WELCOME TO OUR WEBINAR SERIES:

Exploring learnings from MNSI safety investigations

We will be starting shortly

MNSI
Maternity & Newborn
Safety Investigations

WELCOME

First trimester deaths in England from venous thromboembolism associated with hyperemesis

Thursday 13 February, 2025

Dr Louise Page
MNSI

Dr Charlotte Frise
Imperial College Healthcare NHS Trust

Chandrima Biswas
MNSI

Paul Bowie
NHS Education for Scotland

Rachel Rees
MNSI

MNSI
Maternity & Newborn Safety Investigations

Webinar series: Exploring learnings from MNSI safety investigations

Housekeeping

- We welcome your questions, please put these in the Q&A box, not the chat
- Please use the chat box to engage in the webinar and with one another
- Your sound and video will not be visible during the webinar
- The session is being recorded and will be sent a short while after the session
- If you want to discuss anything further, please email enquires@mnsi.org.uk
- The chat is moderated, please use kind and respectful language
- We will share slides, resources and a recording after the session

MNSI
Maternity & Newborn Safety Investigations

MNSI overview

Purpose

- To provide independent, standardised and family focused investigations of maternity patient safety events
- To provide learning to the healthcare system via reports at local, regional and national level
- To analyse data to identify key trends and provide system wide learning; be a system expert in standards for maternity safety investigations and to collaborate with system partners to escalate safety concerns
- MNSI focus on systems and processes that impacted on care, we do apportion blame or liability

HSIB maternity investigation programme

Started 2018

Ended 30 Sept 2023

Maternity and Newborn Safety Investigations (MNSI) programme

Born 1 October 2023

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MNSI investigation criteria

- Babies
  - Term, following labour
  - Intrapartum stillbirth
  - Early neonatal death
  - Severe brain injury

- Maternal deaths
  - During pregnancy or up to 42 days from the end of a pregnancy
  - Direct & indirect deaths
  - Excludes accidental, homicide and suicide

The Care Quality Commission (Maternity and Newborn Safety Investigation Programme) Directions 2023 (publishing.service.gov.uk)

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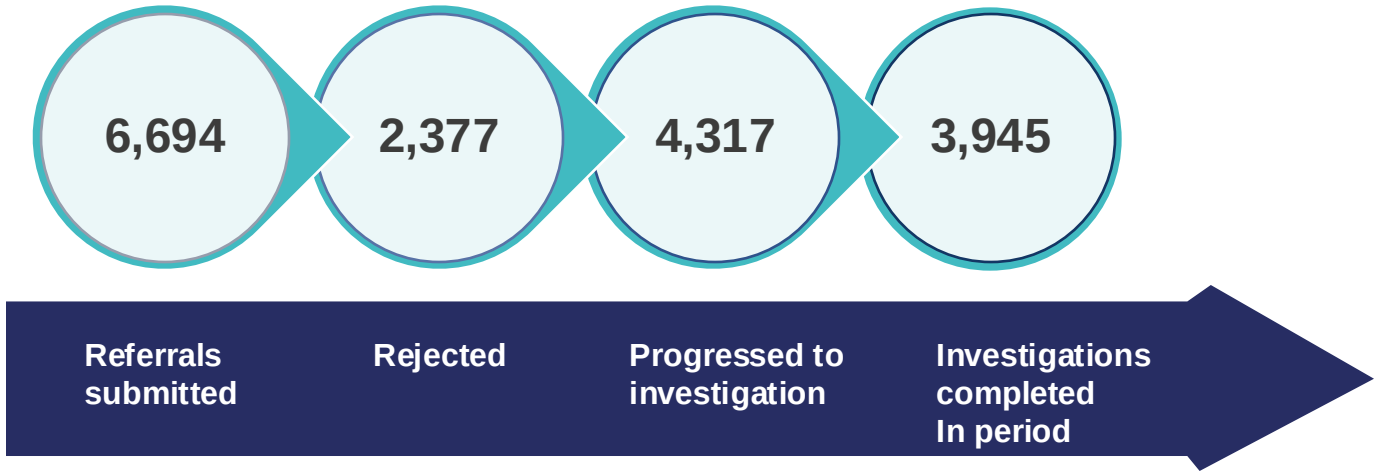
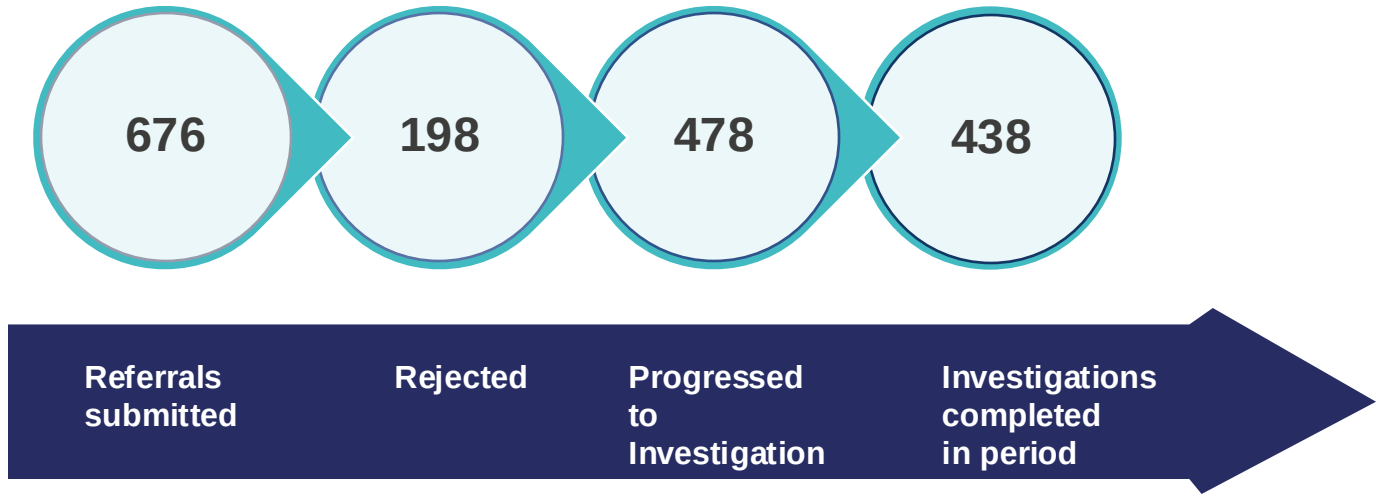
Maternity referrals: summary

01 April 2018 – 31 December 2024

Programme to date
01 Apr 2018 – 31 Dec 2024



Year to date
01 Apr 2024 – 31 Dec 2024



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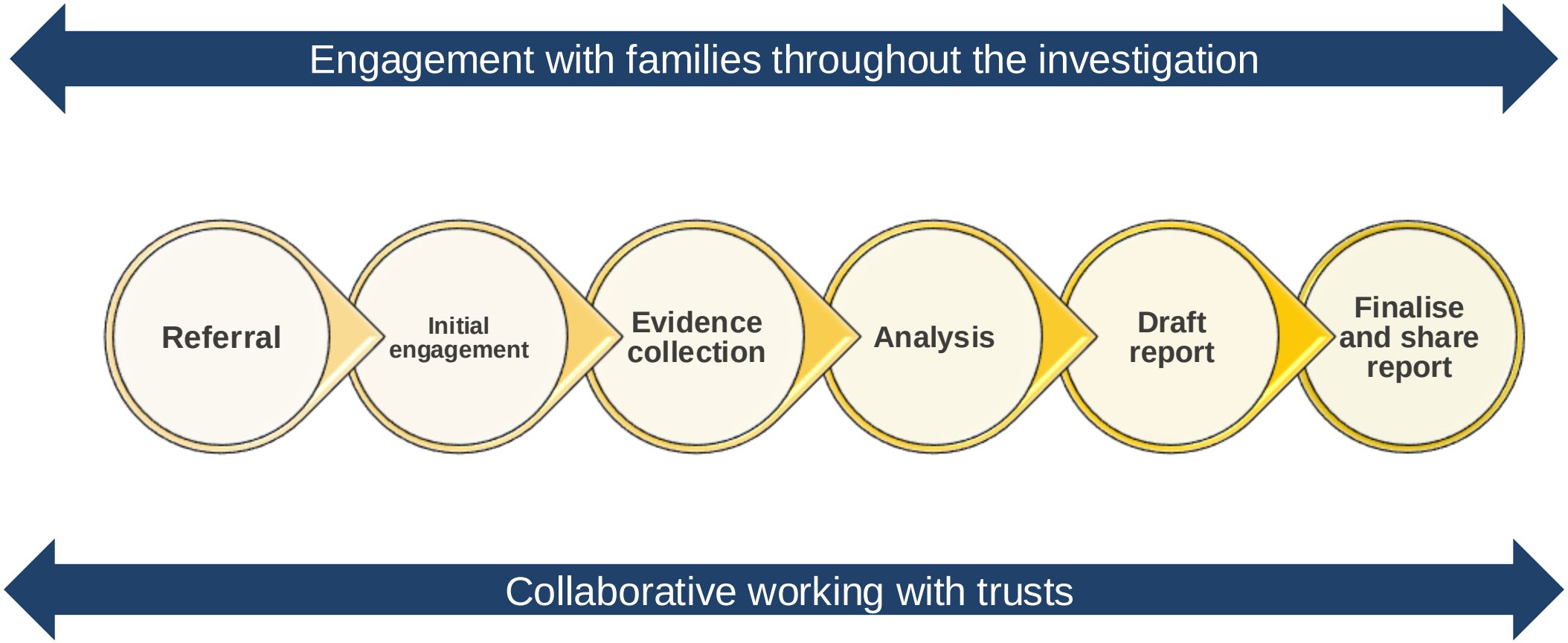
Maternity investigation approach



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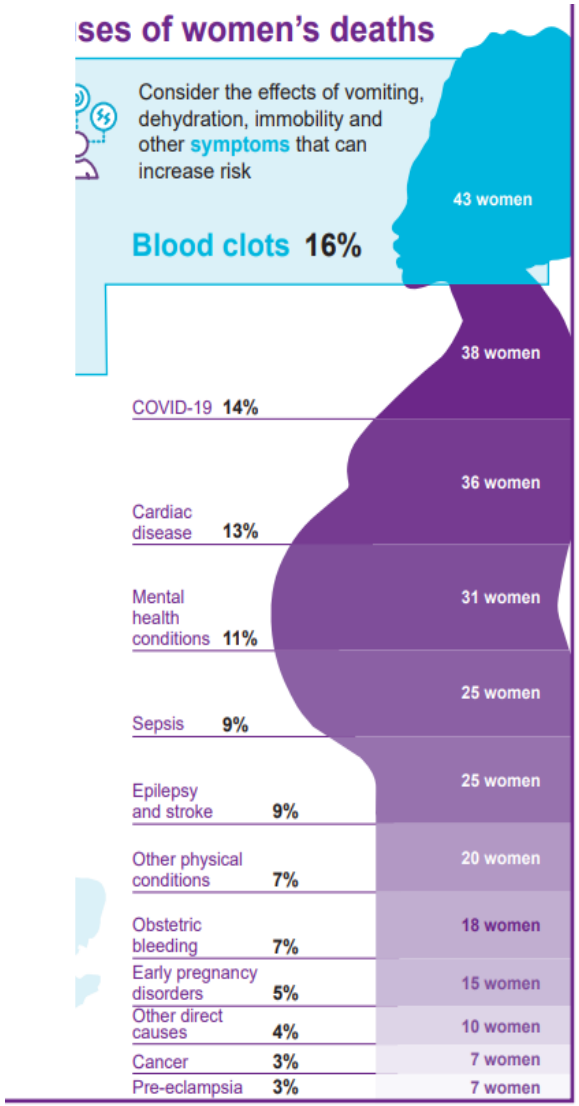
Rachel Rees

1. The 2015 national maternity ambition in England aimed to half maternal deaths by 2025

2. The maternity mortality rate for 2020-2022 is significantly higher than that reported for 2017-2019

3. The rates of death remain significantly higher when deaths due to COVID-19 are excluded

4. In 2020-2022: 275 women died during or up to six weeks after pregnancy



Key learning points

1. Standardisation of care for women with hyperemesis gravidarum (HG) is lacking
2. Awareness of its severity and associated risks of morbidity and mortality are essential to provide safe antenatal care

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Methods

25 first trimester maternal deaths (2019-2023)

28% (7 of 25) VTE secondary to HG

Thematic analysis

Focus on systems.

Round table discussion

Recurring themes extracted

Main theme: Use of national scoring systems

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VTE score EXCLUDING risk factor of HG:

- 6 of 7 sought treatment for severe vomiting
- 5 of 7 received hospital treatment, 1 managed in primary care
- 4 of 5 in hospital no VTE risk assessment on admission
  1 of 5 VTE risk assessed and LMWH
- 4 of 5 discharged from hospital, none received LMWH
- All eligible to receive LMWH for HG and immobility[1]
- All died within 2 weeks of healthcare contact (mean 6 days)

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[1] Reducing the Risk of Thrombosis and Embolism during Pregnancy and the Puerperium (Green-top Guideline No. 37a).

Implementing safety improvements

SAFETY PROMPTS

- Has your hospital embedded the routine use of approved scoring systems (such as pregnancy-unique quantification of emesis (PUQE) score) to enable a consistent approach to assessing the severity of HG?
- Is there consideration given to the need for LMWH in women who are dehydrated and immobile as inpatients or at home?
- Do women with HG receive robust advice about the indicators of VTE?
- Should consideration be given in the national VTE guidance to reflect ‘severe nausea and vomiting’ rather than waiting for a diagnosis of HG to be made?

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Paul Bowie

NHS Education for Scotland

Human Factors and the design of work procedures

Paul Bowie
PhD C.ErgHF FRCPEd (hon) FRCGP (hon)
Programme Director (Safety & Improvement)

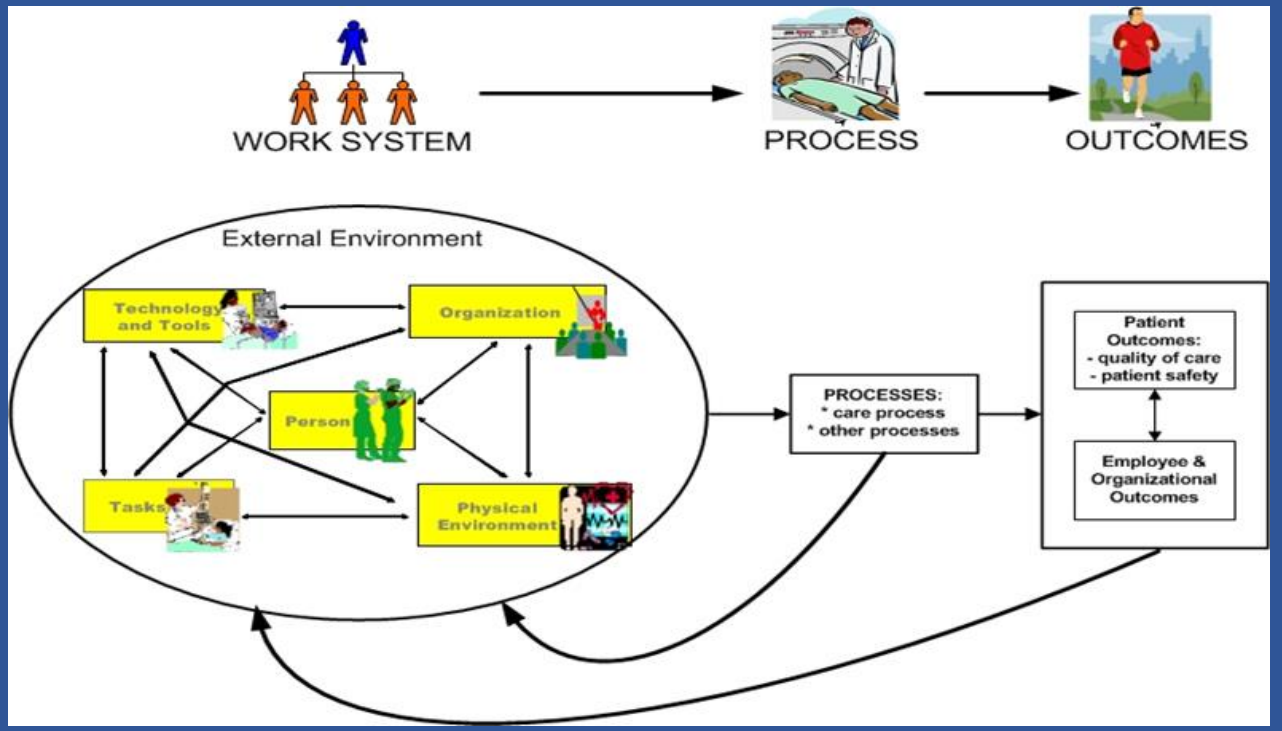
NHS Education for Scotland

Why Human Factors?

1. **It ALWAYS takes a Systems Approach** (holistic)

2. **It is ALWAYS Design Driven** (to take account of human characteristics, needs, capabilities and preferences)

3. **It focuses ALWAYS on two closely related outcomes: System Performance** and **Human Well-being** ("Twin Aims" = "Joint Optimisation")



Why Work Procedures – Such as Risk Assessment Tools?

- Essential tools in supporting safe and effective care
- Use routinely in most care processs
- Especially important in supporting safety-critical tasks
- We rely heavily on them
- Agreeing and standardising processes
- Clarifying who is responsible for which steps
- Ensuring recommended good practice is followed;

But…

- Not trained in design and implementation – hugely problematic
- 'Non/Mixed/Variable adherence'
- Cited in safety investigations
- Many other problems identified

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Human Factors

Human Factors in Health and Care

Why People Don't Follow Work Procedures

[Such as Protocols, Checklists, Standard Operating Procedures, Policies, Guidelines]

Accessibility	• We don't know where they are kept. • We don't know they exist.
Accuracy	• We think they're inaccurate. • We think they're out-of-date. • We don't think they reflect how best to do the job.
Culture & Policy	• We don't understand why they're needed. • We're unclear on when they should be used and by whom. • We think they've been created by people who don't do our job. • We're unsure which work procedure version to use. • We think their purpose and content needs to be reviewed. • We think they're designed to help other peoples' work, not ours. • We think the organisation is unnecessarily risk averse. • We don't think they will solve the problem at hand.

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Design & Usability	• We weren't involved in their co-design, testing and evaluation. • We don't think they reflect the reality of how the work is done. • We think they're too complex to fully understand. • We think it's difficult to find the right information in the work procedure. • We think the format is cumbersome, unclear, and unusable. • We think greater logic, clarity and readability are needed. • We think more testing and improvement is needed.
Feasibility	• We think they're too restrictive. • We think they're too time consuming. • We think they're impracticable and unworkable. • We need training to understand and use the work procedure. • We think if they were followed exactly as intended, they could not be completed on time. • We don't think they're needed.
Job Control	• We already know what is in the work procedure. • We are very experienced and don't need them. • We don't like being told what to do. • We think they're infantile and belittle us. • We think they interfere with our autonomy and deskill us. • We much prefer to rely on our own knowledge and skills. • We know a better way to complete the job.

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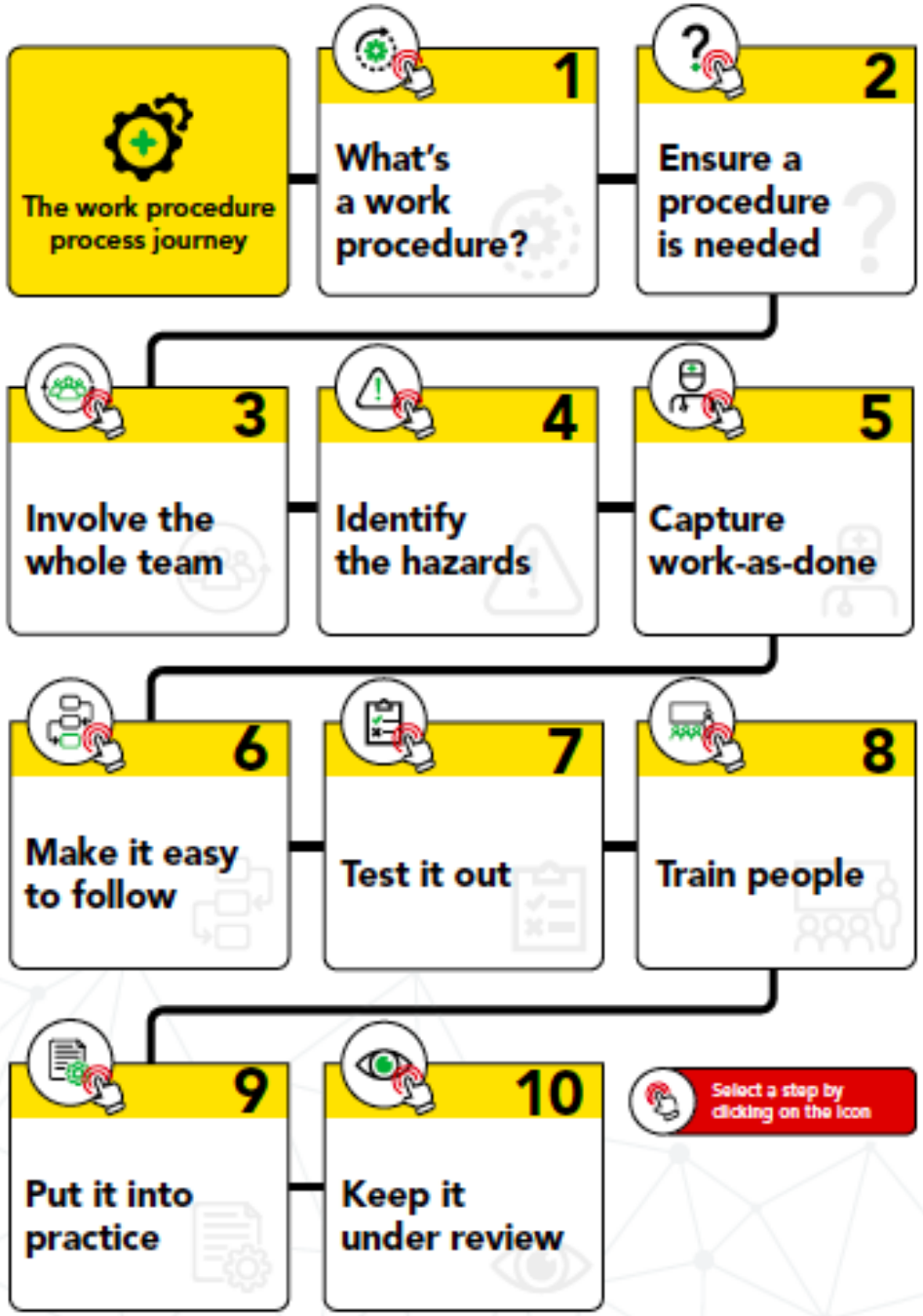
Chartered Institute of Ergonomics & Human Factors

Guidance to help design effective and usable work procedures for health and social care teams

NHS Education for Scotland · chfg · west midlands



Typically Involve a lot of Work-as-Imagined!

- Work Procedures often not adequately designed
- Developed by a single person?
- Not user-tested at every stage
- Lacking strategic approach to implementation
- Not evaluated etc
- Lack of shared understanding on how to use?’

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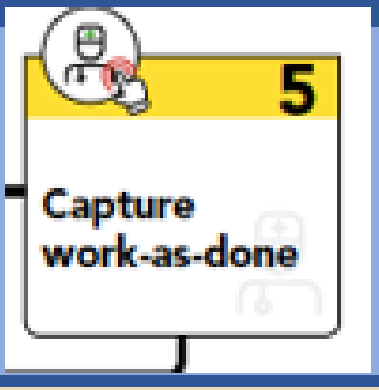
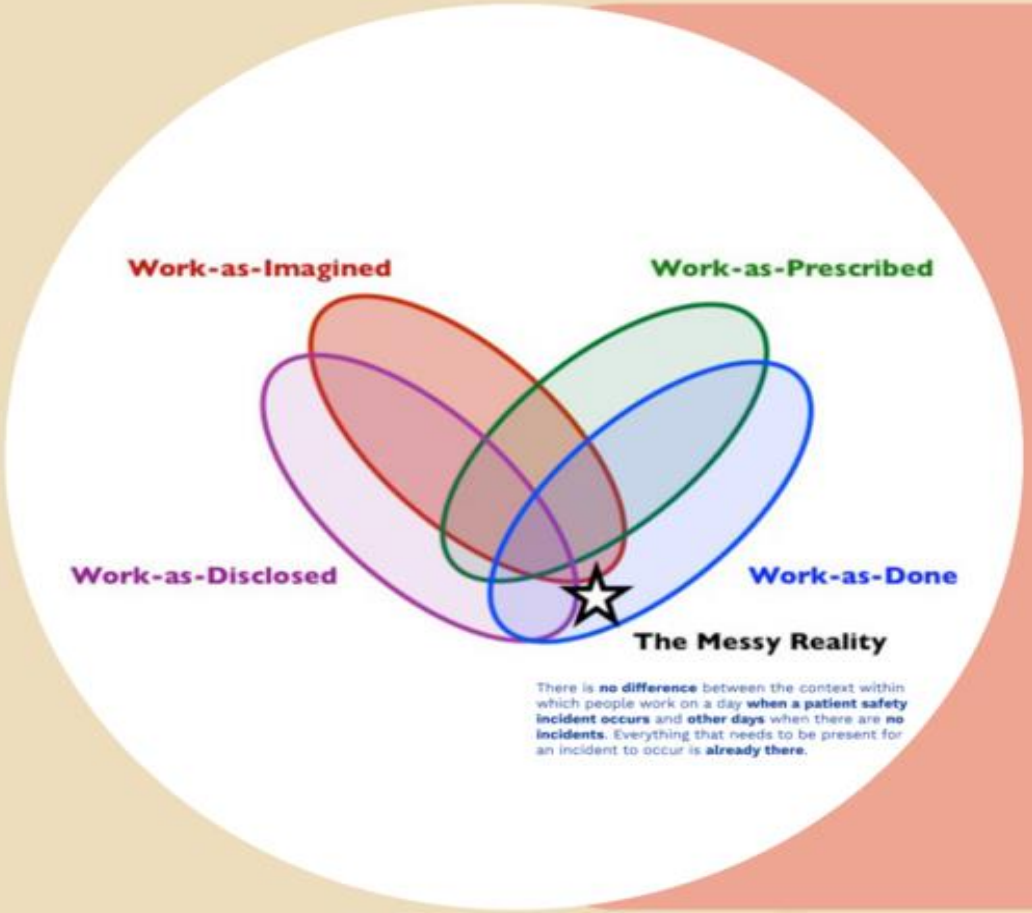
Ned to Capture and Reflect Reality of Work-as-Done





Messy reality of human work

Much work-as-done is not as-prescribed (either different to procedures, guidelines, or where there are no procedures).

Work-as-done is **usually not known** to others who are **not at the sharp end** of the work (usually not as-imagined).

The focus of The Messy Reality is the **actual work** and the **messy details**, which **may or may not be disclosed** during interviews.

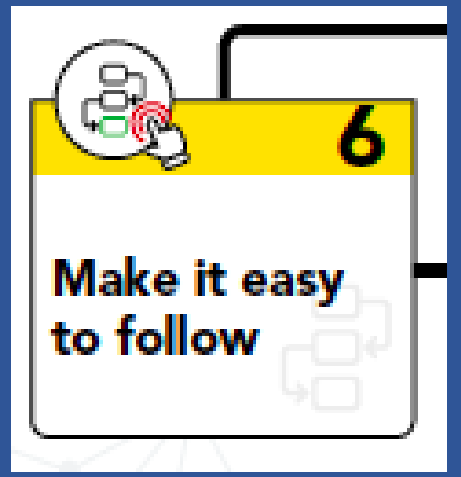
Source: https://humanisticsystems.com/2017/01/13/the-archetypes-of-human-work/

Obvious?
To whom?

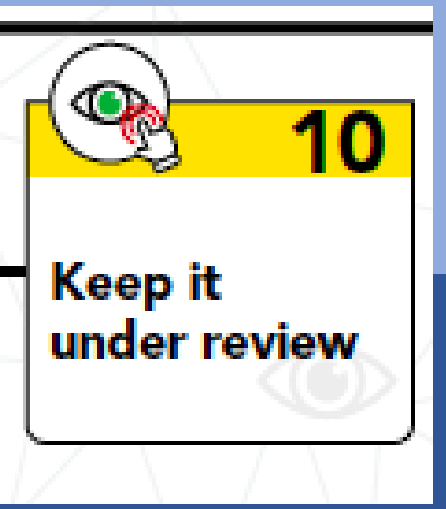
People	Tasks	Tools	Environ-ment	Organis-ation	External
Patient (carers etc)	Complexity	Availability	Location	Rosters	Legislation
Staff (capability)	Safety	Usability	Size	People plans	Guidelines
Teamwork	Number	Access.	Layout	Workload	Funding
Supervision	Design	Safety	Lighting	Fatigue	Targets
Leadership	Standard-isation	Fit for purpose?	Temp	Culture	Policy
Training		Design	Noise	Hierarchy	Incident reports
					Goals

Design - Make it easier to follow/use

- Concise and clear, plain language etc
- Format (paper or electronic)
- Accurate and readable
- Agree meanings of terms (define)
- Avoid subjectivity
- Active voice



Keep it under review



- Many of the same principles apply
- ‘Procedure-as-done’!
- What mechanisms can you use for this?
- Schedule regular review
- Be aware of factors that might change and make review critical

SUMMARY – RECOGNISING CHALLENGES

Design and Successful Implementation is Hard!

- ….are mainly social and cultural e.g. undermine expertise; are infantilising; impede quick decision-making etc.
- Major assumption: a technical solution (e.g. a checklist/scoring ‘thing’) can solve a cultural problem (‘process’) in the workplace

- Successful implementation is NOT down to the ‘checklist/scoring system’ BUT
  - to team ‘buy-in’ and co-design
  - attitude changes
  - efforts to remove barriers
  - finding creative solutions to normalise their use
  - acting on the feedback and driving improvement
  - system analysis and redesign

SUMMARY – ENHANCING CONDITIONS FOR SUCCESS

- "There must be a predefined problem with full team agreement that the scoring system is the right tool for solving it"
- "It must be co-designed, tested and evaluated with ALL usrs"
- "There's flexibility, we can break it and redefine for our context".
- "The end user must not get the feeling that he or she is deprived of the opportunity to apply common sense"
- "It must be better than the old way of working"

Chandrima Biswas

Scoring systems to assess VTE in maternity

Agenda

01

Appropriate use of scoring systems

02

Confusion around scoring systems

03

Evaluation of nausea and vomiting of pregnancy and scoring systems

Appropriate use of scoring systems

MBRRACE 2024

An older multiparous Black woman presented with vomiting late in the first trimester. She had a history of hyperemesis in a prior pregnancy. Her GP prescribed an antiemetic without further assessment. Two weeks later, at her booking appointment, she was noted to still be vomiting and her midwife referred her to the emergency department. A VTE assessment was carried out using the hospital's local assessment tool and she was deemed low-risk. She was discharged and advised to continue taking cyclizine. Four days later her nausea and vomiting seemed to be improving but she complained of pain in her upper leg which persisted for two days. She collapsed and died at home before a scheduled GP appointment. Bilateral pulmonary emboli and a DVT were found at postmortem.

Confusion around scoring systems (MBRRACE 2018)

- Local, simplified versions of national risk assessment scoring frameworks had been produced. These appeared to have significant deviation from national guidance, and it was not clear on what basis the simplifications had been made.
- This inconsistency in risk assessment was noted between
  - different units
  - different clinicians caring for the women who died
  - MBRRACE assessors reviewing the same woman's care.

Appendix I: Obstetric thromboprophylaxis risk assessment and management

Antenatal assessment and management (to be assessed at booking and repeated if admitted)

- Any previous VTE except a single event related to major surgery → **HIGH RISK**: Requires antenatal prophylaxis with LMWH. Refer to trust-nominated thrombosis in pregnancy expert/team
- Hospital admission
- Single previous VTE related to major surgery
- High-risk thrombophilia + no VTE
- Medical comorbidities e.g. cancer, heart failure, active SLE, IBD or inflammatory polyarthropathy, nephrotic syndrome, type I DM with nephropathy, sickle cell disease, current IVDU
- Any surgical procedure e.g. appendicectomy
- OHSS (first trimester only) → **INTERMEDIATE RISK**: Consider antenatal prophylaxis with LMWH
- Obesity (BMI > 30 kg/m²)
- Age > 35
- Parity ≥ 3
- Smoker
- Gross varicose veins
- Current pre-eclampsia
- Immobility, e.g. paraplegia, PGP
- Family history of unprovoked or estrogen-provoked VTE in first-degree relative
- Low-risk thrombophilia
- Multiple pregnancy
- IVF/ART → **Four or more risk factors**: prophylaxis from first trimester; **Three risk factors**: prophylaxis from 28 weeks; **Zero to two risk factors**: prophylaxis if admitted to hospital
- Transient risk factors: Dehydration/hyperemesis; current systemic infection; long-distance travel → **LOWER RISK**: Mobilisation and avoidance of dehydration

APL = antiphospholipid antibodies (lupus anticoagulant, anticardiolipin antibodies, β_2-glycoprotein 1 antibodies); ART = assisted reproductive technology; BMI based on booking weight; DM = diabetes mellitus; FHx = family history; gross varicose veins = symptomatic, above knee or associated with phlebitis/oedema/skin changes; high-risk thrombophilia = antithrombin deficiency, protein C or S deficiency, compound or homozygous for low-risk thrombophilias; IBD = inflammatory bowel disease; immobility = ≥ 3 days; IVDU = intravenous drug user; IVF = in vitro fertilisation; LMWH = low-molecular-weight heparin; long-distance travel = > 4 hours; low-risk thrombophilia = heterozygous for factor V Leiden or prothrombin G20210A mutations; OHSS = ovarian hyperstimulation syndrome; PGP = pelvic girdle pain with reduced mobility; PPH = postpartum haemorrhage; thrombophilia = inherited or acquired; VTE = venous thromboembolism.

Postnatal assessment and management (to be assessed on delivery suite)

- Any previous VTE
- Anyone requiring antenatal LMWH
- High-risk thrombophilia
- Low-risk thrombophilia + FHx → **HIGH RISK**: At least 6 weeks' postnatal prophylactic LMWH
- Caesarean section in labour
- BMI ≥ 40 kg/m²
- Readmission or prolonged admission in the puerperium
- Any surgical procedure in the puerperium except immediate repair of the perineum
- Medical comorbidities e.g. cancer, heart failure, active SLE, IBD or inflammatory polyarthropathy; nephrotic syndrome, type I DM with nephropathy, sickle cell disease, current IVDU → **INTERMEDIATE RISK**: At least 10 days' postnatal prophylactic LMWH
- Age > 35 years
- Obesity (BMI ≥ 30 kg/m²)
- Parity ≥ 3
- Smoker
- Elective caesarean section
- Family history of VTE
- Low-risk thrombophilia
- Gross varicose veins
- Current systemic infection
- Immobility, e.g. paraplegia, PGP, long-distance travel
- Current pre-eclampsia
- Multiple pregnancy
- Preterm delivery in this pregnancy (< 37+0 weeks)
- Stillbirth in this pregnancy
- Mid-cavity rotational or operative delivery
- Prolonged labour (> 24 hours)
- PPH > 1 litre or blood transfusion

Two or more risk factors → **NB If persisting or > 3 risk factors consider extending thromboprophylaxis with LMWH**

Fewer than two risk factors → **LOWER RISK**: Early mobilisation and avoidance of dehydration

Antenatal and postnatal prophylactic dose of LMWH

Weight < 50 kg = 20 mg enoxaparin/2500 units dalteparin/3500 units tinzaparin daily
Weight 50–90 kg = 40 mg enoxaparin/5000 units dalteparin/4500 units tinzaparin daily
Weight 91–130 kg = 60 mg enoxaparin/7500 units dalteparin/7000 units tinzaparin daily
Weight 131–170 kg = 80 mg enoxaparin/10000 units dalteparin/9000 units tinzaparin daily
Weight > 170 kg = 0.6 mg/kg/day enoxaparin/ 75 u/kg/day dalteparin/ 75 u/kg/day tinzaparin

Research evidence is needed to restructure the existing national VTE risk assessment tool

The national assessment tool should:

- Be easy to use, clear and accurate
- Take into account factors that may arise during pregnancy or in the postnatal period
- Be based on research evidence

Women should be assessed:

- At booking or as early in pregnancy as possible
- After pregnancy, regardless of how the pregnancy ends
- If they are admitted to the hospital or develop other problems

Evidence-based

The Pregnancy-Unique Quantification of Emesis (PUQE) Score

Mild <6; Moderate 7-12; severe 13-15

In the last 24 hours, for how long have you felt nauseated or sick to your stomach?	Not at all (1)	1 hour or less (2)	2–3 hours (3)	4–6 hours (4)	More than 6 hours (5)
In the last 24 hours have you vomited or thrown up?	I did not throw up (1)	1-2 times (2)	3–4 times (3)	5-6 times (4)	7 or more times (5)
In the last 24 hours how many times have you had retching or dry heaves without bringing anything up?	No time (1)	1–2 times (2)	3–4 times (3)	5–6 times (4)	7 or more times (5)

Use of PUQE scores

- Embedding routine use of approved scoring systems (such as pregnancy-unique quantification of emesis (PUQE) score) to enable a consistent approach to assessing the severity of Hyperemesis Gravidarum
- Consideration in the next VTE guidance to reflect ‘severe nausea and vomiting’ rather than waiting for a label of ‘Hyperemesis Gravidarum’ to be made, as it is associated with issues with mobility as well as dehydration. Mobility may have contributed to subsequent thrombosis

Dr Charlotte Frise

Beyond maternity staff…

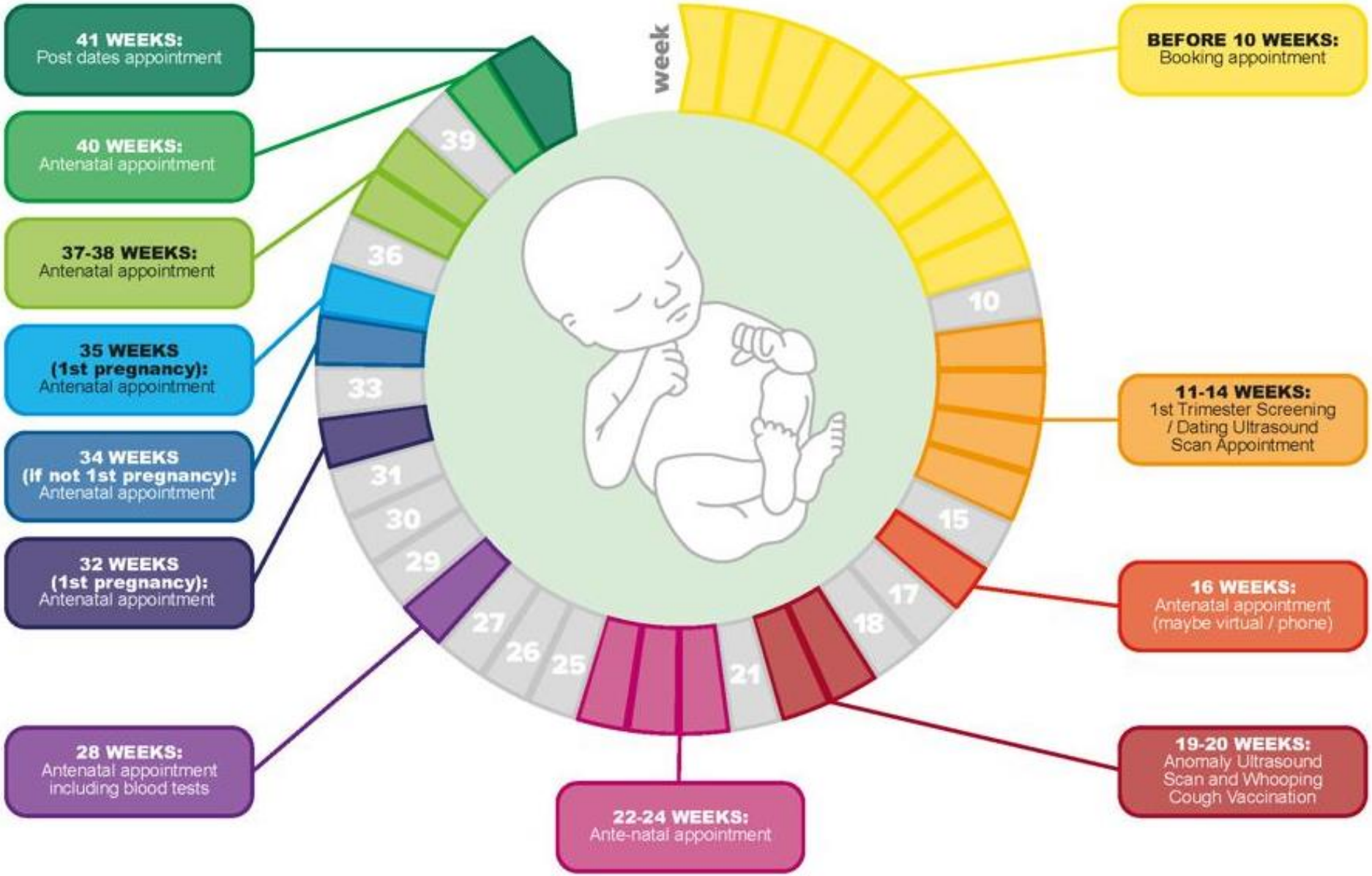
Charlotte Frise

Consultant Obstetric Physician, Queen Charlotte's and Chelsea Hospital

Lead Obstetric Physician for NW London Maternal Medicine Network

Senior College Lecturer in Clinical Medicine, Keble College, Oxford

@obstetricmedic


41 WEEKS:
Post dates appointment
40 WEEKS:
Antenatal appointment
37-38 WEEKS:
Antenatal appointment
35 WEEKS
(1st pregnancy):
Antenatal appointment
34 WEEKS
(If not 1st pregnancy):
Antenatal appointment
32 WEEKS
(1st pregnancy):
Antenatal appointment
28 WEEKS:
Antenatal appointment
including blood tests
22-24 WEEKS:
Ante-natal appointment
19-20 WEEKS:
Anomaly Ultrasound
Scan and Whooping
Cough Vaccination
16 WEEKS:
Antenatal appointment
(maybe virtual / phone)
11-14 WEEKS:
1st Trimester Screening
/ Dating Ultrasound
Scan Appointment
BEFORE 10 WEEKS:
Booking appointment
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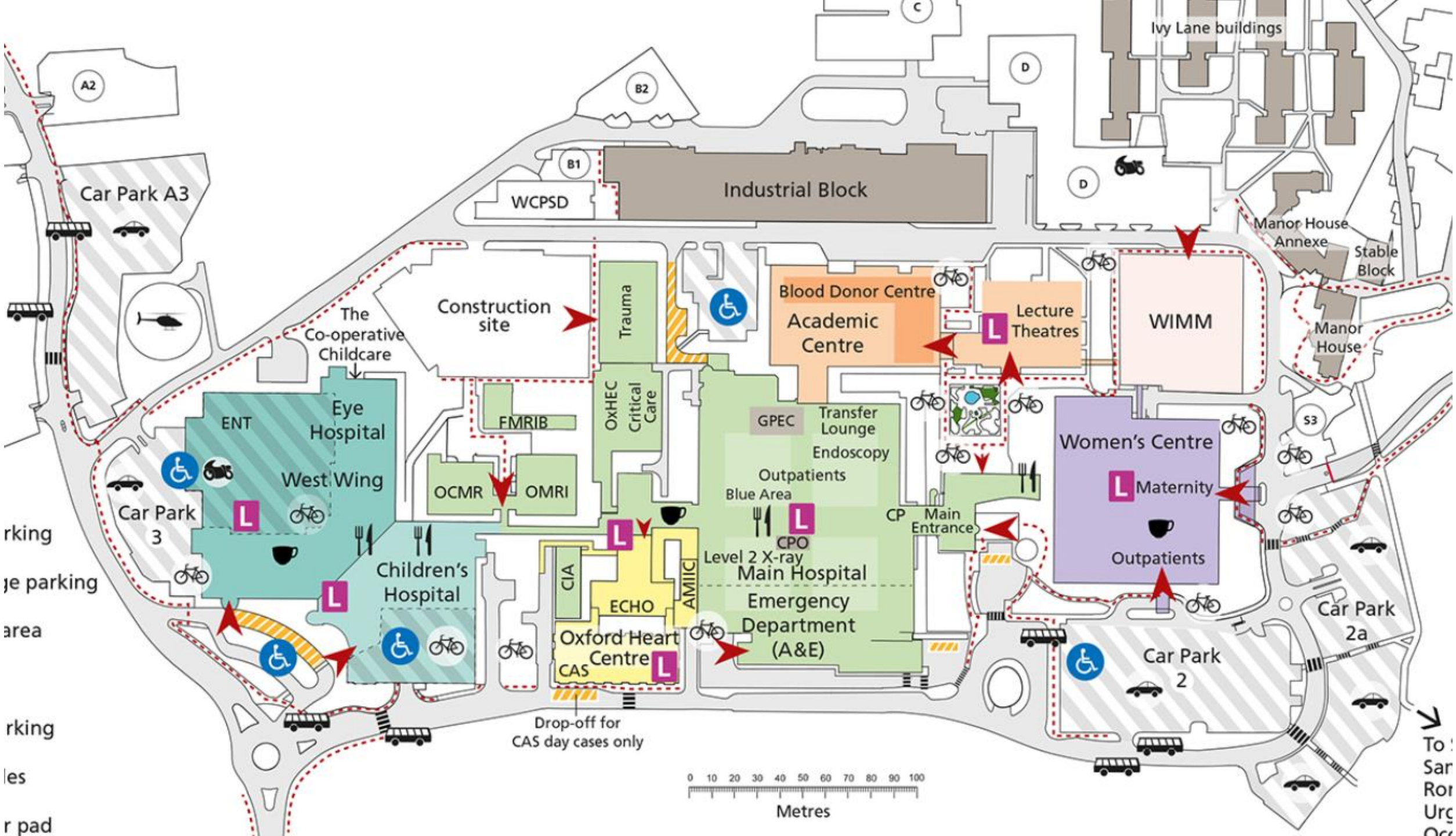
NHS Fife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Ivy Lane buildings
Car Park A3
WCPSD
Industrial Block
Manor House Annexe
Stable Block
Manor House
The Co-operative Childcare
Construction site
Trauma
Blood Donor Centre
Academic Centre
Lecture Theatres
WIMM
ENT
Eye Hospital
West Wing
FMRIB
OxHEC
Critical Care
GPEC
Transfer Lounge
Endoscopy
Outpatients
Blue Area
OCMR
OMRI
Car Park 3
CP
Main Entrance
Women's Centre
Maternity
Outpatients
S3
Children's Hospital
CIA
ECHO
AMIIC
CPO
Level 2 X-ray
Main Hospital
Emergency Department (A&E)
Oxford Heart Centre
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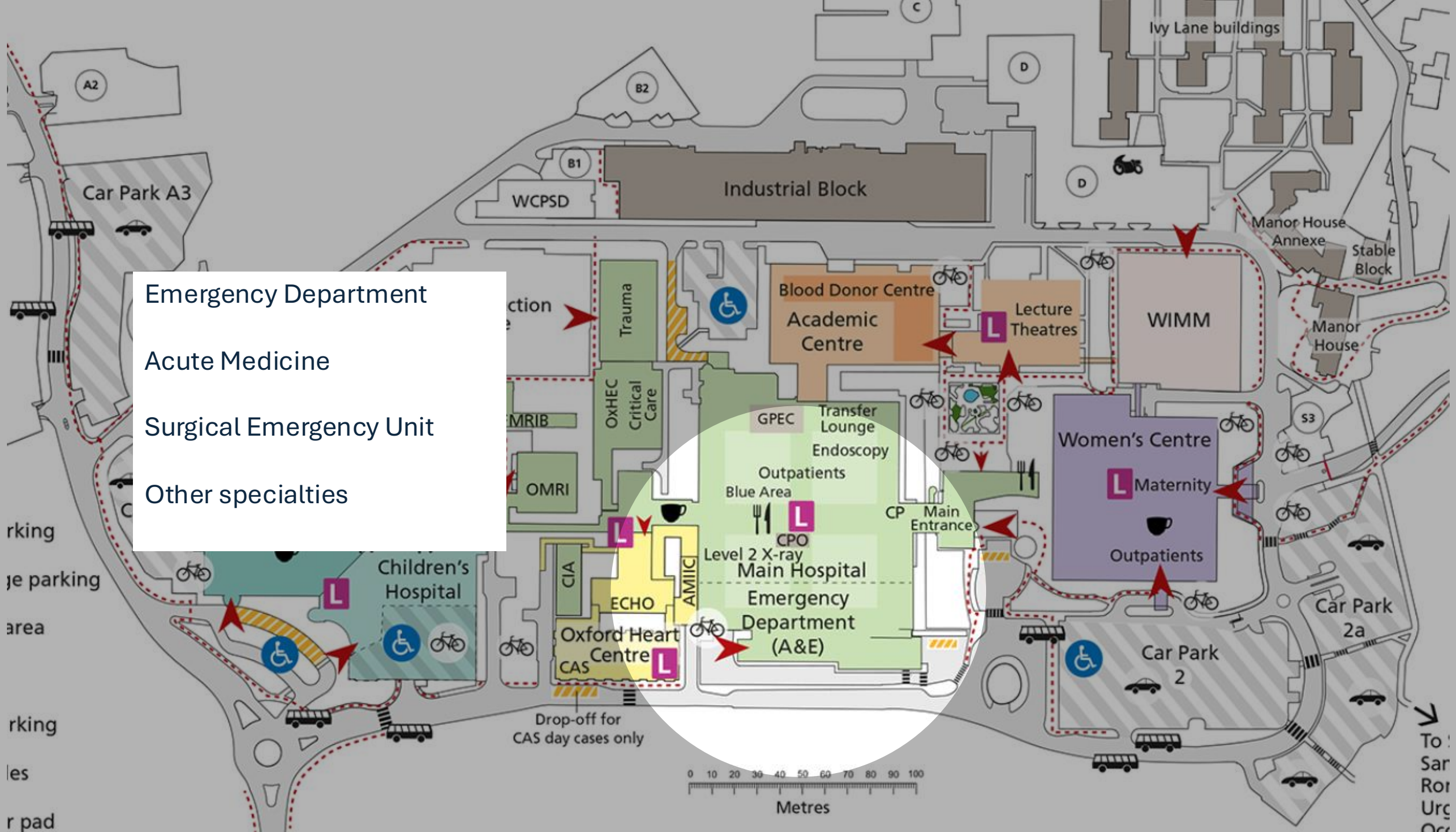
Emergency Department
Acute Medicine
Surgical Emergency Unit
Other specialties
Ivy Lane buildings
Industrial Block
WCPSD
Car Park A3
Manor House Annexe
Stable Block
Manor House
Blood Donor Centre
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Oxford Heart Centre
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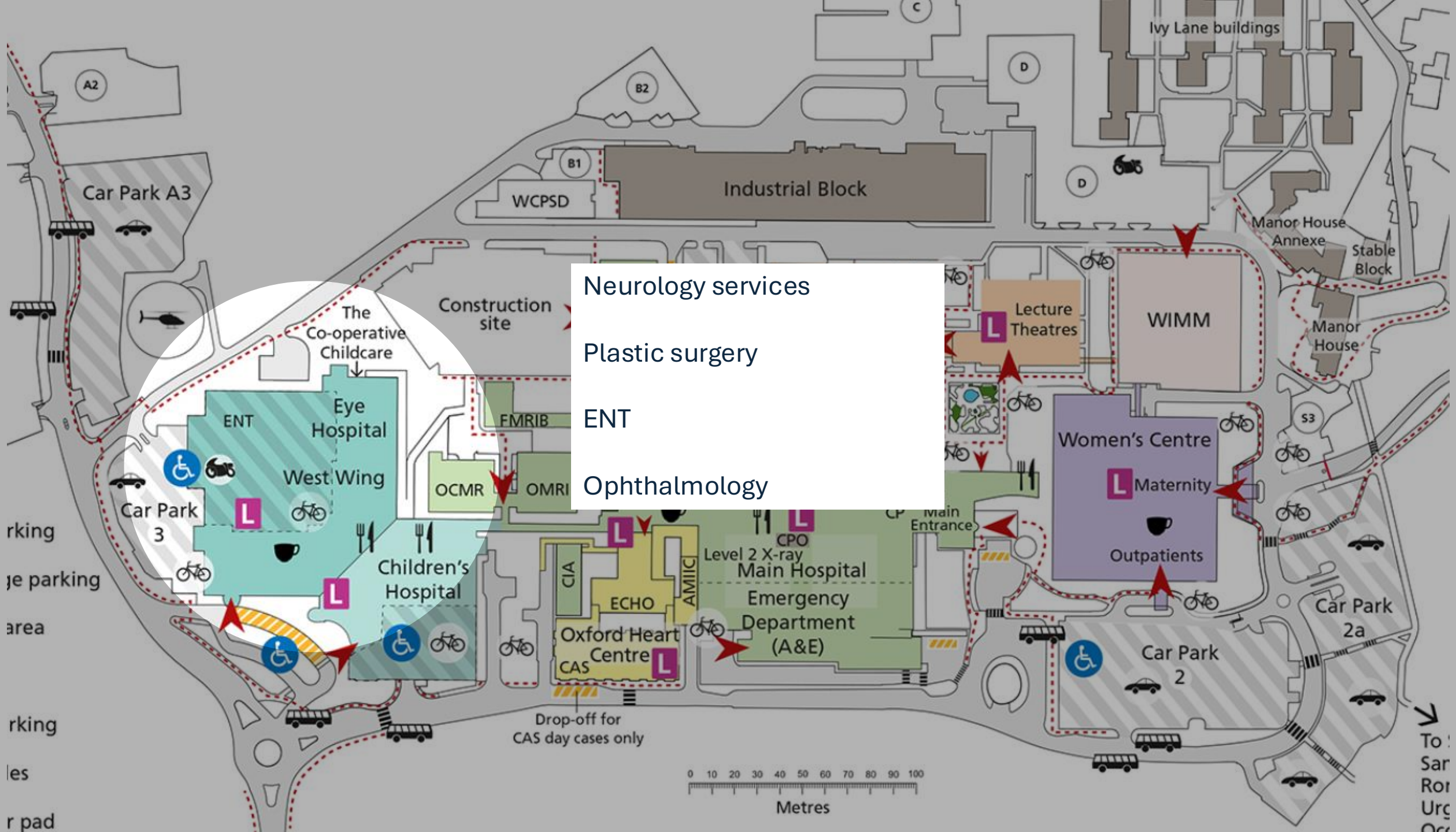
Neurology services
Plastic surgery
ENT
Ophthalmology
Ivy Lane buildings
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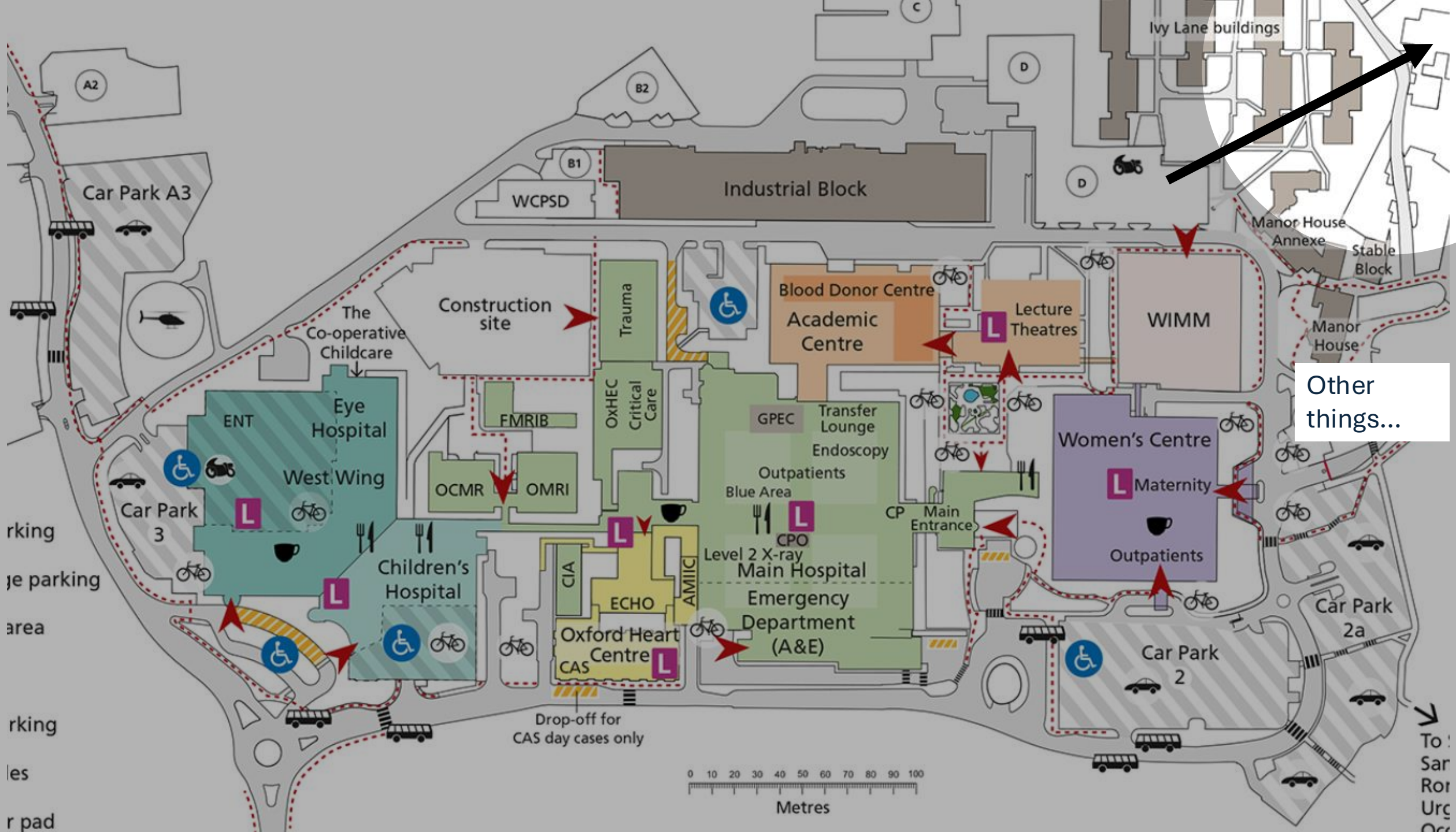
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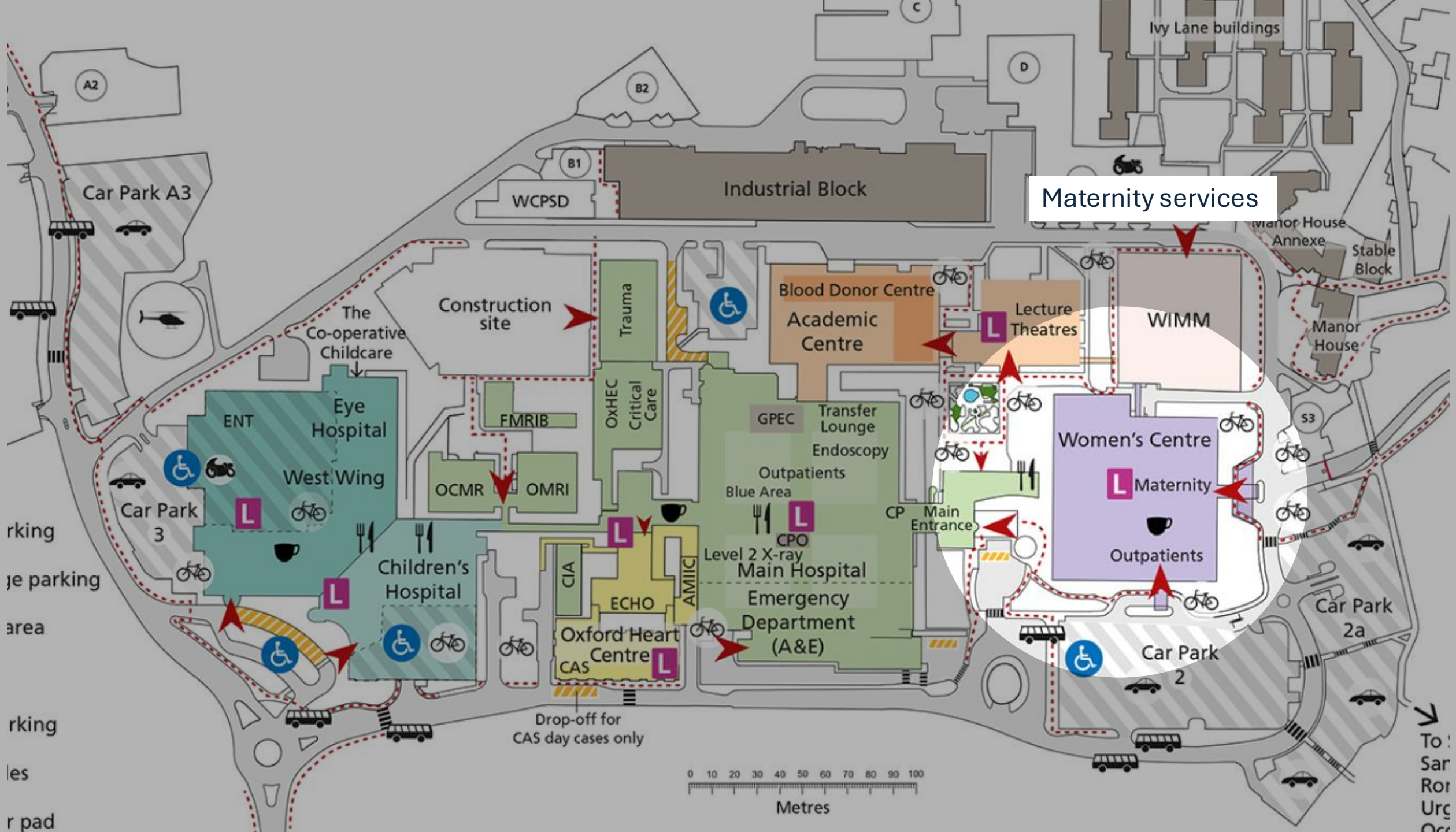
Manor House Annexe
Stable Block
Manor House
The Co-operative Childcare
Construction site
Trauma
Blood Donor Centre
Academic Centre
Lecture Theatres
WIMM
Other things...
ENT
Eye Hospital
West Wing
FMRIB
OxHEC
Critical Care
GPEC
Transfer Lounge
Endoscopy
Outpatients
Blue Area
OCMR
OMRI
Women's Centre
Maternity
Outpatients
Car Park 3
Children's Hospital
CIA
ECHO
AMIIC
Level 2 X-ray
Main Hospital
Emergency Department (A&E)
CPO
CP
Main Entrance
Oxford Heart Centre
CAS
Car Park 2a
Car Park 2
Drop-off for CAS day cases only
0 10 20 30 40 50 60 70 80 90 100
Metres


Maternity services
Ivy Lane buildings
Industrial Block
WCPSD
Car Park A3
A2
B2
B1
C
D
The Co-operative Childcare
Construction site
Trauma
Blood Donor Centre
Academic Centre
Lecture Theatres
WIMM
Manor House Annexe
Stable Block
Manor House
S3
ENT
Eye Hospital
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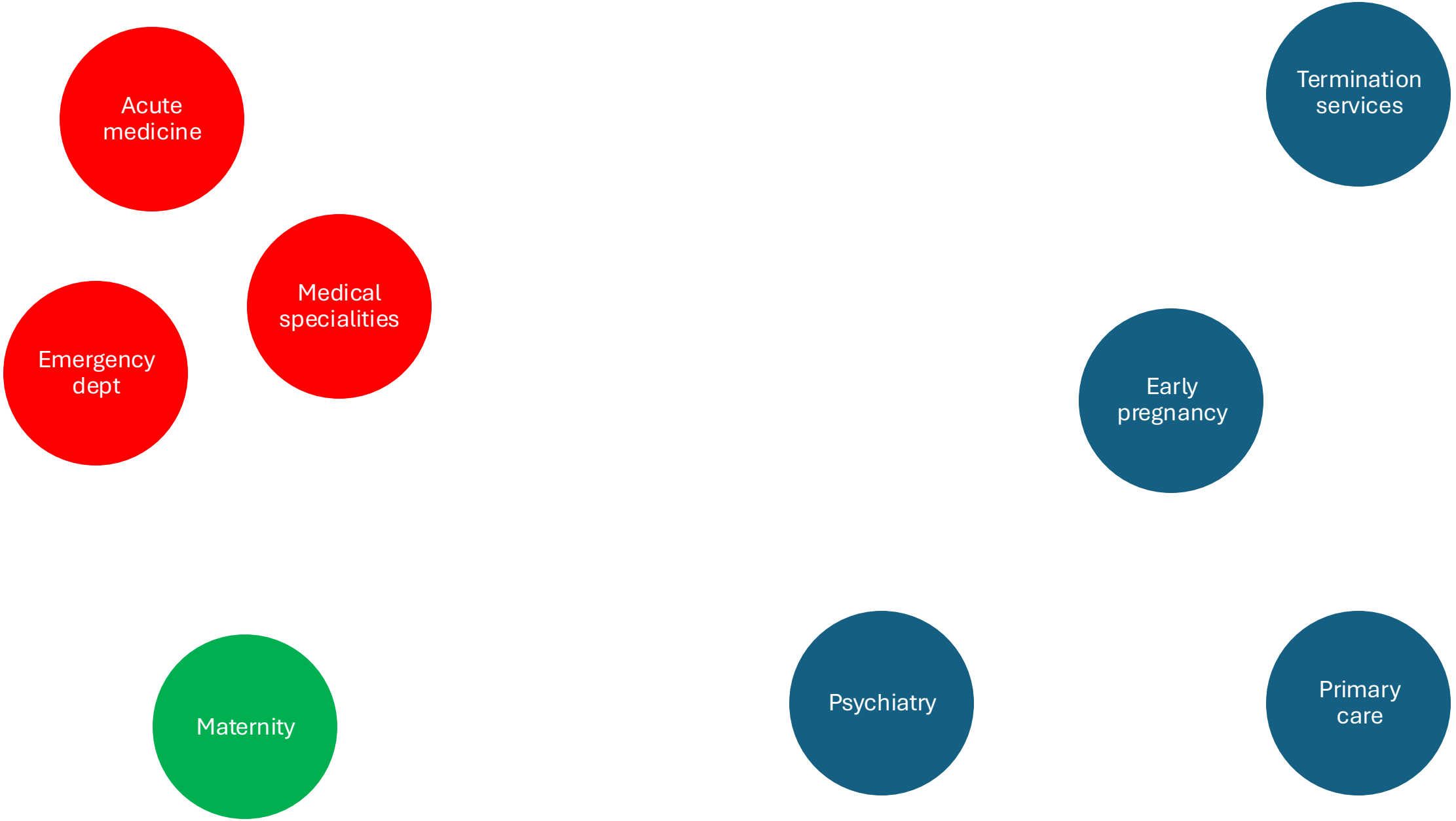
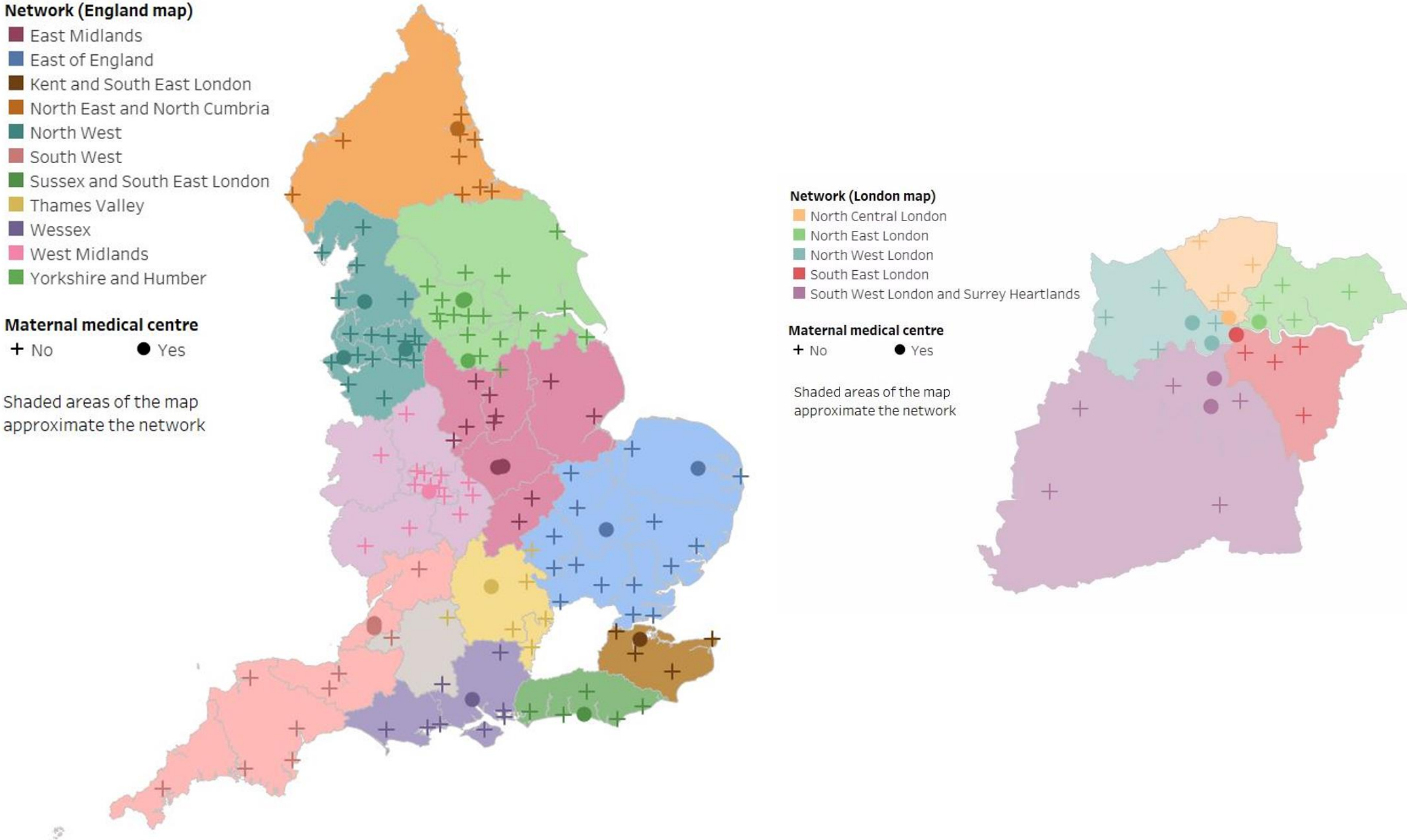
Car Park 2a
0 10 20 30 40 50 60 70 80 90 100
Metres


Acute medicine
Termination services
Medical specialities
Emergency dept
Early pregnancy
Maternity
Psychiatry
Primary care


Network (England map)
East Midlands
East of England
Kent and South East London
North East and North Cumbria
North West
South West
Sussex and South East London
Thames Valley
Wessex
West Midlands
Yorkshire and Humber
Maternal medical centre
No
Yes
Shaded areas of the map approximate the network
Network (London map)
North Central London
North East London
North West London
South East London
South West London and Surrey Heartlands
Maternal medical centre
No
Yes
Shaded areas of the map approximate the network

NW LONDON
Maternal Medicine Network

North West London Maternal Medicine Network

Imperial.MMC@nhs.net

[insert date]

Maternity Units in NW London

Dear [name]

The recent MBRRACE report (October 2024) has again emphasised venous thromboembolism (VTE) as a leading cause of maternal mortality. Of significant concern were the deaths that occurred in the first trimester, including women with a previous VTE, and those with hyperemesis gravidarum.

A new recommendation in this report was therefore:

"Clearly define the rapid access pathways for prescribing thromboprophylaxis to ensure that women known to be at risk are able to access thromboprophylaxis when they need it, particularly in the first trimester"

As a Network, we recognise the difficulties with provision of thromboprophylaxis in the first trimester, when women potentially lack continuity of care, and may be seen in several different health care settings including primary care, early pregnancy services, termination services, medical emergency services and maternity.

There are three groups of pregnant women needing thromboprophylaxis that require separate consideration by service providers:

1. Women with a previous VTE
2. Women with 4 or more risk factors for VTE according to RCOG guideline 37a
3. Women who present to non-maternity settings such as the Emergency Department and develop new risk factors for example hyperemesis

We therefore met in November 2024 to discuss these urgent concerns and have agreed the following recommendations which now need to be implemented:

1. Prophylactic low molecular weight heparin should be provided to those who need it within 72 hours of initial patient contact
2. A scan to confirm a viable intrauterine pregnancy is **not** required prior to prescription; referral to an Early Pregnancy Unit is recommended at the time of prescription of thromboprophylaxis to facilitate a scan in due course
3. Information about safety advice (bleeding, abdominal pain etc. and the need to seek urgent medical attention) should be provided at the time of provision of thromboprophylaxis
4. A VTE risk assessment is required for all women attending termination of pregnancy or early pregnancy services
5. A VTE risk assessment is also required for all pregnant or recently pregnant women (up to 6 weeks after delivery or pregnancy loss) attending an urgent/emergency care setting.

These recommendations and amended pathways should be shared widely, to ensure that all health care professionals who may be involved are aware (for example to include the on-call teams who may be contacted by primary care, Emergency Department / Acute Medicine teams) and we would be grateful for your assistance with this.

Yours sincerely

Electronically signed on behalf of

Charlotte Frise, Lead Obstetric Physician

Mandish Dhanjal, Lead Obstetrician

Joanna Girling, Clinical Director

NW LONDON
Maternal Medicine Network

Questions & answers

Please only use the Q & A box to input your questions

NEXT WEBINAR:

Deaths in England in the first trimester of pregnancy

Wednesday 26 February, 1pm – 2pm

Dr Louise Page
MNSI

Dr Charlotte Frise
Imperial College Healthcare NHS Trust

Dr Vidya Sundar
Royal Free NHS Foundation Trust, UK

Julian Sutton
MNSI

Louise Wake
MNSI

Kirsty MacLennon
MNSI

MNSI
Maternity & Newborn Safety Investigations

Webinar series: Exploring learnings from MNSI safety investigations

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