Consent for the Vulnerable Adult

Mental Capacity Act

Emma Young
Divisional Research Lead - Medicine

Key Points

- What is consent and what is a vulnerable adult
- Outline the main points from the Mental Capacity Act
- Different types of Consent
- Important things to consider when consenting vulnerable patients
- Case Study

What is valid Informed consent?

For consent to be valid the person must:

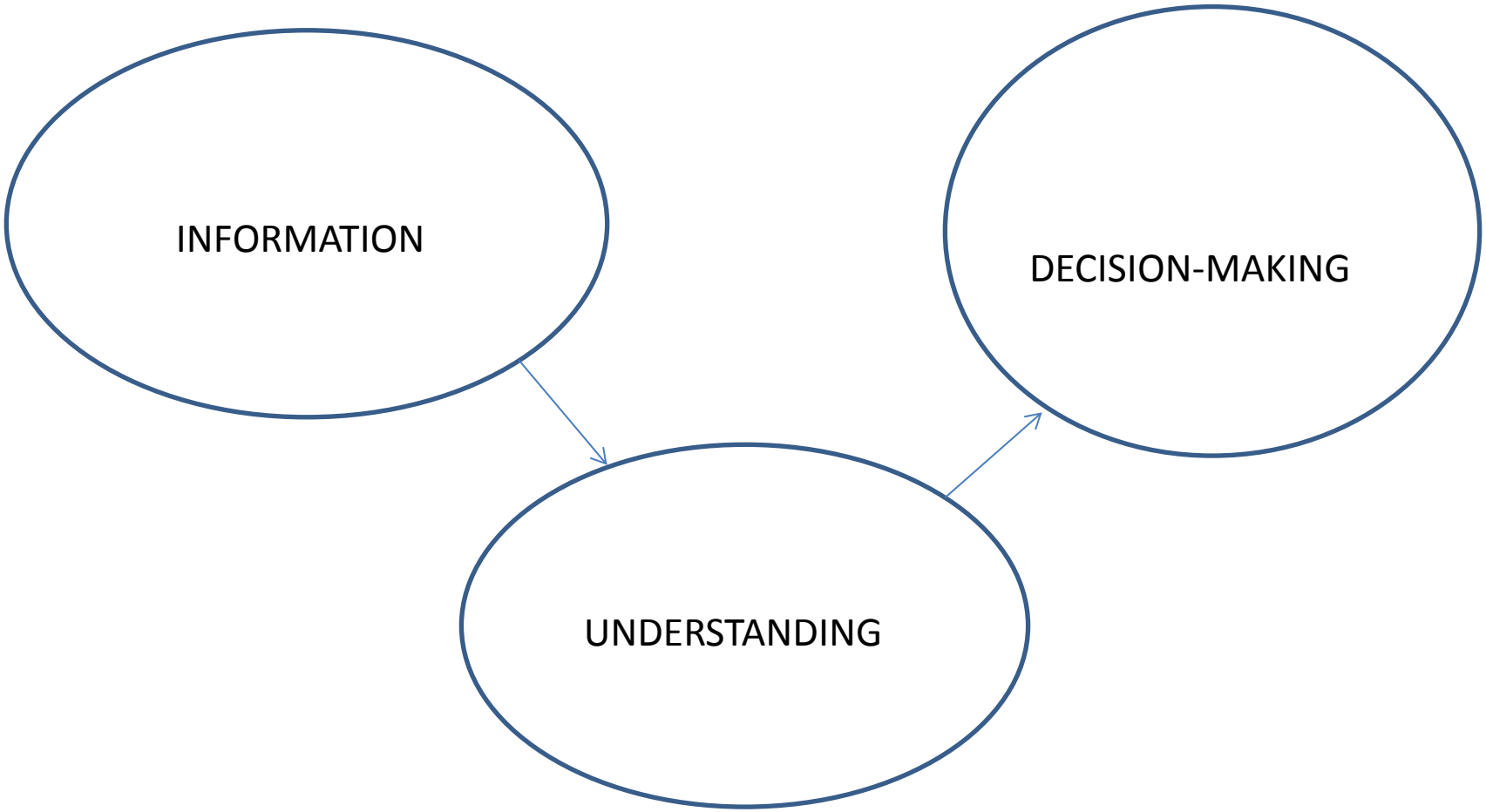
1. Be competent to make that **decision**
2. Have received sufficient **information** to use to make that decision
3. Not be pressured to take part or make a **decision**
4. Information needs to be given in a means they **understand**; (writing, pictures, discussions, question and answers)

What do we mean by vulnerable adult?

The Mental Capacity Act (2005) states that an adult is vulnerable when they cannot make a decision themselves as they are:

1. Unable to retain the **information** being given to them

2. Unable to understand how this information is relevant to the **decision** they have to make and how it may have consequences


INFORMATION
DECISION-MAKING
UNDERSTANDING

Key Principle No 1

Every adult has the right to make his or her own decisions and must be assumed to have capacity to make them unless it is proved otherwise

Key Principle No 2

A person must be given all practicable help before anyone treats them as not being able to make their own decisions

Key Principle No 3

Just because an individual makes what might be seen as an unwise decision, they should not be treated as lacking capacity to make that decision

Key Principle No 4

Anything done or any decision made on behalf of a person who lacks capacity must be done in their best interests

Key Principle No 5

Anything done for or on behalf of a person who lacks capacity should be the least restrictive of their basic rights and freedoms

The Mental Capacity Act (2005)

Mental Capacity Act states that an individual should be enabled and encouraged to make decisions themselves.

It asks does that person have the ability to make a decision or carry out an action that is going to affect their life in one way or another?

To make a decision about something we gather information and we use that information to make a decision. If we don't understand/retain that information in the first place then how can we possibly make a decision from it.

As a researcher it your personal responsibility to discern if an individual lacks the capacity to understand and retain information.

Assessing Capacity as a Researcher

Time and patience – choosing the right time to start the process

Discuss the patient with fellow MDT colleagues; SALT, Physio, OT, Nurses

Read medical notes thoroughly to assess level of deficit & discuss with medical team

Check screening tools carried out for capacity issues – MMSE/MOCA/Care plans in care homes

Assessing continued...

- Speak to the patient!

  Have a chat - ask them if they been to the hospital before, do they live locally, have they got children (make sure you know the answers beforehand!)

- Ask them to repeat some of the main parts of the trial back to you

- Ask them to tell you how they are going to explain to their family later that they are in a trial and what its about

Use this information to choose the right consent procedure and ensure it is valid informed consent

Types of Consent

Participant Consent:

✓ Able to fully understand trial and outcomes
✓Provide written informed consent

Relative/Consultee Assent:

✓Relative can sign the assent form after reading the Relative Information Sheet
✓ This occurs when the patient has reduced conscious level, cognitive or communication problems
✓Nominated consultee can give assent (these are usually legal guardians) and are usually used when consenting patients with dementia

Consent continued…

Independent Physician Assent:

✓Third party consent by an experienced, independent clinician

Witnessed verbal consent:

✓If the patient is unable to sign and has no NOK for assent then verbal consent can take place (check this is in the protocol)

If ever in doubt regarding consent procedures then always contact the study teams as different studies allow different consenting approaches

Important Points

- Acknowledge their communication need
- Take as much time as possible – explain no need to rush
- By reading notes and talking to MDT you will know how the patient communicates- nodding, squeezing hand
- Read the Information sheet to the patient if the patient cannot do this themselves
- Ask closed yes or no questions- ask patient to respond yes or no

Important Points

- Step by step approach to the trial and outcomes:

Blood will be taken / MRI will take place / Notes will be looked at / GP informed

- Ask a Specialist nurse/lead nurse/MDT member to sit in with you for the 'witness consent'

- Read through each part of the consent and ask patient to nod/squeeze hand

- Ask witness to sign

IF IN DOUBT OF THE PATIENTS UNDERSTANDING DO NOT CONSENT

What if a patient regains mental capacity?

Mental capacity is based on that **time and place**
If a patient regains mental capacity after assent has taken place the team should ensure that the patient is informed about the trial and should confirm that the patient is willing to continue to participate.

Where practical the patient should be given the appropriate patient information brochure and sign a consent form.

If such a patient is unwilling to continue with follow up then only data collected up to that point will be stored and analysed.

Consent is not a single event!

Documenting Consent

- Ensuring the right documentation:

  Consent process written in the Medical notes, any source data such as CRF, participants research file and the screening notes

  1 copy given to patient,1in site file and 1 in medical notes

  All drug trials require a doctor who is signed on the delegation log to take consent, assent

  Researchers are allowed to take consent, assent in most observational trials

  EVERYONE TAKING CONSENT/ASSENT MUST BE ON THE DELEGATION LOG AND SIGNED OFF BY THE PI

Case Study

- Inclusion Criteria:

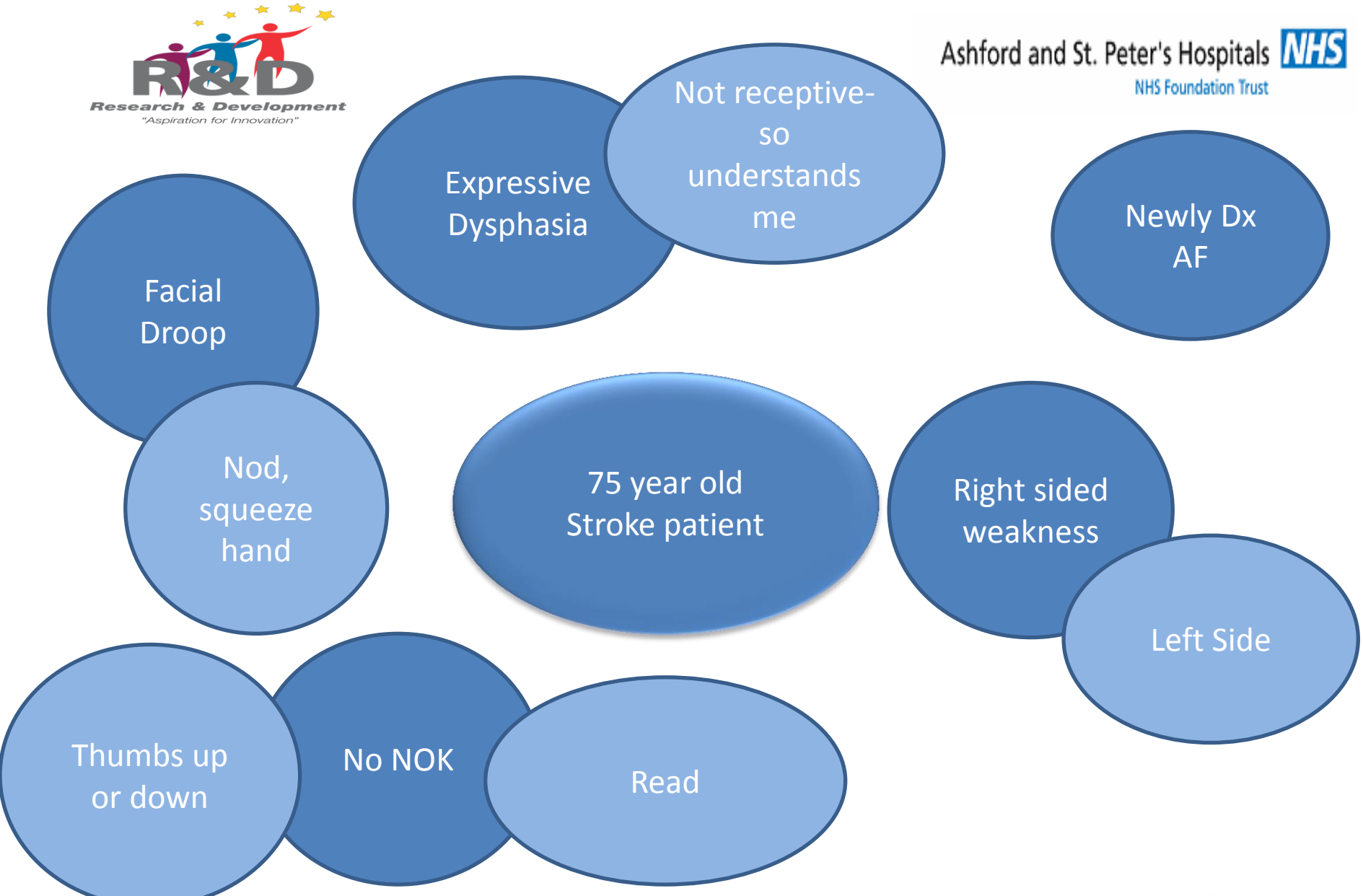
Stroke

Newly Diagnosed Atrial Fibrillation (AF)

Intention to treat with Warfarin

MRI

Able to consent


Not receptive- so understands me
Expressive Dysphasia
Newly Dx AF
Facial Droop
Nod, squeeze hand
75 year old Stroke patient
Right sided weakness
Left Side
Thumbs up or down
No NOK
Read

Weighing it all up

Often a lot more choice than you realise – patients have abilities – we just need to find the right tools for these abilities

- ✓ *Patient consent – if can use left hand*
- ✓ *Witness consent*

Giving the patient all the tools they need to gain Valid Informed Consent

Summary

Patients need to have sufficient Information, understand the information and retain it – to weigh up and make a decision

Assume capacity, enable capacity, freedom to say no, always act in best interests of patient & the least restriction of human rights

Different consenting approaches allow greater freedom

Researchers need to be conscientious, open and honest

Consenting vulnerable adults takes time - but they deserve the right to take part in studies just as much as anyone else!

Thank you for listening!