ISRCTN11384058 https://doi.org/10.1186/ISRCTN11384058

A collaborative pilot study to monitor and optimise access to urgent surgery during the period of reduced resources in Genoa, Italy caused by the COVID-19 pandemic, using a bespoke referral process and the SWALIS 2020 model to prioritise surgery by clinical urgency and waiting time

Submission date
20/05/2020

Registration date
26/05/2020

Last Edited
14/06/2023

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Nations all over the world are under dramatic pressure due to the COVID-19 pandemic. One of the most severe consequences of such pressure for healthcare services is the reduction in capacity to perform elective surgical operations, due to the work of anaesthesia and theatre staff on COVID-19 patients care. As a consequence, theatre sessions are often reduced to less than one fifth and it makes extremely difficult to select the patients with the most need, maintain safe and appropriate care, and optimise the healthcare service work. In this context immediate actions are required to monitor, prioritise and optimise access to cancer surgery, during and after the pandemic, adapting to a changing and normalising scenario, balancing the needs of COVID-19 against cancer and urgent surgery patients. Previous nationally-funded research run by the University and the San Martino Hospital in Genoa has developed the Surgical Waiting List InfoSystem (SWALIS) model to prioritise patients according to waiting time and clinical urgency by implicit criteria, according to the Italian national categories. These stratify clinical urgency by the presence of disease progression, and the degree of symptoms, dysfunction and disability. The Italian Liguria Regional Health Trust has commissioned the development of a collaborative pathway for cancer cases from hospitals in the Metropolitan area of Genoa (840.000 inhabitants). This study includes a 2-week feasibility and a 4-week pilot implementation of a newly designed, software-aided, inter-hospital, collaborative surgical pathway to prioritise, monitor and optimise access to surgery, balancing the needs of COVID-19 against cancer and urgent patients during the pandemic.

Who can participate?
Any urgent surgery patient referred to any Department of Surgery in the metropolitan area of Genoa during the spring 2020 COVID-19 peak

What does the study involve?
Each unit in the metropolitan area selects amongst their waiting patients those in urgent category (less than 30 days) and refers them to the pooled CoV-2-GOA-Surgery waiting list, the A- urgency category. The key information provided in the referral forms includes clinical and socio-organisational information, such as the expected procedure time and complexity, expected hospital stay and potential complications of discharge due to socio-familial reasons. The referring surgeons also acknowledge that in the context of the COVID-19 pandemic, the relative value of theatre time is extremely precious, that failure to rescue is increased and that patients run the additional risk of hospital-acquired COVID-19 infection. A direct referring accepting clinical handover is advised. Referring surgeons are allowed to update and track their patients' levels of clinical urgency. The list is ordered dynamically on the basis of the SWALIS 2020 score (i.e. the percentage of patients' maximum allowed waiting time), according to a novel method adopting cumulative prioritisation, including recording any change in the level of urgency. Once weekly all new referrals are assessed for appropriateness by the CoV-2-GOA-Surgery MDT in a videoconference. Appropriateness includes governance, clinical, and organisational aspects. According to the Regional Health Service policies, in order to maximise safety and quality of care, referrals from general surgery units are addressed to super-speciality hubs at PSMRH. Whilst exploring the forthcoming calendar, the waiting list order is computed by the future theatre scheduling date. Certain flexibility is allowed to avoid wasting theatre time, provided all the patients close to breaching their maximum time are scheduled weekly. Similarly, some degree of practical freedom to services and firms is allowed in scheduling their surgeries, provided the allocation reflects the suggested priority. In case of a last-minute re-schedule or cancellation, the same Unit schedules the next closest suitable patient on the priority list. In order to allow for COVID-19 swab analysis, patients are scheduled for admission 48 hours prior to surgery based on theatre availability, expected ITU needs, length of stay, complications of discharge. The pathway also includes admission, post-discharge and follow-up arrangements.

What are the possible benefits and risks of participating?
By appropriately pooling the referrals from all surgical units in the metropolitan area, the researchers expect to be able to measure the waiting list to consistently allow priority-selection of the patients with the most need without damaging the others. They will monitor the priority (as the SWALIS priority score) at surgery, how this will be equally distributed among patients, and how efficiently operative theatres will be scheduled. They will also monitor how the model allows adapting the theatre allocation in the context of changing availability of nurses and anaesthetists as the pandemic peak lowers. The clinical treatment will not change during the study, and the protocol will adhere to the existing governance, hence the risks in participating in the study are expected to be minimal. If results are positive, the researchers will further use the pathway in the COVID-19 "phase 2" by defining a bespoke scheduling policy to finely manage active, backlog and hidden waiting lists.

Where is the study run from?
Policlinico S. Martino Research Hospital (Italy)

When is the study starting and how long is it expected to run for?
March 2020 to June 2020

Who is funding the study?
Italian Liguria Regional Health Trust (Italy)

Who is the main contact?
1. Mr Roberto Valente
roberto.valente@hsanmartino.it
2. Dr Stefano Di Domenico
Stefano.didomenico@hsanmartino.it

Contact information

Type(s)
Scientific

Contact name
Mr Roberto Valente

Contact details
Largo Rosanna Benzi 10
Genoa
Italy
16122
+39 (0)10 555 2549
roberto.valente@hsanmartino.it

Type(s)
Scientific

Contact name
Dr Stefano Di Domenico

Contact details
Largo Rosanna Benzi 10
Genoa
Italy
16122
+39 (0)10 555 2532
stefano.didomenico@hsanmartino.it

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CoV-2-GOASUR-SWALIS2020-FP1

Study information

Scientific Title
Monitoring the introduction of a model to audit, prioritise and optimise access to cancer and urgent surgery to all patients in the metropolitan area of Genoa during and after the COVID-19 pandemic. An inter-hospital collaborative feasibility & pilot study of a dedicated referral pathway adopting the SWALIS 2020 model to prioritise surgery by implicit clinical urgency and waited-against-maximum-time.

Acronym
CoV-2-GOASUR-SWALIS2020-FP1

Study objectives
A collaborative multidisciplinary centralised referral pathway utilising the SWALIS 2020 elective surgery prioritisation model (monitoring and prioritising access to elective surgery by implicit clinical urgency and waited-against-allowed time) delivers appropriate (safe, effective, equitable and transparent) and efficient priority-based theatre planning, allocation and scheduling in the context of very scarce and inconstant resources, such as that during the COVID-19 pandemic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/03/2020, Italian Liguria Regional Ethics Committee (Segreteria Amministrativa del Comitato Etico Regionale, Ospedale Policlinico San Martino – IRCCS, Largo Rosanna Benzi, 10 – 16132 Genoa; Tel: +39 (0)10 555 4214 / 4212 / 4213 / 4215 / 4216; comitato.etico@hsanmartino.it), ref: 233/2020

Study design
Multicentre feasibility (2 weeks) and pilot (4 weeks), single-cohort, before-after, pragmatic interventional service improvement research study

Primary study design
Interventional

Secondary study design
Single-cohort, before-after, pragmatic interventional service improvement research

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

The severe imbalance and variable demand/supply for elective surgery during the COVID-19 pandemic, determined by postponements, backlog and "hidden" waiting lists

Interventions

A bespoke collaborative multicentre patient pathway based on:
- inter-hospital hub & spoke referral and triage
- waiting list management by the SWALIS 2020 model to prioritise and audit access to elective surgery
- video conference MDT appropriateness referrals' assessment
- waiting list monitoring and theatre planning, allocation and scheduling based on the pathway and model

This is a newly designed, software aided, inter-hospital, collaborative surgical pathway covering all specialities in all Departments of Surgery of the Metropolitan area of Genoa during the COVID-19 pandemic. The pathway utilises a multidisciplinary assessment of appropriateness (Regional Inter-hospital Surgical Department, Medical Hospital Director, Anaesthesia Department, Department of Surgery, Hospital Quality, Hospital Cancer Board, and all referring Units). The pathway adopts a modification of the Surgical Waiting List InfoSystem (SWALIS) (Valente et al. 2009) model to prioritise patients based on clinical urgency by implicit criteria, according to the Italian National categories, and waited-against-maximum time.

The modified SWALIS model (SWALIS 2020) runs as follows:
1. Clinical urgency assessment, following the Italian National urgency categories14, with specific adaptations grading the likelihood of progressing to deterioration or emergency for urgent cases. The researchers have re-defined the model introducing three urgent subcategories: A1-15 days (certain rapid progression), A2-21 days (probable rapid progression), and A3-30 days (potential rapid progression) (Table 2).
2. A maximum waiting time is set for each urgency category (A1-15 days, A2-21 days, A3-30days, B-60 days, C-180 days, D-360 days), as key criteria for a time-based prioritisation.
3. The list is dynamically ordered by computing a priority score (SWALIS 2020 score) for each referral, based on the time waited in relation to the corresponding maximum allowed. All patients reach the top of the list at the speed set by their clinical urgency, progressing through pre-admission stages by a priority score obtained by an original prioritisation method (patent pending 2020).

The referral pathway runs as follows:
1. Referral. Each Unit in the Metropolitan area selects amongst their waiting patients those in urgent category (< 30 days) and refers them to the pooled CoV-2-GOA-Surgery waiting list, the A- urgency category. The key information provided in the referral forms is summarised in Figure 1. This includes clinical and socio-organisational information, such as the expected procedure time and complexity, expected hospital stay and potential complications of discharge due to socio-familial reasons. The referring surgeons also acknowledge that in the context of the CoV-2 pandemic, the relative value of theatre time is extremely precious, that failure to rescue is increased and that patients run the additional risk of hospital-acquired SARS-CoV-2 infection. A direct referring – accepting clinical handover is advised. Referring surgeons are allowed to update and track their patients' levels of clinical urgency.
2. Prioritisation: the "SWALIS 2020" method. The list is ordered dynamically on the basis of the SWALIS 2020 score (i.e. the percentage of patients' maximum allowed waiting time), according to a novel method adopting cumulative prioritisation, including recording any change in the level of urgency.
3. Clinical triage. Once weekly all new referrals are assessed for appropriateness by the CoV-2-

GOA-Surgery MDT in a videoconference. Appropriateness includes governance, clinical, and organisational aspects. According to the Regional Health Service policies, in order to maximise safety and quality of care, referrals from general surgery units are addressed to super-speciality hubs at PSMRH.
4. Admission and theatre scheduling. Whilst exploring the forthcoming calendar, the waiting list order is computed by the future theatre scheduling date. Certain flexibility is allowed to avoid wasting theatre time, provided all the patients close to breaching their maximum time are scheduled weekly. Similarly, some degree of practical freedom to services and firms is allowed in scheduling their surgeries, provided the allocation reflects the suggested priority. In case of a last-minute re-schedule or cancellation, the same Unit schedules the next closest suitable patient on the priority list.
5. In order to allow for COVID-19 swab analysis, patients are scheduled for admission 48 hours prior to surgery based on theatre availability, expected ITU needs, length of stay, complications of discharge.
6. Post-discharge. The pathway also includes admission, post-discharge and follow-up arrangements.

Data management
During 1) 2-week feasibility and 2) 4-week pilot phases, the referral process if refined along its application, discussing each change at the COVID-19-GOA-Surgery MDT. Data is admin-checked at referral for completeness, for appropriateness at MDT. The data-system tools are progressively strengthened, upscaling from 64-bit password-encrypted email referral archives, password-encrypted shared secured folders, spreadsheets (MS ExcelTM) and database live-running user interface (MS AccessTM) code-developed on Visual Basic for Application for Office 2010 (MS VBATM).

Intervention Type
Other

Primary outcome measure
Measured weekly, i.e. every Tuesday following the just-finished week: feasibility (weeks 1 and 2), pilot (weeks 3, 4, 5, 6):
1. Clinical complications and adverse events reportedly caused by the pathway (safety), measured by recording and numbering single reports by surgeons responsible for patient care on identified proforma at weekly MDT meetings
2. According to the SWALIS model, the waiting list is measured weekly through purposely designed performance indexes, including cross-sectional (for patients currently on the list at an index day) and retrospective views (for patients who received treatment during a given period T):
2.1. Priority (as average and SD) on the list (new for SWALIS 2020) (for each and all urgency categories)
2.2. Waiting time in days (as median and range) (for each and all urgency categories)
2.3. Waiting list length (as average and SD) (for each and all urgency categories)

Secondary outcome measures
Measured weekly, i.e. every Tuesday following the just-finished week: feasibility (weeks 1 and 2), pilot (weeks 3, 4, 5, 6):
1. Appropriate Performance Index (API) (for each and all urgency categories):
1.1. Retrospective: percentage of patients receiving treatment within their respective MTBT in a given period T
1.2. Cross-sectional: percentage of patients currently on the list at an index day having waiting time less than their respective MTBT

2. Deviation events (total and percentage). These include updates in urgency during wait, number of postponements (prior to the day of admission) or cancellations (on the day)

Overall study start date
25/03/2020

Completion date
15/06/2020

Eligibility

Key inclusion criteria
Any urgent surgery patient (Italian Category A-30 Days) referred to any Department of Surgery in the metropolitan area of Genoa during the spring 2020 COVID-19 peak

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200 patients referred for surgery, 100 operated

Total final enrolment
240

Key exclusion criteria
1. Emergency surgery patients
2. Routine surgery patients

Date of first enrolment
01/04/2020

Date of final enrolment
10/05/2020

Locations

Countries of recruitment
Italy

Study participating centre
Policlinico S. Martino University Research Hospital
Largo Rosanna Benzi 10

Genoa
Italy
16122

Study participating centre
International Evangelical Hospital
Salita Superiore di S. Rocchino 31/A
Genoa
Italy
16122

Study participating centre
Galliera Hospital
Via Alessandro Volta 8
Genoa
Italy
1612

Sponsor information

Organisation
Policlinico San Martino Genoa

Sponsor details
Largo Rosanna Benzi 10
Genoa
Italy
16122
+39 (0)10 5558722
direzione.scientifica@hsanmartino.it

Sponsor type
Hospital/treatment centre

Website
https://www.ospedalesanmartino.it/

Organisation
Azienda Liguria Sanità (ALiSa)

Sponsor details

Piazza della Vittoria
Genoa
Italy
16100
+39 (0)10 548 4162
direzione.alisa@regione.liguria.it

Sponsor type
Government

Website
https://www.alisa.liguria.it/

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Liguria Health System

Results and Publications

Publication and dissemination plan
1. The study protocol and the statistical analysis plan will be available at publication
2. International journals and meetings, study website (in progress)

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mr Roberto Valente (roberto.valente@hsanmartino.it) and Dr Stefano Di Domenico (Stefano.didomenico@hsanmartino.it). The dataset is in an MS Access TM format, and can be anonymised to any level required, as allowed by the Liguria Ethics Committee. The dataset will be made available 3 months after study completion, for 12 months, extendable. Any sharing request will be submitted to the Liguria Ethics Committee for approval.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Preprint results	non-peer-reviewed results in preprint results	05/11/2020	17/03/2021	No	No

Results article	01/02/2021	17/03/2021	Yes	No
Results article	27/01/2021	16/04/2021	Yes	No
Abstract results		14/06/2023	No	No