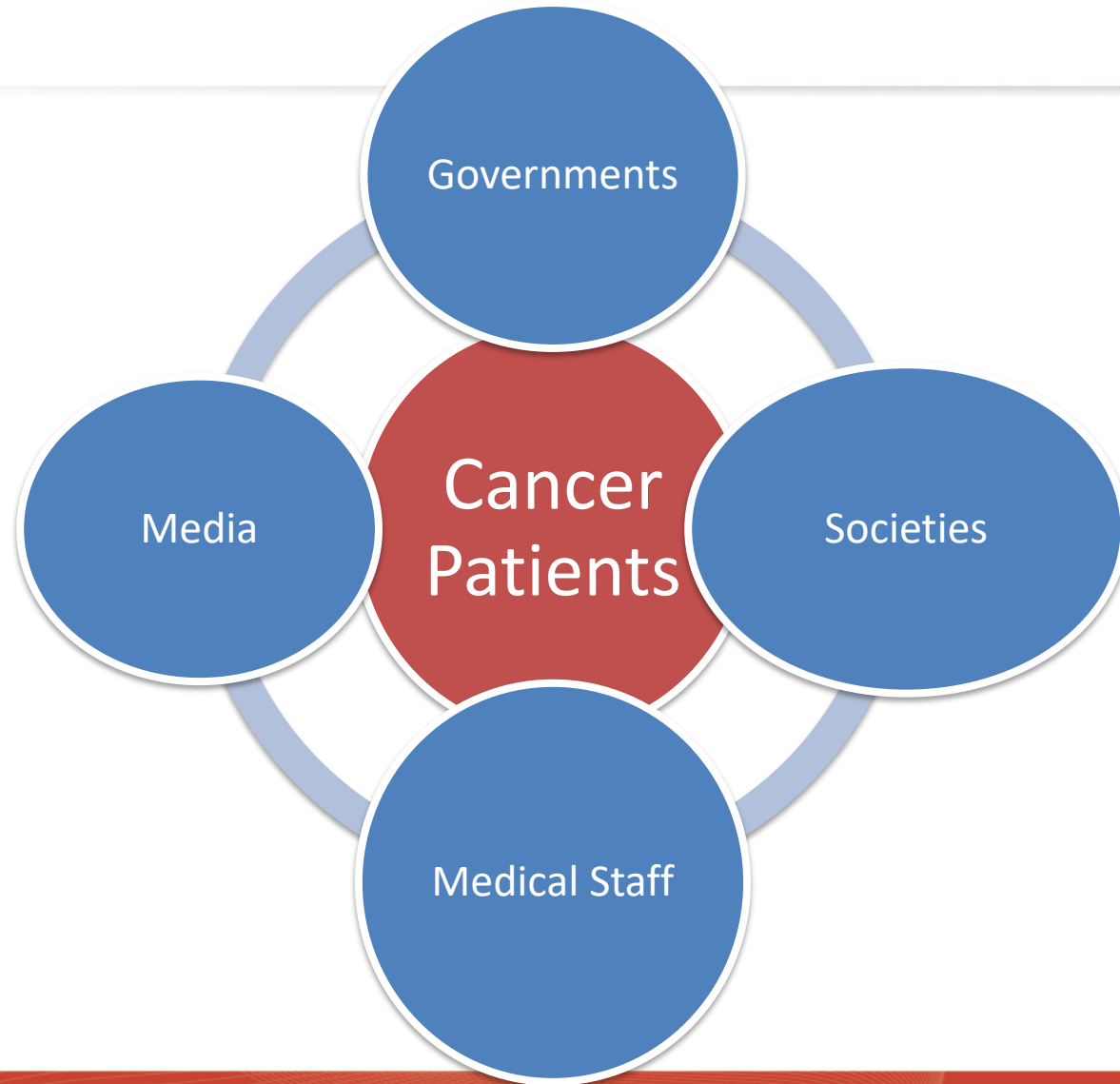
6-12 MONTHS

- Patients with **“positive high-risk HPV test with normal cervical cytology,” “low-grade squamous intraepithelial lesion (LSIL),” or “atypical squamous cells of undetermined significance (ASC-US)”** at cervical cytology or
- Patients with a histopathological diagnosis of low-grade intraepithelial lesion from a cervical, vaginal, or vulvar biopsy/excision

Effect on Invasive Cancer Treatments

- Less radical surgery
- More Chemotherapy (Neo-adjuvant Chemo)
- More oral forms of chemotherapy
- RTX : More fractionized
- Less hospitalization and visits, more teleweb consultations

Windows of COVID Pandemic : Secret Window



- The urgency of the situation required dynamic decision-making processes across all levels, with little or no time to incorporate or even consider any patients perspectives.
- However, increasing cancer deaths are likely to be a major outcome of this pandemic and it is critical that the **patients voice is expressed and presented in a public forum**, so that we can learn from this episode and plan for future waves of COVID-19 or similar crisis

Method of the Study

- This is a **prospective survey** study conducted in 16 European countries, May 1 –May 30
 - France, United Kingdom, Italy, Spain, Greece, Turkey, Czech Republic, Germany, Netherlands, Denmark, Poland, Serbia, Hungary, Belarus, Ireland, Finland
- **All patients** above 18 years of age with gynecological cancers of any stage, histology and type were eligible to participate as long as they were still under active treatment or surveillance.
- Depending on the stage of their treatment journey, patients were divided into 3 categories:
 - **Type 1** with a diagnosis of primary or recurrent cancer scheduled for **surgery**;
 - **Type 2** when receiving **chemotherapy and/or radiotherapy** for primary or recurrent disease (neoadjuvant chemotherapy and maintenance targeted treatment was included here)
 - **Type 3** when under routine oncologic **follow up**.

SURVEY

- Sections:
 - Section A : Demography
 - Section B : Perspectives and Experiences Against COVID
 - Multiple Choice and Open Ended Questions
 - Section C : HADS-Anxiety
 - Section D : HADS-Depression
 - HADS-questionnaires have a maximum score of 21
 - 0 - <8 representing healthy individuals,
 - 8 - <11 borderline
 - ≥ 11 being abnormal.
- All measures were undertaken to overcome any barriers induced by social isolation, language or technical difficulties especially faced by elderly patients.
 - Translations, applicability, survey mentors
 - Online (survey monkey) and hard copies

Results : Countries

Country	N (%)	Country	N (%)
Belarus	59 (4.7)	Ireland	42 (3.4)
Czech Rep	13 (1.0)	Italy	161 (12.9)
Denmark	37 (3.0)	Netherlands	39 (3.1)
Finland	26 (2.1)	Poland	142 (11.4)
France	14 (1.1)	Serbia	12 (1.0)
Germany	41 (3.4)	Spain	109 (8.7)
Greece	133 (10.6)	Turkey	133 (10.6)
Hungary	165 (13.2)	UK	93 (7.4)
Ireland	42 (3.4)	Other	31 (2.5)

Europe	%
East	26.7
West	20.6
North	11.4
South	12,9
Central	14.2

COVID-19 related fears of patients with gynaecological cancers during the COVID- 19 pandemic

Question/Answer	Strongly disagree or disagree % (N)	Neither agree nor disagree % (N)	Strongly agree or agree % (N)
“I'm more afraid of cancer compared to COVID”	17.5% (211)	23.7% (289)	58.8% (708)
“I think cancer patients have a higher risk of COVID infection”	10.6% (130)	16.3% (201)	73.2% (901)
“I think that chemotherapy suppresses the immune system and creates a predisposition for COVID infection”	8.8% (107)	14.9% (181)	76.3% (928)
“I am afraid of getting COVID infection from the hospital setting while receiving my treatment / follow-up”	24.4% (296)	22.6% (274)	53.1% (644)
“I am concerned about the progression of my disease if my treatment / follow-up is cancelled/postponed”	14.5% (177)	14.5% (177)	71.0% (864)

Risk Factors for more "Being more afraid of COVID compared to cancer": Multivariate Analysis (logistic regression)

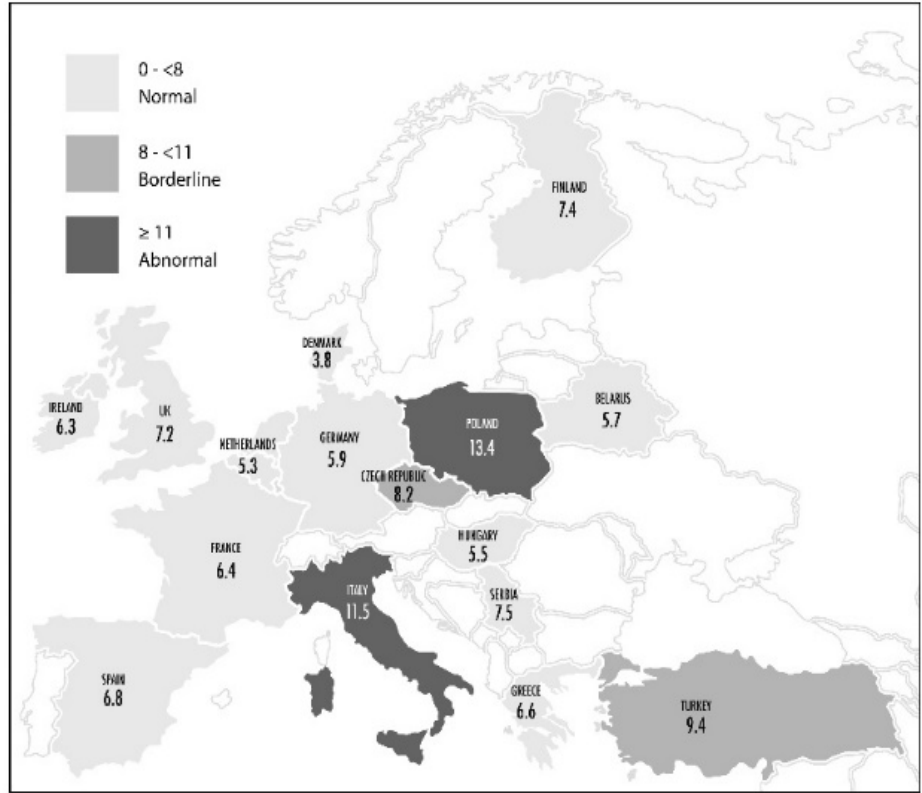
Variable	Odds ratio	95% Confidence interval:		p- value
		Lower	Upper	
Age (≥70 vs <70 years)	4.09	2.01	8.32	<0.001
Type of treatment (1 or 2 versus 3)	0.68	0.38	1.21	0.19
Ovarian cancer (yes vs no)	1.12	0.60	1.90	0.68
Additional comorbidities (yes vs no)	1.53	0.91	2.58	0.11
Experienced modification of care due to the pandemic (of any type) (yes vs no)	1.29	0.74	2.24	0.37
Presence of COVID-19 infected individuals (patients or doctors) in the hospital where the patient is treated (yes vs no)	0.8	0.44	1.45	0.45

Impact of COVID-19 Pandemic on Patients' Care?

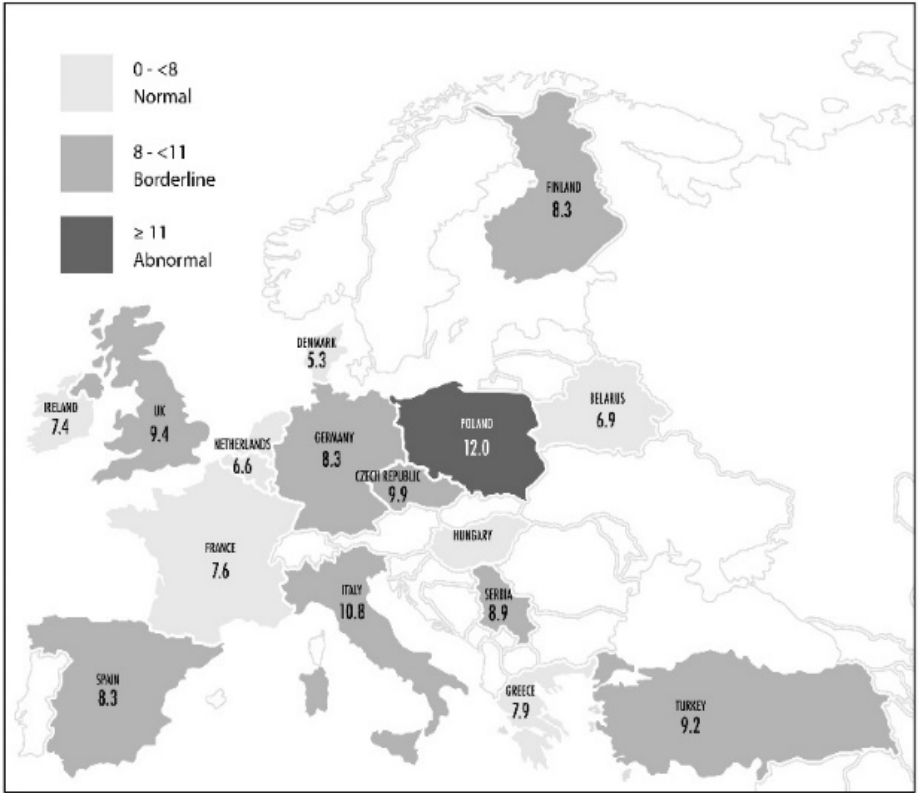
My care continued as planned during the COVID pandemic	64% (n=772)
Due to the fear of COVID infection, I did not go for my check-ups at the hospital	7.4 % (n=89)
I wanted to go myself, but my doctors cancelled my appointments.	12.9% (n=156)
It was a joint decision and we postponed our appointment together	7.9% (n=96)
Others	

Results : HADS Anxiety and Depression

HADS	Mean Score
Anxiety	8.1
Depression	8.8



(a) HADS Depression Scores (n=1251)



(b) HADS Anxiety Scores (n=1251)

Risk Factors for abnormal (i.e. 11-21) **HADS Anxiety score**: Multivariate Analysis (logistic regression)

variable	Odds ratio	95% Confidence interval:		p- value
		Lower	Upper	
Age (≥70 vs <70 years)	1.24	0.74	2.08	0.41
Type of treatment (1 or 2 versus 3)	0.8	0.57	1.13	0.20
HADS depression score (≥11 versus <11)	11.98	8.52	16.84	<0.001
Additional comorbidities (yes vs no)	1.27	0.91	1.76	0.16
Experienced modification of care due to the pandemic (of any type) (yes vs no)	1.52	1.07	2.16	0.02
COVID-19 fear more than cancer fear (yes vs no)	1.04	0.7	1.54	0.86
Ovarian cancer (yes vs no)	1.08	0.78	1.49	0.66
Concerned about not being able to visit the oncology doctor during the COVID pandemic (yes vs no)	1.94	1.35	2.80	<0.001
Concerned about the progression of cancer if treatment / follow-up is cancelled/postponed (yes vs no)	1.05	0.70	1.56	0.82

Risk Factors for abnormal (i.e. 11-21) **HADS Depression score**: Multivariate Analysis (logistic regression).

Variable	Odds ratio	95% Confidence interval:		p- value
		lower	upper	
Age (≥70 vs <70 years)	0.84	0.49	1.42	0.51
Type of treatment (1 or 2 versus 3)	0.86	0.6	1.22	0.39
HADS anxiety score (≥11 versus <11)	12.02	8.55	16.9	<0.001
Additional comorbidities (yes vs no)	1.52	1.09	2.13	0.02
Experienced modification of care due to the pandemic (of any type) (yes vs no)	0.75	0.52	1.08	0.12
Covid fear more than cancer fear (yes vs no)	1.15	0.77	1.71	0.51
Ovarian cancer (yes vs no)	0.88	0.63	1.22	0.44
Concerned about not being able to visit the oncology doctor during the COVID-19 pandemic (yes vs no)	9.65	0.45	0.95	0.03
Concerned about the progression of cancer if treatment / follow-up is cancelled/postponed (yes vs no)	1.24	0.83	1.86	0.30

SO.....SECRET WINDOW GIVES US CLUES for FUTURE

- Cancer patients are more concerned for being abandoned from their treatment teams
 - They are frightened about progression of their disease as a result of the undertaken modifications and because they won't be able to visit or reach their treating team.
 - They wish to have maximal effort care and high-quality care, including clinical trials participation, even during the challenging times of a worldwide crisis.
- They appeal for transparency from the healthcare professionals about decision making processes, infection rates and measures taken to protect them.
- **TAKE HOME MESSAGE**
 - Even in times of crisis such as a pandemic, governments, healthcare systems and oncology societies should sustain oncology services as much as possible, avoid disruption of cancer care and ensure cancer patients don't feel abandoned and alone.
 - It should be ensured that transparency and adequate information flow to the affected patients are a priority and that they are being involved in the decisions made around their care.

DOCTOR'S Perspective

ESGO-ENGOT SURVEY

Name: Jalid Sehouli and Sarah Nassar



Why is a Disaster Situation different?

Paradigm Shift

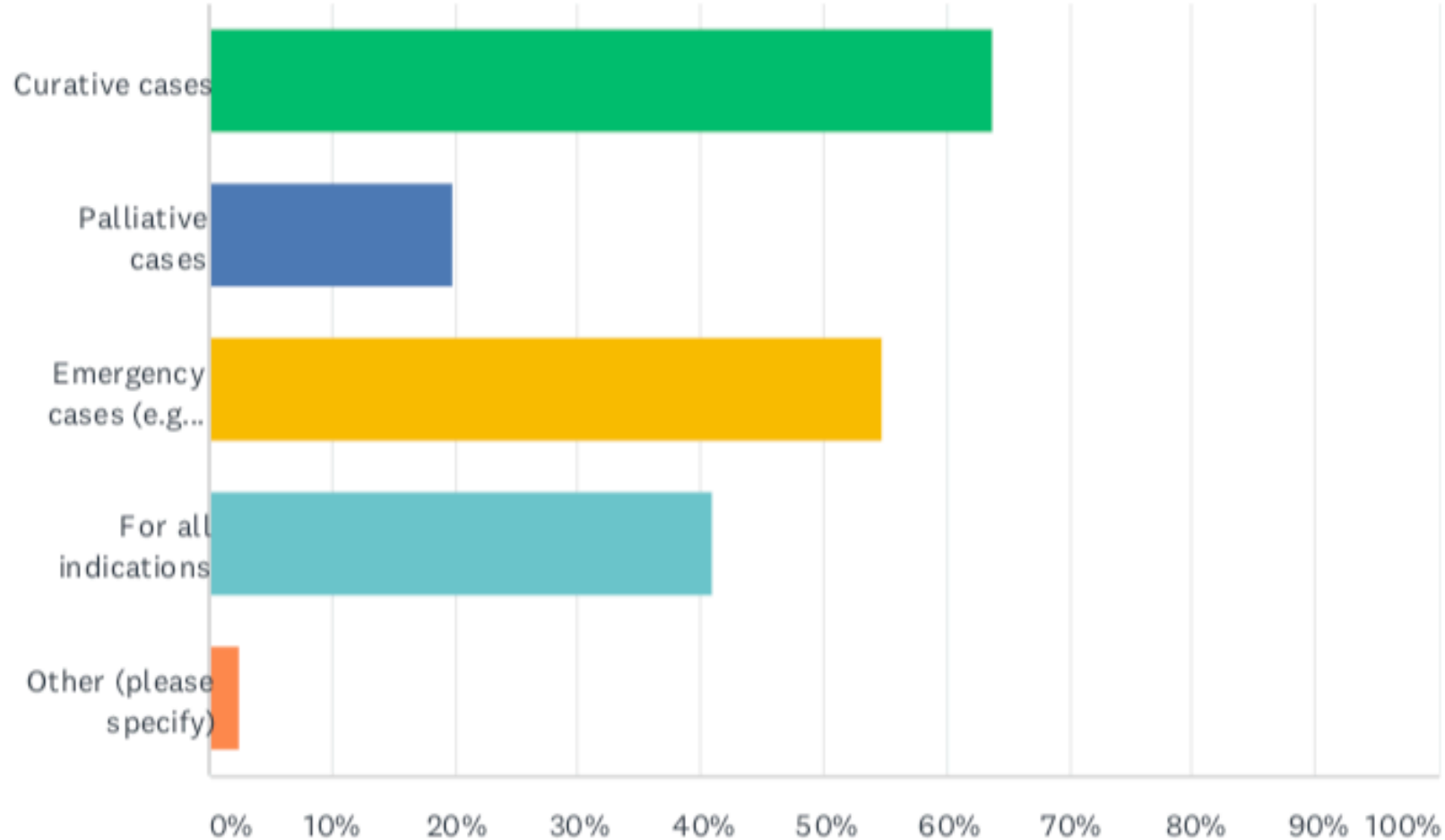
- **All for one** vs. **One for all**



Aims & Methodology

- Evaluate the impact of the COVID-19 Pandemic from a doctor's perspective:
 - Management of patients with gynecological malignancies from the multidisciplinary physicians' perspective,
 - Clinical infrastructures
 - Trial participation
 - Maintenance therapy.
- Prospective survey study sent to all ESGO/ENGOT members
- Online Survey (Survey Monkey) consisting of 53 questions
- Sent out April 2020- ongoing

Results : Operative Interventions



- Majority continued to perform elective surgeries (69%)
- With 98% of the elective surgeries being gynecological oncology cases
- Of those gynecological oncology cases 64% (106) were classified as curative cases, 55% (68) emergency cases (Perforation, Ileus), 20% (33) palliative cases

Results : Operative Interventions

- Reduction in operative interventions:
 - Gynecological oncology cases: On average less than 10% reduction (0-10%)
 - Benign cases: On average 80% reduction (60-100%)

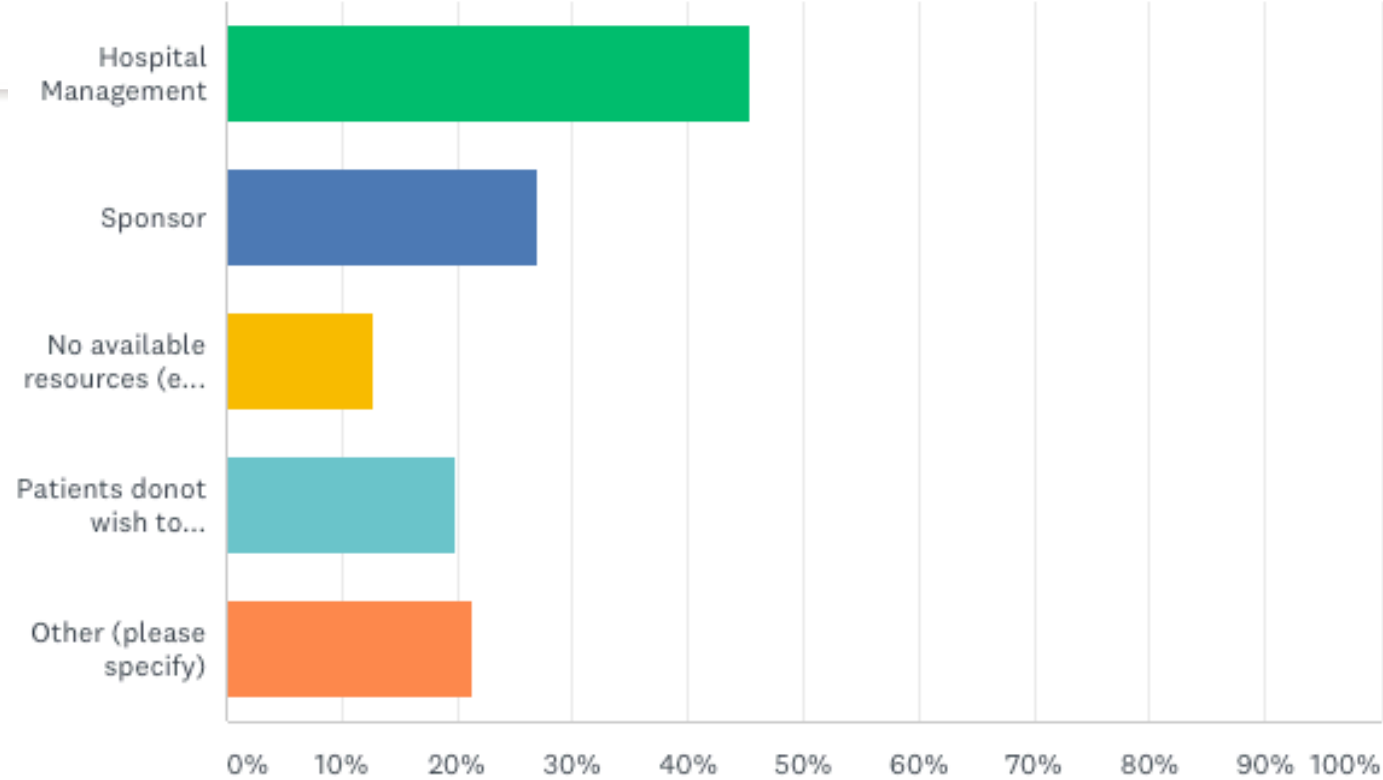
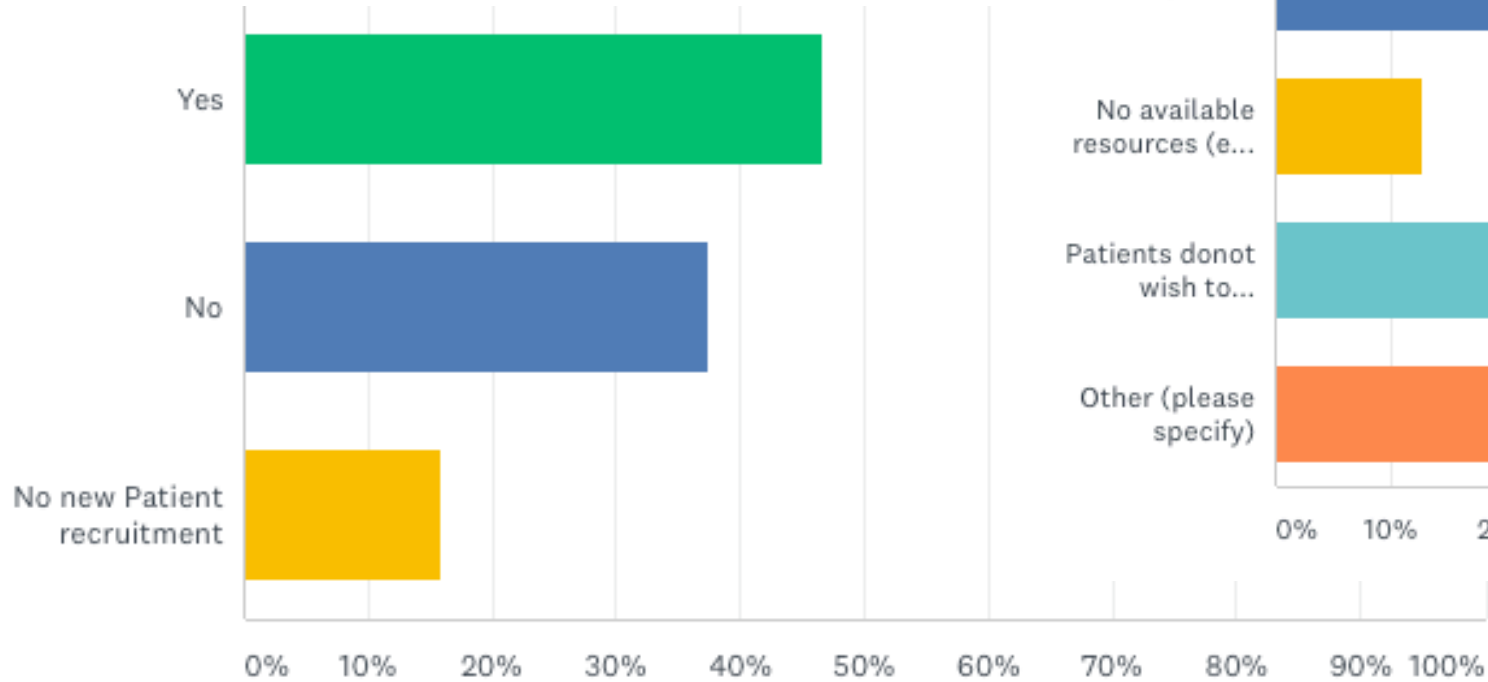
- Patients waited an average of 2 weeks longer (0-12 weeks) for elective surgery appointments compared to previous years.

Do you treat more with neoadjuvant therapy?

Cancer	Yes N(%)	No N(%)	Type of Treatment
Ovarian	85 (52%)	75 (45%)	Chemotherapy
Endometrium	25(15%)	134(81%)	Medical Therapy (44%) Radiation (12%) CHT (36%)
Cervix	28 (17%)	130(79%)	Radiation (50%) CHT (46%)

Clinical Trials

- Ongoing Trials



96% continue to provide maintenance therapy

Radiation Therapy

- For patients requiring radiation therapy or radiochemotherapy majority did not need to postpone treatment (77%and 83% respectively)
- Only 16% (27) stated that they needed to change the radiation regimen in light of the COVID pandemic
- Half of those specified Fractionation as the aspect most frequently changed.

Patient Information

- Patients are kept informed about risks, pathways and guidelines:
 - Telephone 87% (138)
 - Videoconference 17% (27)
 - Email 31 % (49)
 - Mail 14% (23)

Summary

- More tendency to treat with neoadjuvant chemotherapy
- Longer waiting times
- Difficulty in providing medical care due to staff shortage
- Concerns are present regarding triaging and prioritising and more clear cut guidance is needed
- **ONGOING:** Final closing Survey to assess the situation 5 months from the begin of the pandemic

Ultimately if we cant change the cards....



...we need to change the table