

Alistair Nichol

Bottlenecks and solutions in pandemic research: lessons learned from within PREPARE



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Micaela Gal
Nina Gobat
Angela Watkins

MU: Gen Oneill





Disclosure Statement (professional)

1

Personal support

University College Dublin

ANZIC-RC

Health Research Board of Ireland



2

Consultancy

University of Oxford / European
commission



<http://www.glopid-r.org/wp-content/uploads/2016/04/glopid-r-connecting-and-mapping-final-report.pdf>

Disclosure Statement (personal)

1

Wreck of human being



Disclosure Statement (personal)

1

Wreck of human being



2

Aetiology- multifactorial?

Disclosure Statement (personal)

1

Wreck of human being



2

Aetiology- multifactorial?





Clinical Trials



Clinical Trials



PREPARE

Platform foR European Preparedness Against (Re-) Emerging Epidemics

EARL: Ethical, Administrative, Regulatory and Logistical solutions

REPORT PART B: APPENDIX

1. Country data
2. Survey cover letter for network leads
3. Survey questionnaire
4. Participant information sheet for telephone interviews
6. Telephone informed consent form
6. Aide Memoire for telephone interviews
7. Network maps



June 2014



Clinical Trials



PREPARE

Platform for European Preparedness Against (Re-) Emerging Epidemics

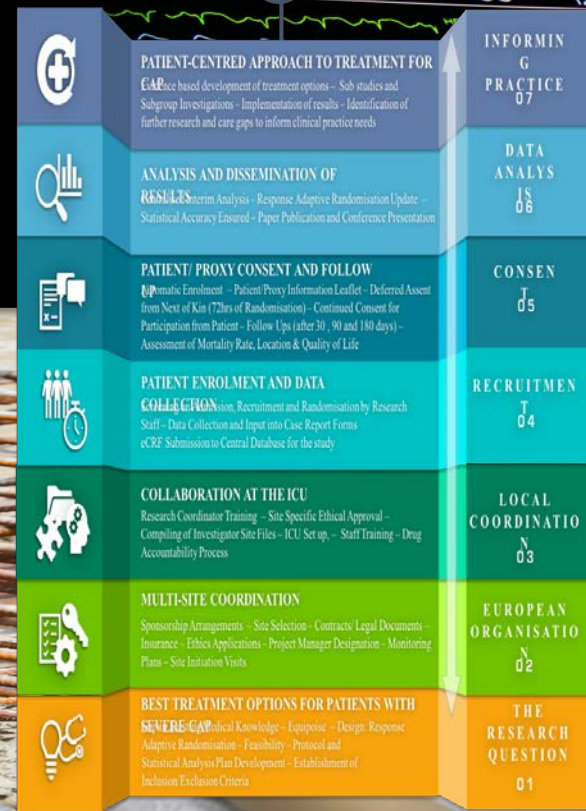
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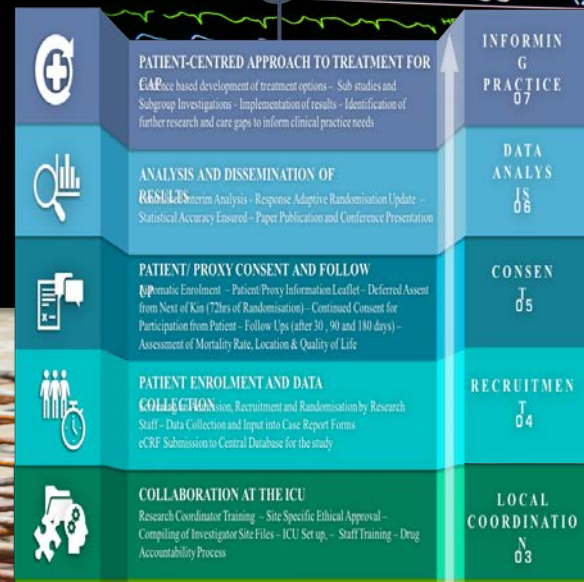
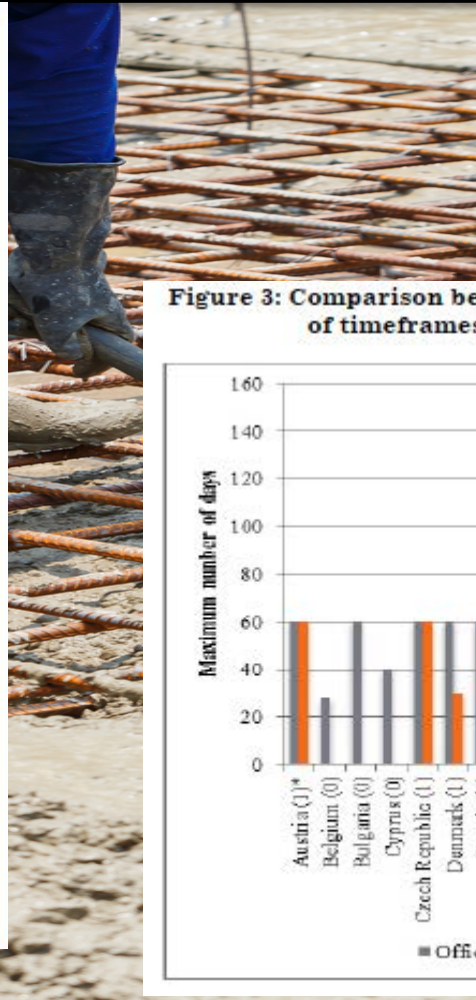
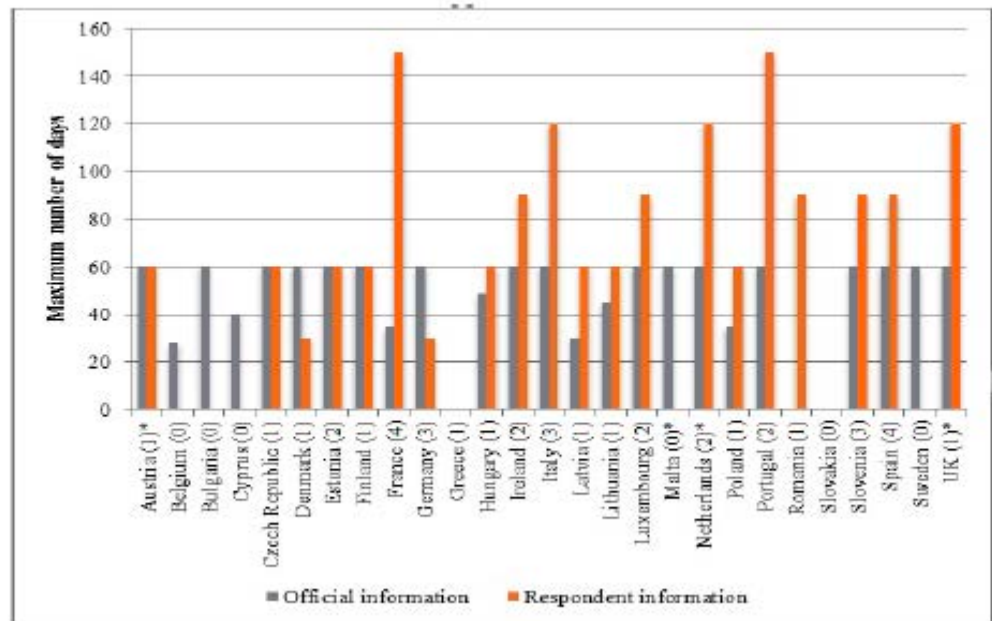


Figure 3: Comparison between official information and respondent experience of timeframes for ethics approvals in EU member states*



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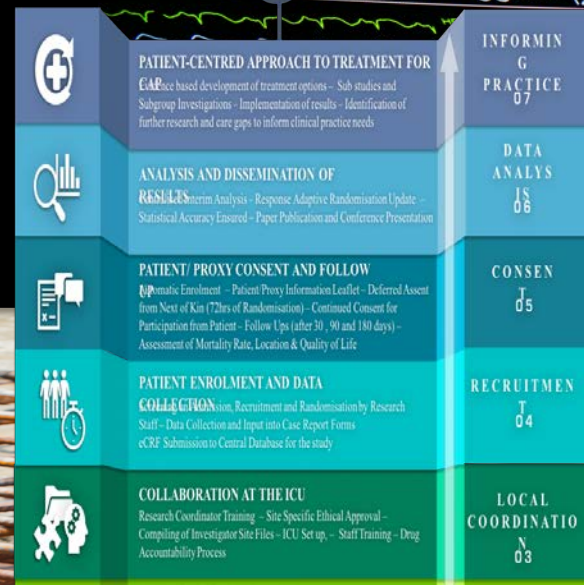
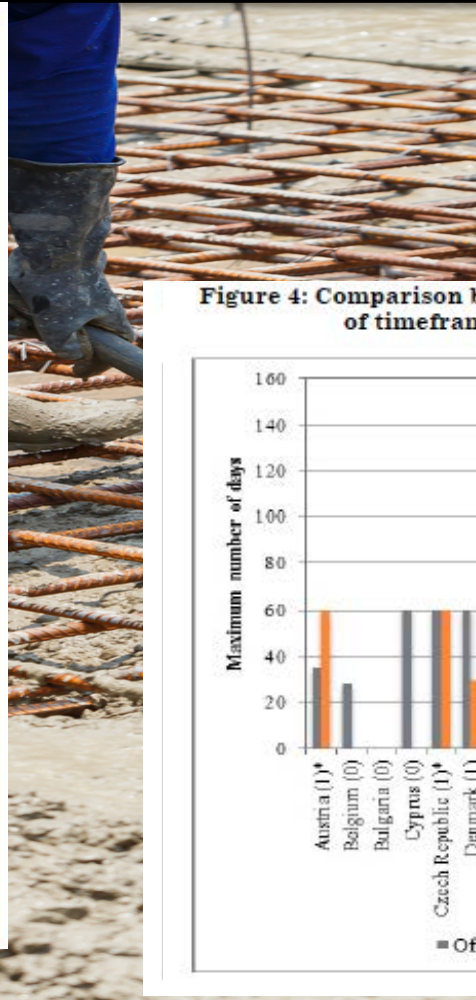
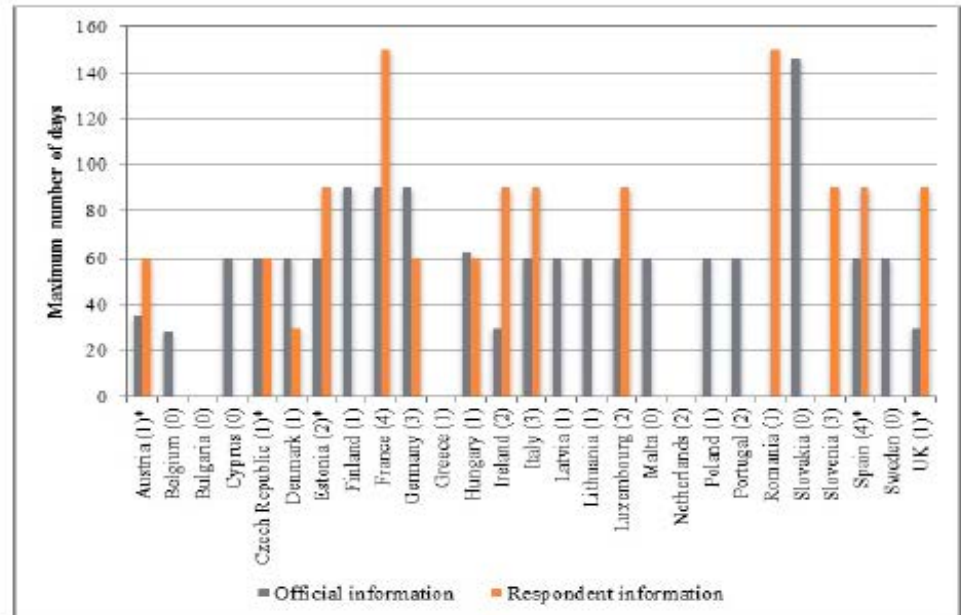


Figure 4: Comparison between official information and respondent experience of timeframes for IMP approvals in EU member states*



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AUSTRIA

Total Population: 8.43 Million

Languages: German

Time Zone: UTC+01:00

Further demographic info (cultural/religious etc.)

Religions: Roman Catholic 73.6%, Protestant 4.7%, Muslim 4.2%, other 3.5%, unspecified 2%, none 12% (2001 census)

Urban population: 68% of total population (2010)

Life expectancy at birth: 80.17 years (male: 77.25 years, female: 83.24 years)

Health expenditures: 10.6% of GDP (2011)

Physicians density: 4.86 physicians/1,000 population (2010)

Hospital bed density: 7.6 beds/1,000 population (2010)



Health System

Primary care system

A fundamental characteristic of the Austrian health-care system is that all members of the population have relatively unrestricted access to all levels of care (GPs, specialists and hospitals). Patients can choose between single-person practices, hospital outpatient clinics, free-standing outpatient clinics and, group practices. An exact division between primary care and secondary care is not possible, as hospital outpatient clinics also play an important role in primary care provision. Treatment by specialist physicians is available at individual practices as well as at free-standing and hospital-based outpatient clinics.

Social insurance is the most important source of health care funding. Out-patient care is almost entirely financed by social health insurance funds. Expenditure for in-patient care is shared between the public sector and social insurance. Long-term care services are mostly funded through taxes.

Source: Health system in Transition 2013

http://www.euro.who.int/_data/assets/pdf_file/0017/233414/HtT-Austria.pdf

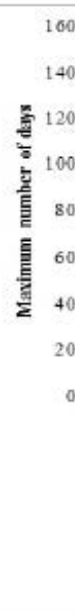
Acute hospital system

For inpatient care standard (basic secondary care services) and specialist (eg. orthopaedic surgery) hospitals as well as highly developed "central" (full secondary and tertiary services, eg. university) hospitals are available.

Source: Health system in Transition 2013

http://www.euro.who.int/_data/assets/pdf_file/0017/233414/HtT-Austria.pdf

Figure



Clinical Trials



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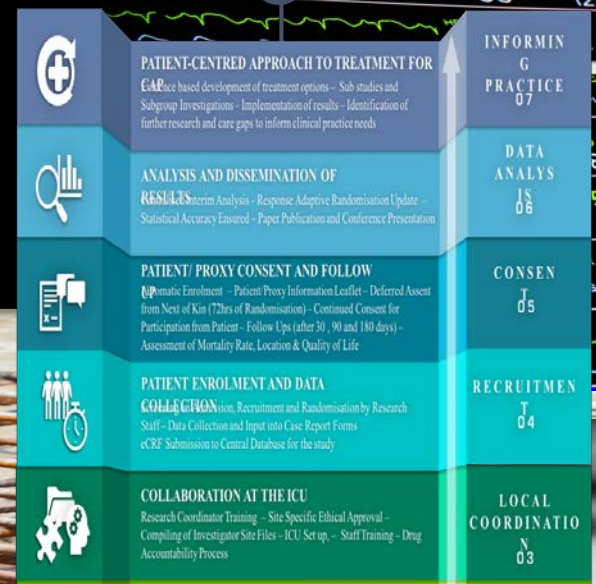
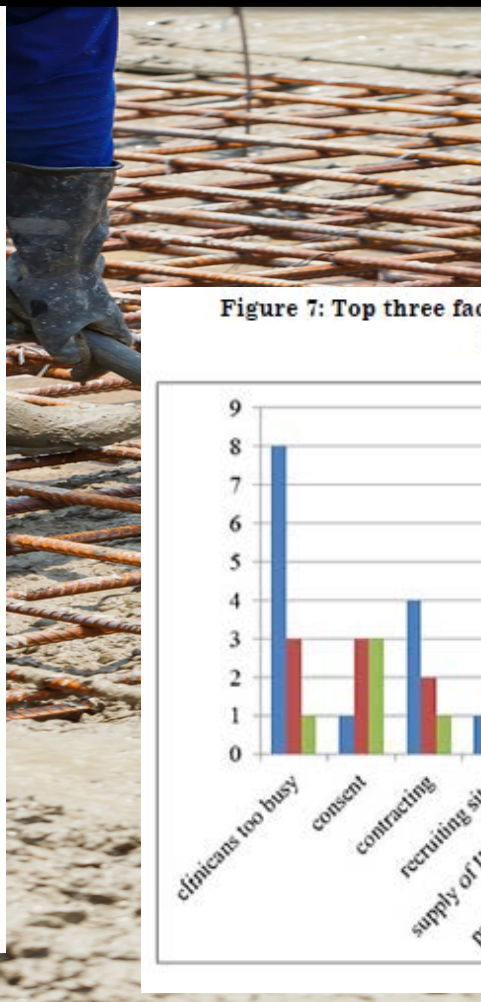
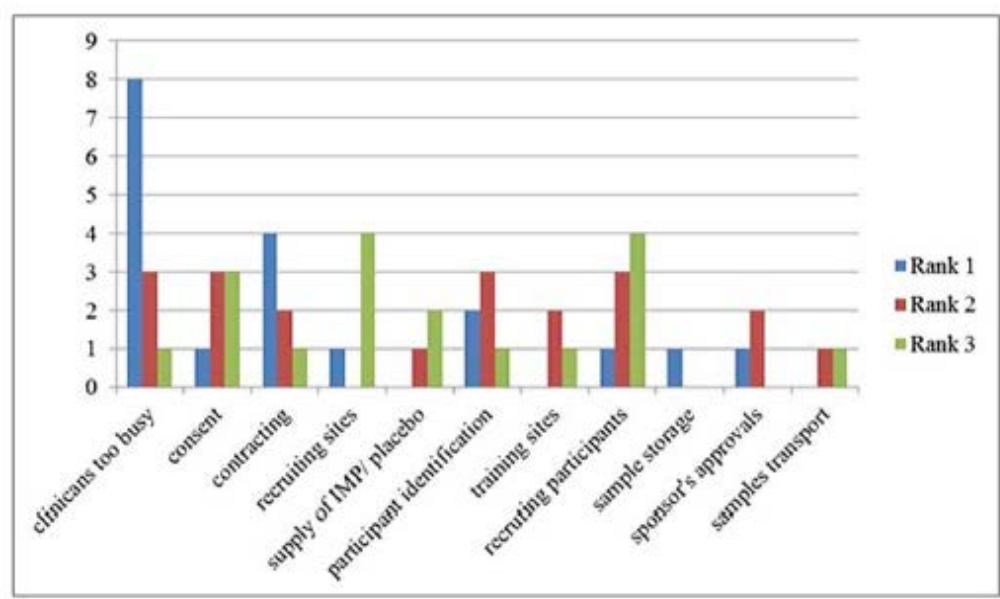
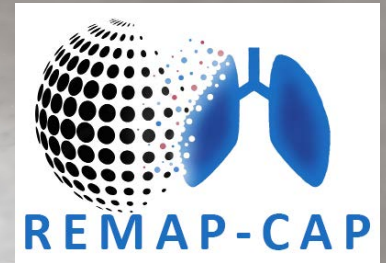


Figure 7: Top three factors presenting a challenge to study set up during a pandemic or epidemic (n=18)



Adaptive Trials

TIME TO
ADAPT-
REMAPs!



Ethics and consent

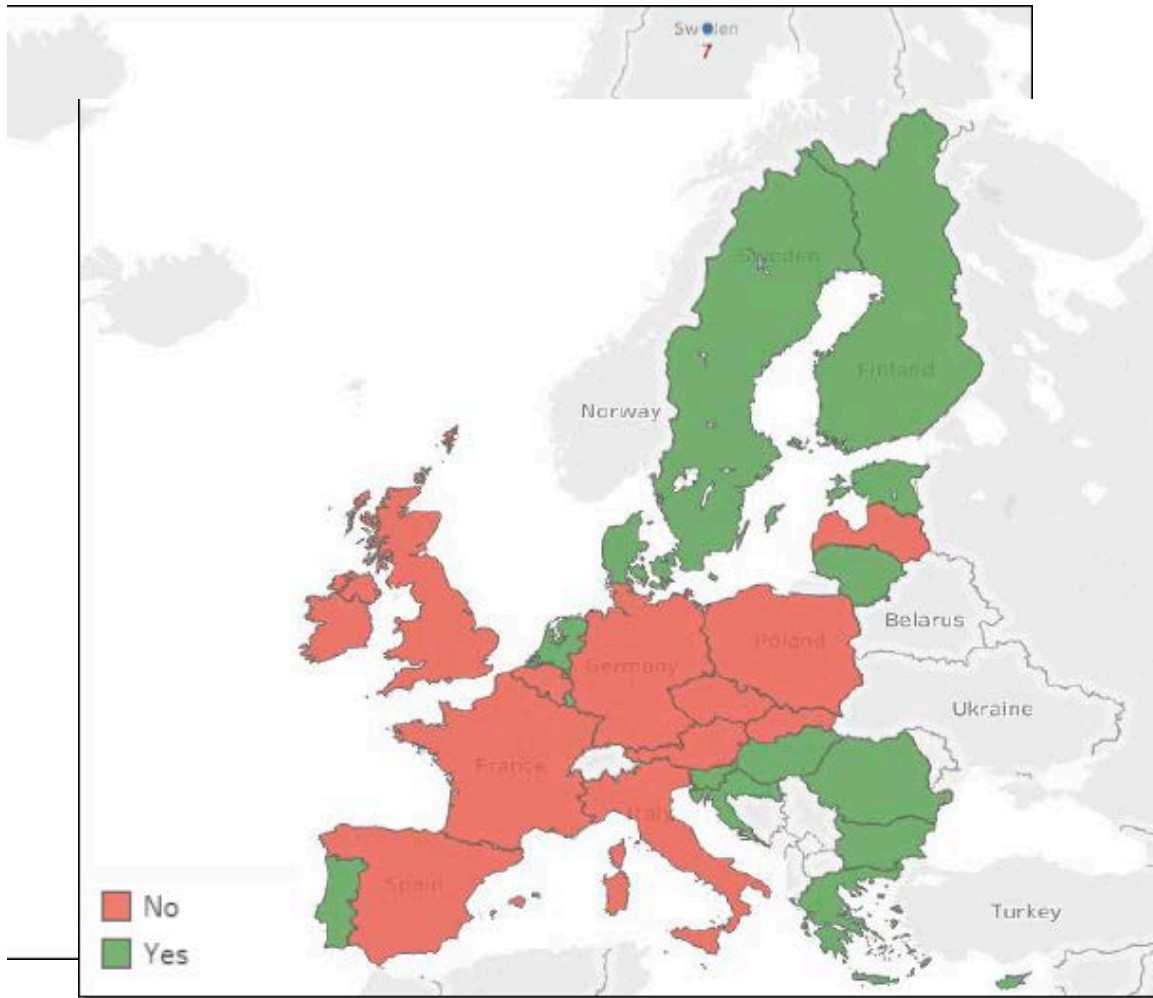
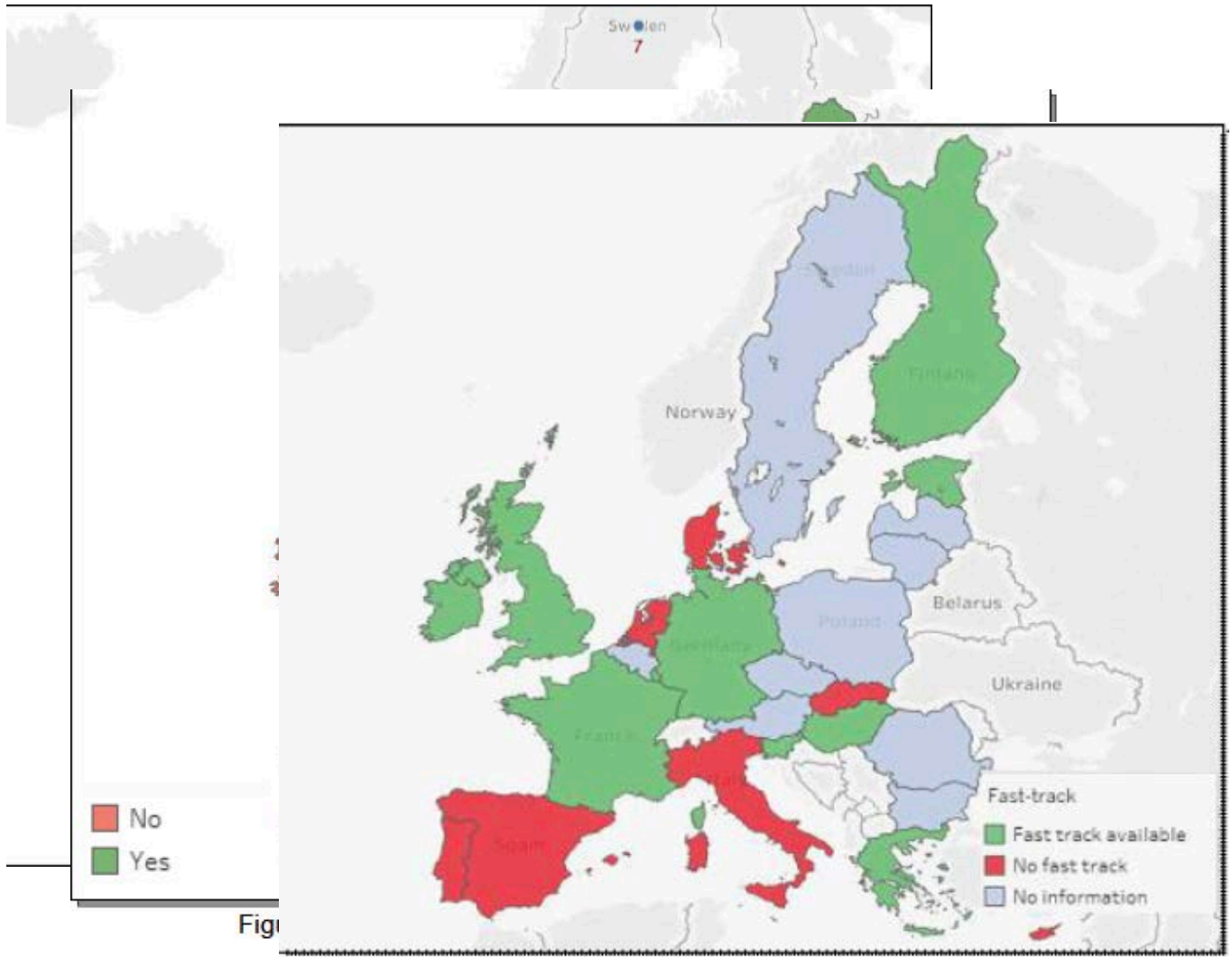


Figure 3 Countries having central ethics committee

Ethics and consent



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Figure 4 Map showing countries having fast-track ethical approval

Ethics and consent

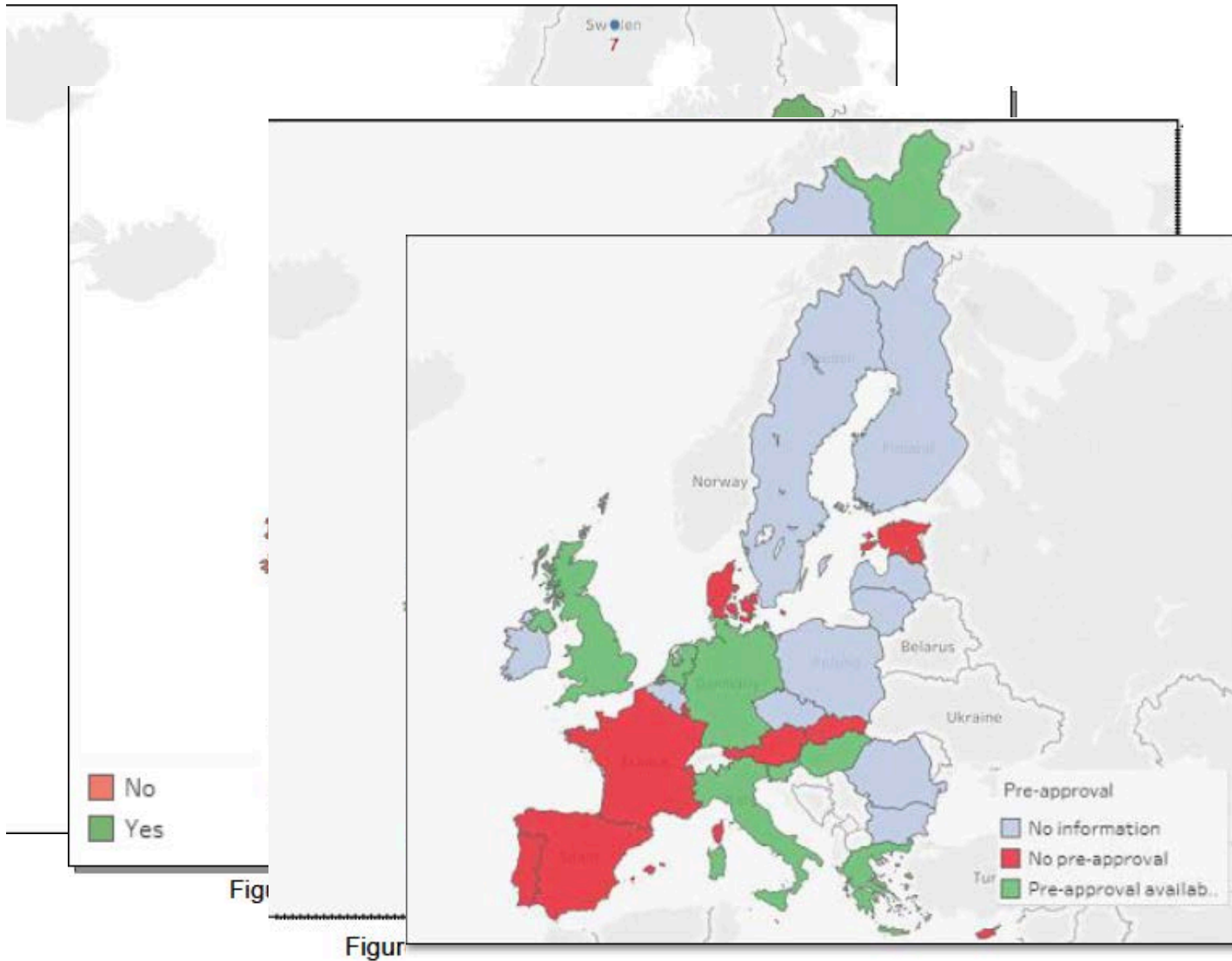


Figure 5 Map showing countries having pre-approval of protocol

Ethics and consent



PRELIMINARY RESULTS

Pandemic Research Preparedness Survey of National Competent Authorities and Research Ethics Committees across Europe

Contributors: JP Byrne¹, Maha Rahmani¹, Hugh Davies², Nina Gobat³, Alistair Nichol¹ for PREPARE WP1
¹University College Dublin, ²Oxford Research Ethics Committee, ³Cardiff University



Figure 5 Map showing countries having pre-approval of protocol

Ethics and consent



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Contributors: JP Byrne¹, Maha Rahmani¹, Hugh [unclear]
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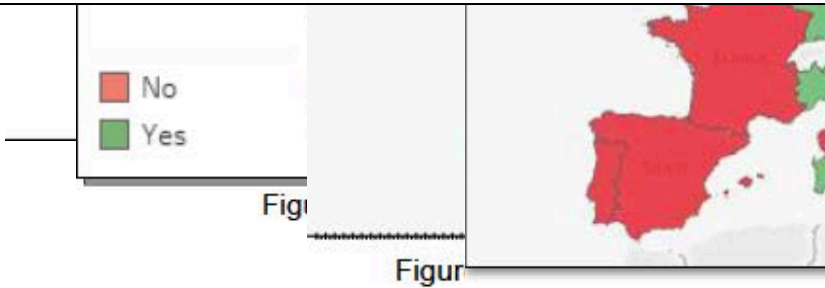


Fig 1

Figur

Figure 5 Map showing

RESEARCH

Open Access



Key stakeholder perceptions about consent to participate in acute illness research: a rapid, systematic review to inform epi/pandemic research preparedness

Nina H. Gobat^{1*}, Micaela Gal¹, Nick A. Francis¹, Kerenza Hood², Angela Watkins¹, Jill Turner³, Ronald Moore³, Steve A. R. Webb⁴, Christopher C. Butler⁵ and Alistair Nichol³



Ethics and consent

What members of the public think about taking part in medical research during a pandemic of an influenza-like illness: a study across four European countries


REPORT FOR STUDY PARTICIPANTS



Accepted: 11 September 2017
DOI: 10.1111/hex.12634

ORIGINAL RESEARCH PAPER

Talking to the people that really matter about their participation in pandemic clinical research: A qualitative study in four European countries

Nina H. Gobat PhD, Dr¹  | Micaela Gal DPhil, Dr¹ | Christopher C. Butler FMedSci, Professor² | Steve A.R. Webb PhD, Professor³ | Nicholas A. Francis PhD, Dr¹ | Helen Stanton BSc, Mrs¹ | Sibyl Anthierens PhD, Dr⁴ | Hilde Bastiaens PhD, Professor⁴ | Maciek Godycki-Ćwirko PhD, Professor⁵ | Anna Kowalczyk MPH, Ms⁵ | Mariona Pons-Vigués PhD, Dr⁶ | Enriqueta Pujol-Ribera MD, Dr⁶ | Anna Berenguera PhD, Dr⁶ | Angela Watkins BA, Mrs¹ | Prasanth Sukumar MPhil, Mr⁷ | Ronald G. Moore DPhil, Dr⁷ | Kerensa Hood PhD, Professor⁸ | Alistair Nichol PhD, Professor⁹

Health Expectations. 2018;21:387–395.





Ethics and consent

- 6804 respondents: Belgium, Spain, Poland, Ireland, UK, Australia, New Zealand, Canada



Public engagement / Feedback



PREPARE Public Panel: information meeting

Thursday 12 October 2017, 17h30-19h00 (UK time)

Chapter Arts Centre, Cardiff, Wales



Participant gaps



Participant gaps



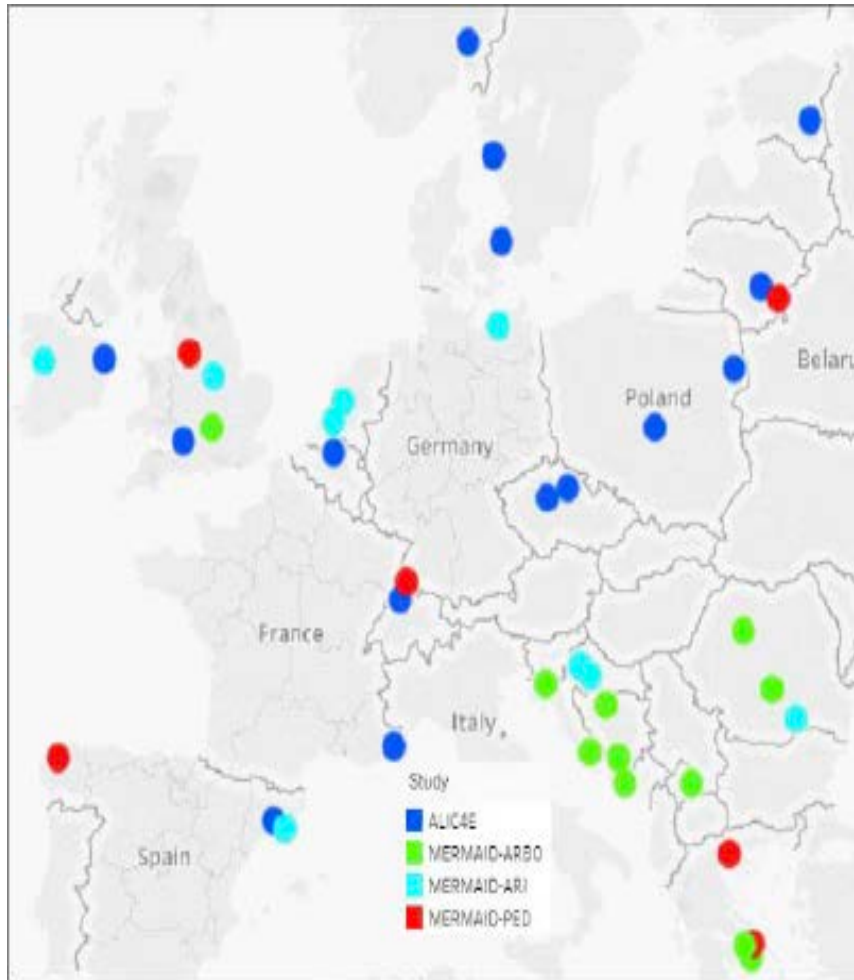
Participant gaps



The ESPID 23

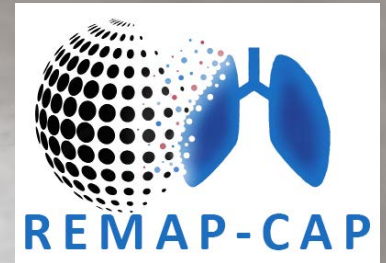


Tracking tools- Contracts



Adaptive Trials

TIME TO
ADAPT-
REMAPs!



The Problem: The Acceptability of Adaptive Design

- **EARL Barrier:** Between adaptive design protocol and stakeholder experiences exists a range of uncertainties.

▪ **Protocol** ↔ **Stakeholder Perspectives**

Recruitment Procedures

Novel Trial Design
Information &
Communication

Resources for
Understanding &
Decision-making

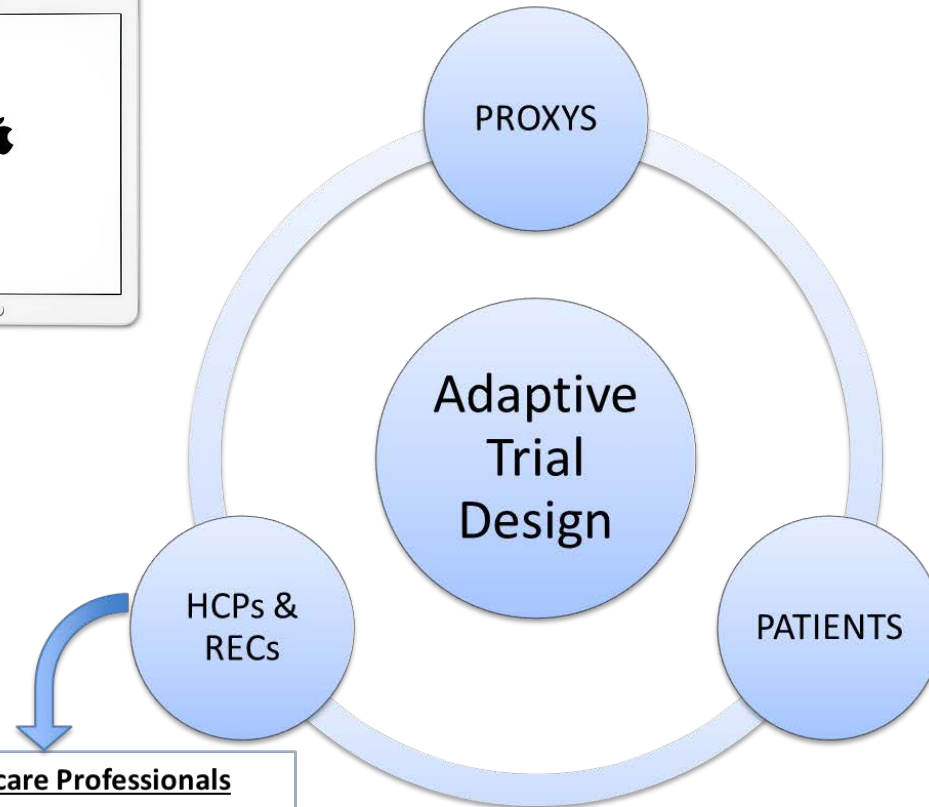
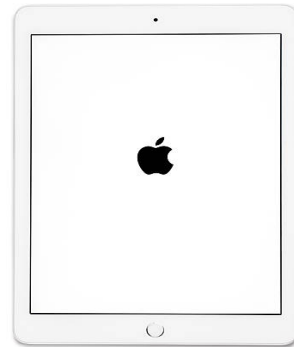
Viable &
Acceptable
Consent
Models

Pandemic Scenario
Modifications
– outbreak related
acceptability –
processes,
information,
consent

REMAP-CAP: SWAT Overview

THEMES

1. **Consent:** process, timing, understanding, questions, requirements etc.
2. **Decision-making:** considerations, resources (info/people), rationale, tools to assist etc.
3. **Embedding:** marrying research practice and routine care, randomising, barriers, buy-in, engagement, autonomy etc.
4. **Pandemic Scenario:** acceptable consent models; readiness.



Healthcare Professionals

1. Nurses
2. Clinician
Researchers/Recruiters
3. Consultants
4. Ethics Committee Members
5. Healthcare Ethics Experts

ICU CONTEXT

- Time-critical
- Distressed decision-making
- De-sensitised authorisation
- Fear & Trust Balance



Identify Barriers

Identify Key targets

Generate Evidence

Engagement

Process evaluation

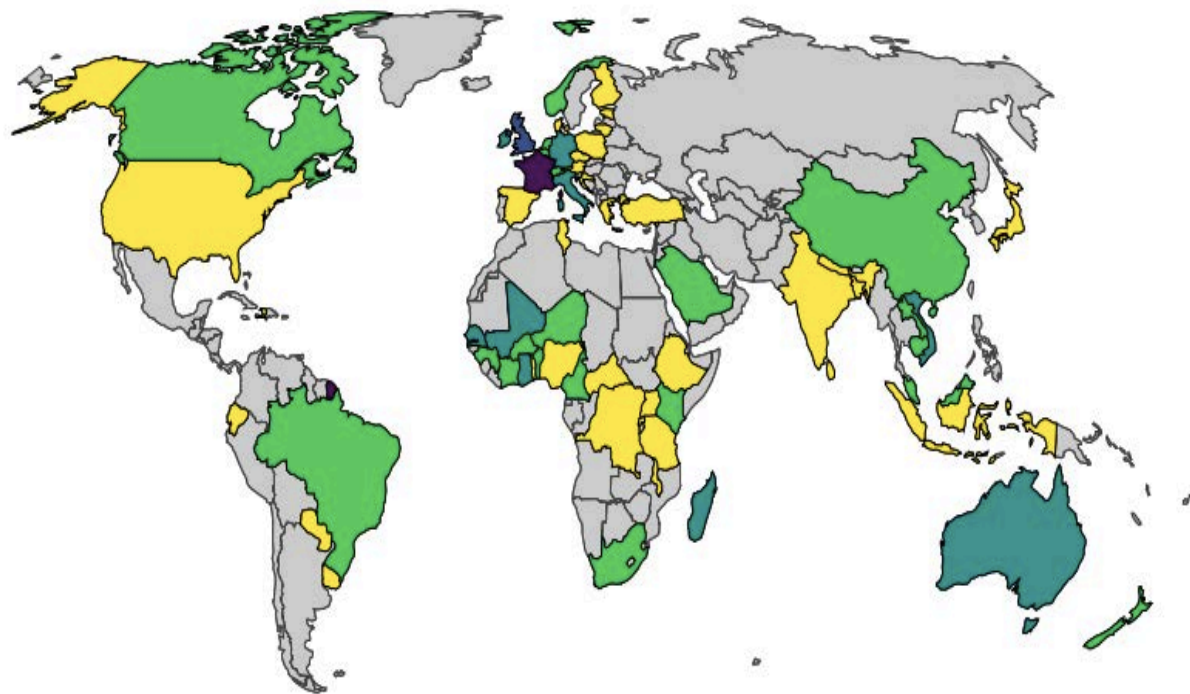
Improve processes

Collaborate

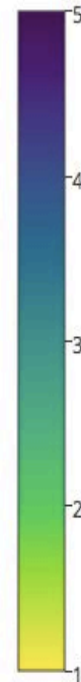


GLPID-R

GLOBAL RESEARCH COLLABORATION FOR INFECTIOUS DISEASE PREPAREDNESS



Countries





Identify Barriers

Identify Key targets

Generate Evidence

Engagement

Process evaluation

Improve processes

Collaborate

Eliminate barriers

Thanks!!

Questions?



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