

Covid a catalyst for change: Expanding your dialysis access options

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Disclosure

Speaker name:

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I have the following potential conflicts of interest to report:

- Consulting BD Bard
- Employment in industry
- Stockholder of a healthcare company
- Owner of a healthcare company
- Other(s)

- I do not have any potential conflict of interest



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Headlines from around the world

Covid's 'devastating impact' on NHS services exposed by latest figures

Number of patients on waiting lists for more than a year is 123 times larger than 2019



Germany was held up as an example of how to do the pandemic. Now it's struggling.

Hospitals across US cancel elective procedures- again

France's 'Plan Blanc'- Paris and Marseille Hospitals scheduled operations on hold to free up space

David Maguire, a senior analyst at the King's Fund, said:

“The impact of Covid-19 on waiting times will be felt for years to come.

Despite the best efforts of staff there simply isn't the capacity to get through the backlog quickly.”

1. <https://www.theguardian.com/society/2020/dec/10/covids-devastating-impact-on-nhs-services-exposed-by-latest-figures>

2. <https://www.medtechdive.com/news/hospitals-cancel-elective-procedures-again/589207/>

3. <https://www.kingsfund.org.uk/press/press-releases/impact-covid-19-waiting-times-nhs-patients>

4. https://www.washingtonpost.com/gdpr-consent/?next_url=https%3a%2f%2f%3Ca%20href=

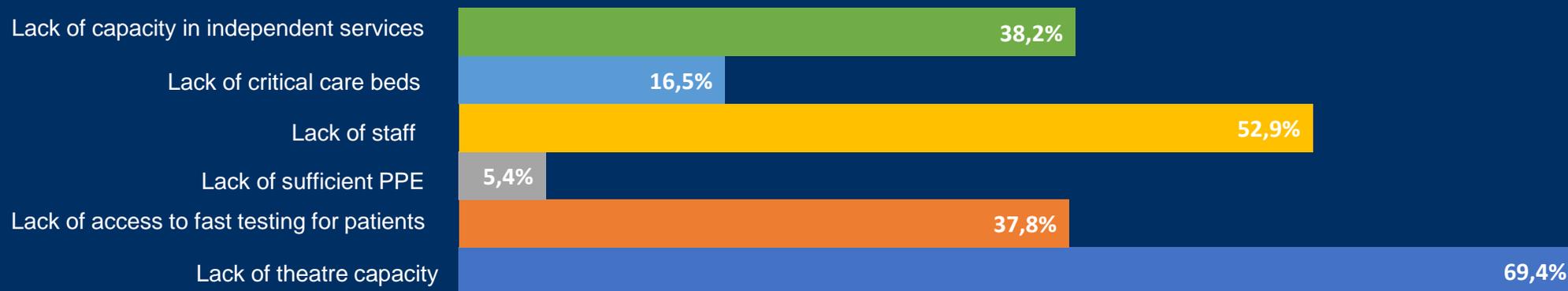
5. <https://www.connexionfrance.com/French-news/Hospitals-in-France-initiate-plan-blanc-as-Covid-19-cases-rise-and-return-in-possible-second-wave>



Protecting surgery through a second wave

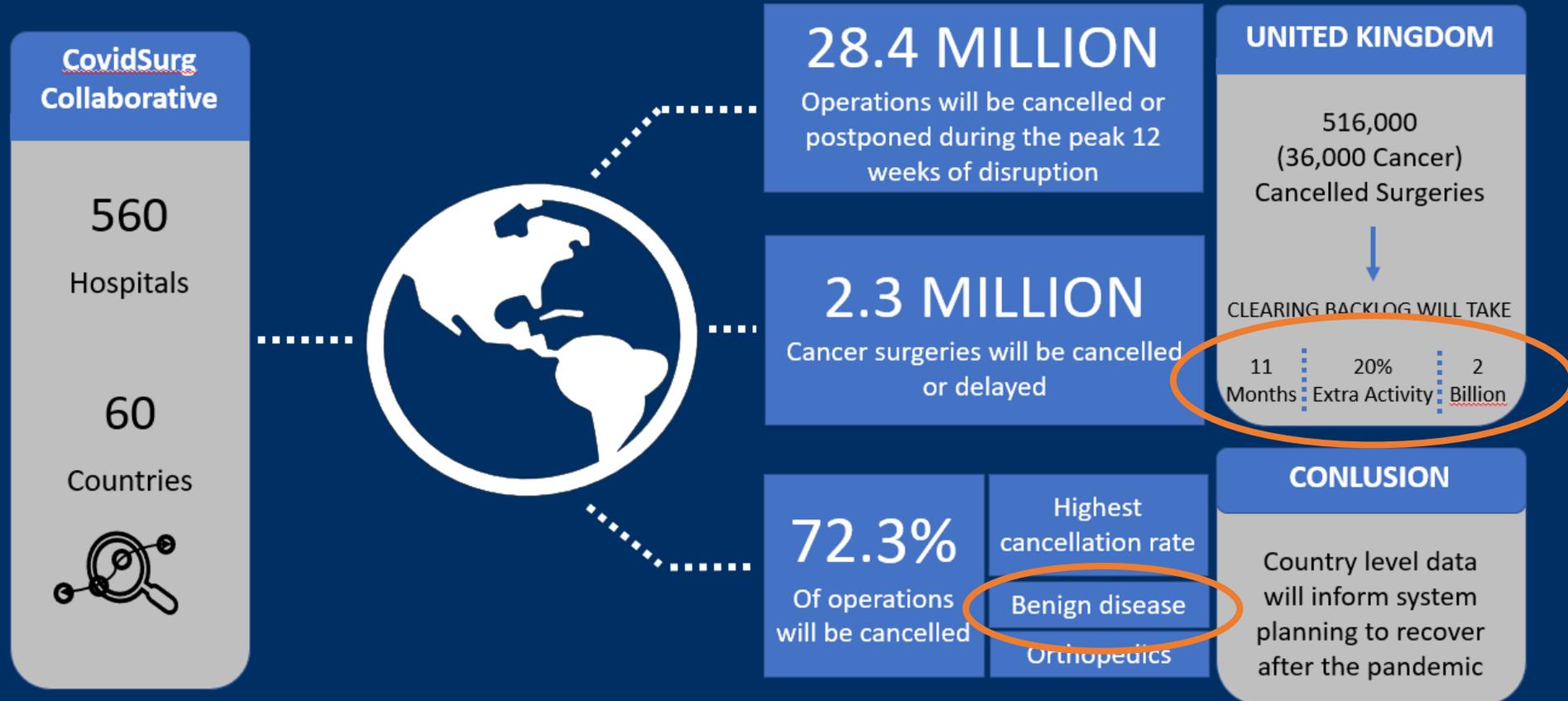
69% of surgeons highlighted a lack of theatre capacity as a significant barrier to resuming planned procedures

Which of the following barriers do you regard as significant to the resumption of planned/elective surgery in your trust/health board (n=875)?



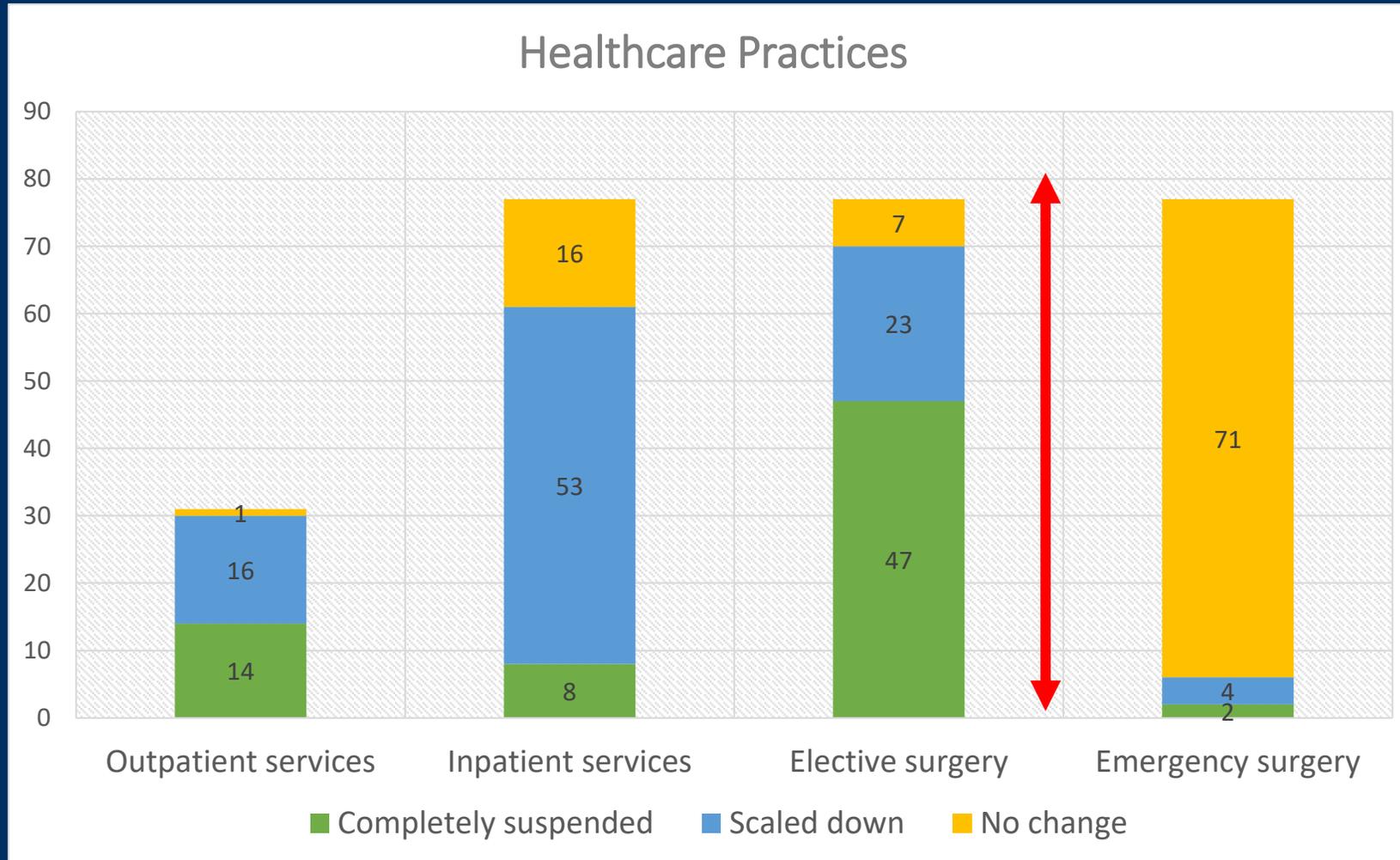
Surgical facilities will be strained – GLOBALSURG 1st wave

Elective surgery cancellations due to COVID-19 pandemic: **Global predictive modelling to inform surgical recovery plans**



Challenging discussions about what surgery takes priority are occurring already

How vascular services have been affected during COVID in Asia



Patients requiring surgery during the COVID-19 crisis have been classified in the following groups (NHS):

- Priority level 1a Emergency - operation needed within 24 hours
- Priority level 1b Urgent - operation needed with 72 hours
- Priority level 2 Surgery that can be deferred for up to 4 weeks
- Priority level 3 Surgery that can be delayed for up to 3 months
- Priority level 4 Surgery that can be delayed for more than 3 months

Vascular
access
creation??



1a. Emergency (24hrs)	Vascular injury/ occlusion (Limb - including compartment syndrome and GIT)	Uncontrolled external haemorrhage - any site/source	Ruptured AAA
1b. Urgent (up to 72 hrs)	Acute on chronic limb ischaemia Amputation for limb ischemia	Symptomatic carotid disease	?Clotted access Risk of rupture / aneurysm
2. Up to 1 month	Chronic severe limb ischaemia - no neurology	AAA >7cms diameter	Dysfunctional Access
3. Up to 3 months	AAA >5.5cm and <7cmin diameter		Vascular access creation
4. Over 3 months	Vein surgery	Thoracic outlet syndrome	Claudication

1. The Royal College of Surgeons. Clinical guide to surgical prioritisation during the coronavirus pandemic. 2020.
2. <https://www.rcsed.ac.uk/media/681262/clinical-guide-to-surgical-prioritisation-during-the-coronavirus-pandemic-version-2-8-june-2020.pdf>



SVS Covid Guidance

Category	Condition	Tier Class
Dialysis	Thrombosed or non-functional dialysis access	3 Do not postpone
	Infected dialysis access	3 Do not postpone
	Fistula revision for ulceration	3 Do not postpone
	Renal failure with need for dialysis access	3 Do not postpone
	Tunnelled Dialysis Catheter	3 Do not postpone
	Fistula revision for malfunction/steal	2b Postpone if possible
	Fistulagram for malfunction	2b Postpone if possible
	AV fistula and graft placement for dialysis (ESRD, CK4 and CK5 only)	2a Consider postponing

1. <https://vascular.org/news-advocacy/covid-19-resources>

2. <https://vascular.org/sites/default/files/Vascular%20surgery%20triage%20by%20Tier%20Class%203.24.20.pdf>



Solutions

1. Compete with other surgical procedures
(Surgical VA Creation is given priority over cancer/AAA/CI etc.)
2. Increase surgical resources
3. Use CVCs and delay Surgical VA
4. Use an alternative route of VA creation



Optimizing Best Vascular Access Practice in Patients on Dialysis during the Covid 19 Pandemic Period

High Surgical and Endovascular Vascular Access Standards

Go to:

Managing surgical and endovascular workload during a protracted COVID-19 outbreak also involves searching for innovative solutions.¹⁹ Therefore, a great proportion of fistula creation or reconstruction should be switched toward minimally invasive strategies, preferably percutaneous, in both the elective and emergency setting. Maintenance percutaneous transluminal angioplasty reduces the thrombosis rate and



Proposal: EndoAVF

Where surgical facilities are limited



Avoid CVC
Maintain VA rates
Decrease Hospitalizations



Reduce overall risk to dialysis patients
Economic benefits of avoiding CVC
Optimize facilities

Discussion

- Surgical AVFs are far from perfect
 - Poor maturation
 - High rates of CVC use
 - Maintenance requirements
 - Complications
- Covid could be a catalyst for change:
- Expanding dialysis access options to include endoAVF creation

“The impact of Covid-19 on waiting times will be felt for years to come.”
“The King’s Fund”



WavelinQ™ 4F EndoAVF System for ELQ-002

Indications: The WAVELINQ™ 4F EndoAVF System is intended for the cutting and coagulation of blood vessel tissue in the peripheral vasculature for the creation of an arteriovenous fistula used for hemodialysis.

Contraindications: Known central venous stenosis or upper extremity venous occlusion on the same side as the planned AVF creation. Known central venous stenosis or upper extremity venous occlusion on the same side as the planned AVF creation. Known allergy or reaction to any drugs/fluids used in this procedure. Known adverse effects to moderate sedation and/or anesthesia. Distance between target artery and vein > 1.5 mm. Target vessels < 2 mm in diameter.

Warnings: The WAVELINQ™ 4F EndoAVF System is only to be used with the approved commercially available devices specified in the IFU. Do not attempt to substitute non-approved devices or use any component of this system with any other medical device system. The WAVELINQ™ 4F EndoAVF System catheters are single use devices. DO NOT re-sterilize or re-use either catheter. Potential hazards of reuse include infection, device mechanical failure, or electrical failure potentially resulting in serious injury or death. Use caution when performing electrosurgery in the presence of pacemakers. Improper use could damage insulation that may result in injury to the patient or operating room personnel. Do not plug device into the electrosurgical pencil with ESU on. Keep active accessories away from patient when not in use. Do not permit cable to be parallel to and/or in close proximity to leads of other devices. Do not wrap cable around handles of metallic objects such as hemostats. Consult the ESU User's Guide on its proper operation prior to use. Do not use closure devices not indicated to close the artery used for access.

Cautions: Only physicians trained and experienced in endovascular techniques should use the device. Adhere to universal precautions when utilizing the device. Do not kink, pinch, cut, bend, twist, or pull excessively or with excessive force on any portion of the devices. Damage to the catheter body may cause the device to become inoperable. Avoid sharp bends. This may cause the device to become inoperable. Do not pinch or grasp the catheter with excessive force or with other instruments. This may cause the device to become inoperable. Do not bend the rigid portion of the catheter near the electrode or backstop. Do not touch or handle the active electrode. Electrode dislodgement may occur. Always use the hemostasis valve crosser to assist insertion of the venous catheter through the introducer sheath. Insertion into introducer sheath without hemostasis valve crosser may damage electrode. Do not attempt to remove the hemostasis valve crosser located on the venous device. Device damage or fracture may occur.

Precautions: Care should be taken to avoid the presence of fluid on the ESU. Care should be taken during handling of the arterial and venous catheters in patients with implantable cardiac defibrillators or cardiac pacemakers to keep the distal 3 inches of the catheters at least 2 inches from the implanted defibrillator or pacemaker. Care should be taken to avoid attempting fistula creation in a heavily calcified location of a vessel as fistula may not be adequately formed. If the device does not perform properly during the creation of the endovascular fistula it is possible that a fistula will not be created or there may be some vessel injury. Keep magnetic ends of catheters away from other metallic objects which may become attracted and collide with devices.

Potential Adverse Events: The known potential risks related to the WavelinQ™ 4F EndoAVF System and procedure, a standard AVF, and endovascular procedures may include, but are not limited to: aborted or longer procedure; additional procedures; bleeding, hematoma, or hemorrhage; bruising; burns; death; electrocution; embolism; failure to mature; fever; increased risk of congestive heart failure; infection; numbness, tingling, and/or coolness; occlusion/stenosis; problem due to sedation or anesthesia; pseudoaneurysm; sepsis; steal syndrome or ischemic swelling, irritation, or pain; thrombosis; toxic or allergic reaction; venous hypertension (arm swelling); vessel, nerve, or AVF damage or rupture; wound problem.

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WavelinQ™ EndoAVF System for WQ4305

Indications: The WavelinQ™ EndoAVF System is intended for the cutting and coagulation of blood vessel tissue in the peripheral vasculature for the creation of an arteriovenous fistula used for hemodialysis.

Contraindications: Known central venous stenosis or upper extremity venous occlusion on the same side as the planned AVF creation. Known allergy or reaction to any drugs/fluids used in this procedure. Known adverse effects to moderate sedation and/or anesthesia. Distance between target artery and vein > 1.5 mm. Target vessels < 2 mm in diameter.

Warnings: The WavelinQ™ EndoAVF System is only to be used with the approved commercially available devices specified in the IFU. Do not attempt to substitute non-approved devices or use any component of this system with any other medical device system. The WavelinQ™ EndoAVF System catheters are single use devices. DO NOT re-sterilize or re-use either catheter. Potential hazards of reuse include infection, device mechanical failure, or electrical failure, potentially resulting in serious injury or death. Use caution when performing electrosurgery in the presence of pacemakers. Improper use could damage insulation that may result in injury to the patient or operating room personnel. Do not plug device into the electrosurgical pencil with ESU on. Keep active accessories away from patient when not in use. Do not permit cable to be parallel to and/or in close proximity to leads of other devices. Do not wrap cable around handles of metallic objects such as hemostats. Consult the ESU User's Guide on its proper operation prior to use. Do not use closure devices not indicated to close the artery used for access.

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Thank you

