



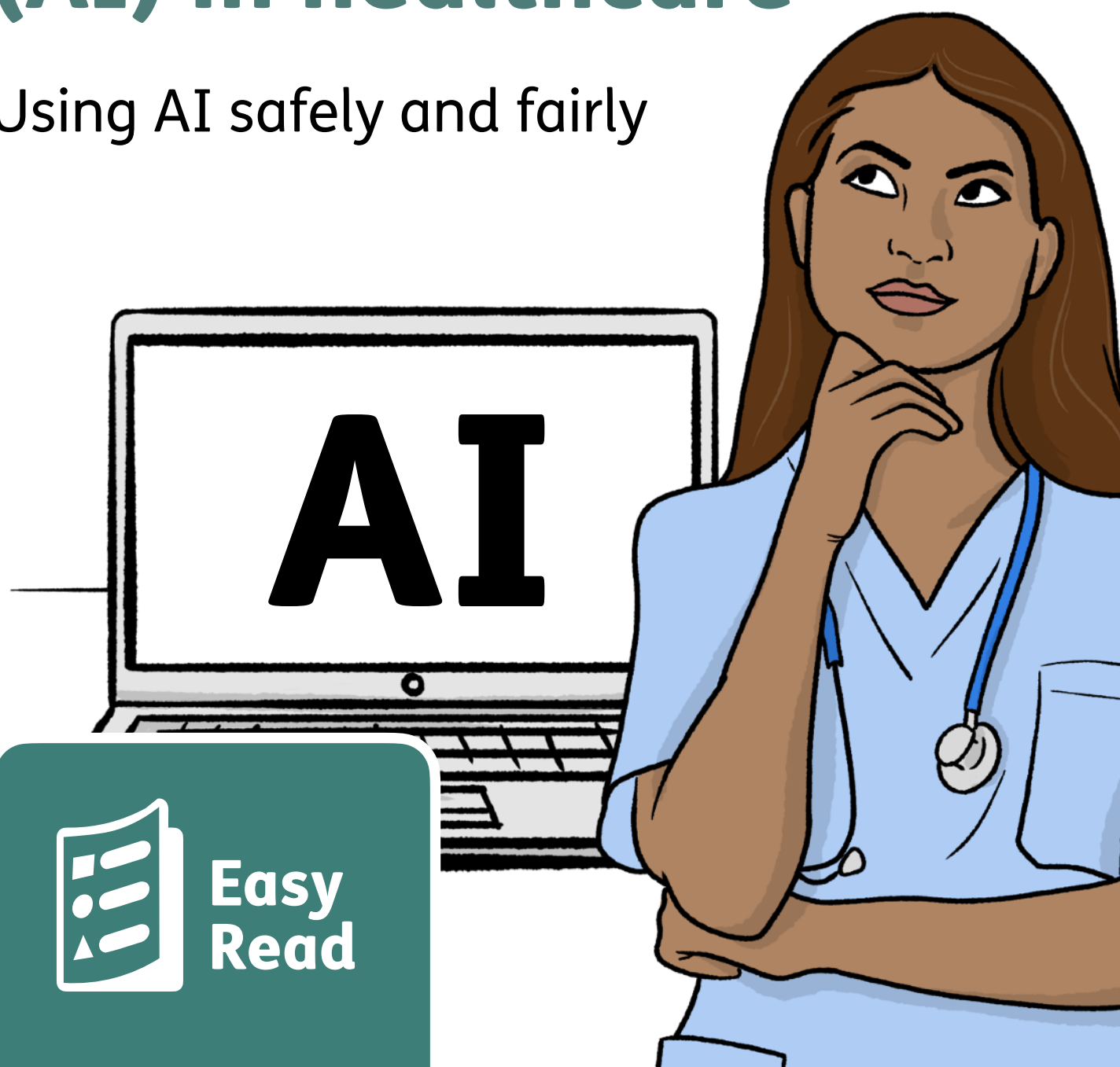
Medicines &
Healthcare products
Regulatory Agency



National Commission
into the Regulation of
AI in Healthcare

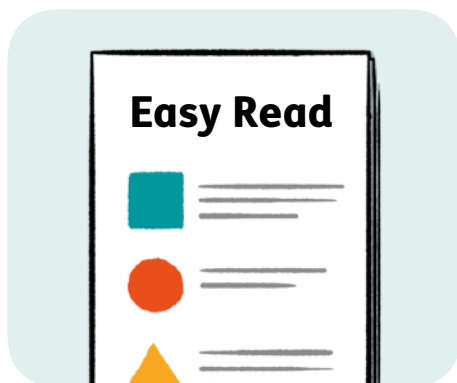
Artificial Intelligence (AI) in healthcare

Using AI safely and fairly



Easy
Read

Easy Read



This is an Easy Read version of some information.

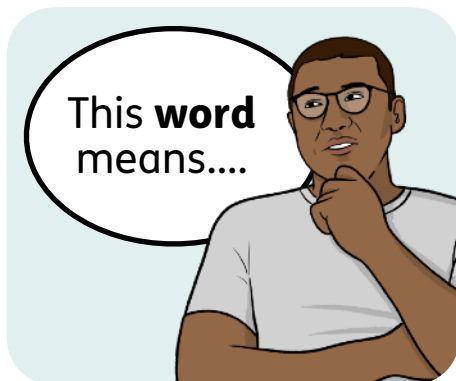
It uses easier words and pictures.



Some people may still want help to read it.



Some words are **bold** to show they are important.



We explain bold words if they are hard to understand.

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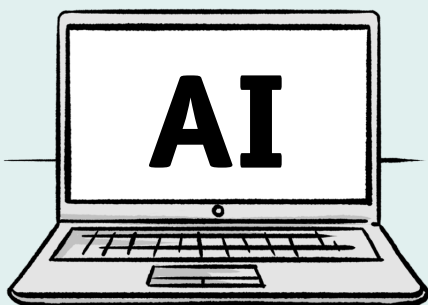
Find out more27

About this report



National Commission
into the Regulation of
AI in Healthcare

We are the
**National Commission into the
Regulation of AI in Healthcare.**



AI stands for **Artificial Intelligence.**

AI is computer technology that can
learn and do tasks like a person.



The **Commission** is a group set up by
the Government.

We have been asked to look at how
AI should be used and checked in
healthcare.



This report explains what we found
out and what should happen.

AI in healthcare



AI could be used to help healthcare staff:

- Find health conditions earlier.



- Choose care and treatment that is right for each patient.



- Spend less time on paperwork and more time with patients.

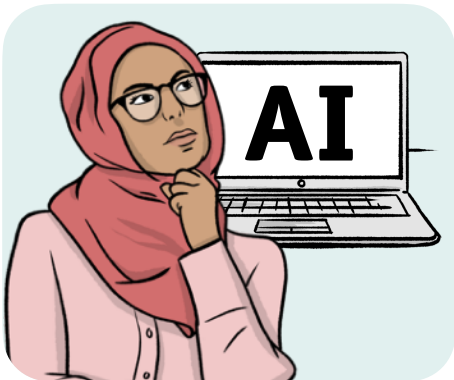


But there need to be clear rules and checks to make sure AI is used safely and fairly.

What we learned



We spoke to lots of people, including patients, carers, healthcare staff and AI experts.



We wanted to find out what they think about using AI in healthcare.



Many people thought AI could help to improve healthcare.



But they would only support using AI if they felt sure it was safe, fair and checked properly.

What should happen

We want clear rules and checks for using AI in healthcare that are:



- **Safe** – they should help to protect patients.



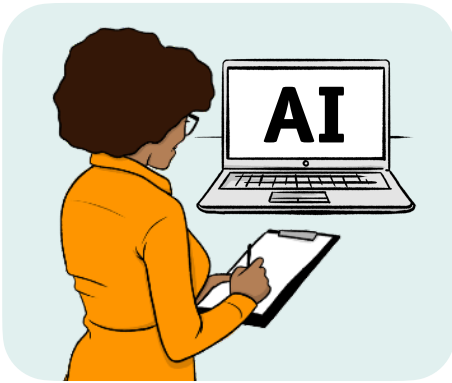
- **Fast** – they should help healthcare staff use AI as soon as the checks show it is safe.



- **Trusted** – they should help people feel sure that AI is being checked and used in the right way.

What needs to change

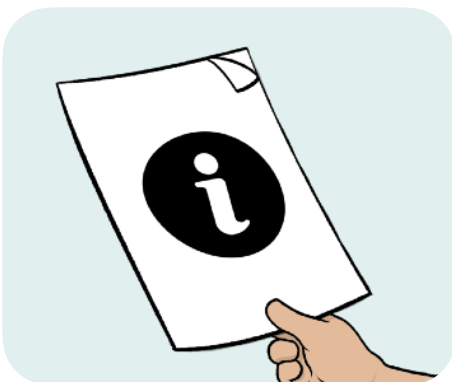
We think 3 main things need to change:



1. AI should be checked at every stage, from when it is made and for as long as it is used.



2. Everyone should help to make sure AI is used safely.



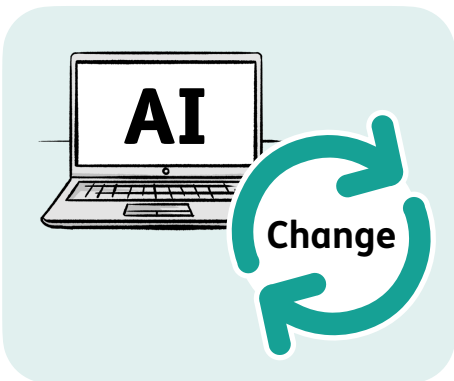
3. People should get clear information about how AI is checked and used.

Rules and checks from start to finish



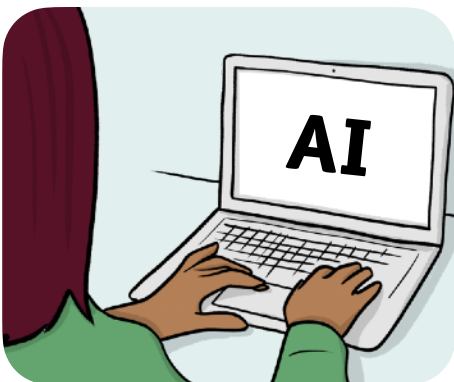
Some technology can be checked once before being used.

Like medical equipment, which will keep working in the same way after it is checked.

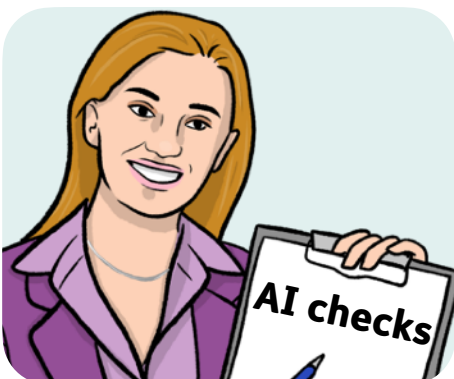


But AI technology can change while it is being used.

So it is not enough to check it once.



AI can also work differently depending on who uses it and where it is used.



So AI should be checked from when it is made and tested.

And it should keep being checked for as long as it is used.

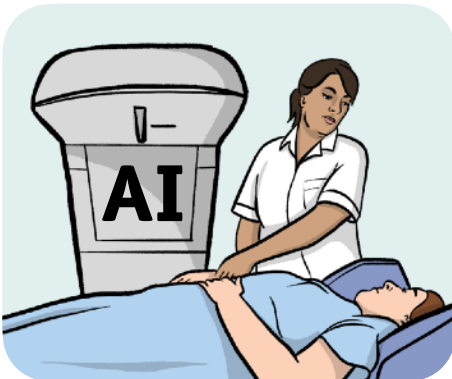
Different checks for different types of AI



There should be clear rules about checks for different types of AI.



For example, AI could be used to help people book appointments.



This may need fewer checks than AI used to make decisions about serious health conditions.



AI needs stronger checks if a mistake could lead to patients getting the wrong care or treatment.

Making sure AI works safely for everyone



AI should be tested with different groups of people, with different backgrounds.

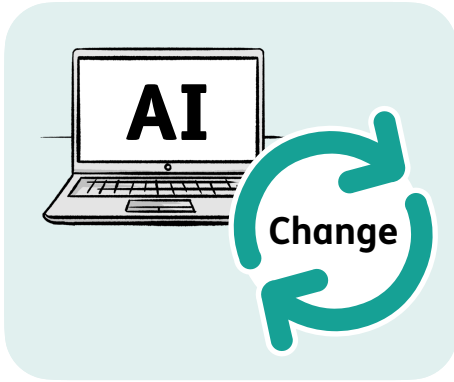


This includes older people, younger people and people from different ethnic backgrounds.



AI should not lead to some groups getting worse care than others.

Changing and updating AI



There should be clear rules about changing or updating AI.



The rules should say what changes are allowed and when the AI should be checked again.

Testing new AI



New AI could first be used with a small number of patients.



It should only be used with more patients if the checks show it is safe and has helped people.

Making sure the rules work

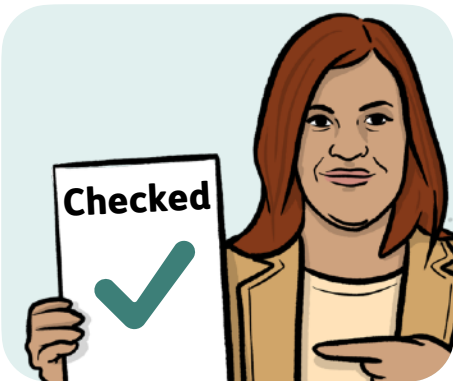


The government should be able to stop unsafe AI from being used.

It should also take action if the rules are broken.



The UK should work with other countries to agree similar rules and checks.



If AI has already been checked in one country, it may not need all the same checks again in another country.

The UK should help lead this work.

Everyone should help to make sure AI is used safely



Rules and checks cannot make AI safe on their own.



Everyone involved with AI in healthcare should help to make sure it is used safely.

This includes companies that make AI, healthcare organisations, healthcare staff and the government.

Making safety part of everyday work



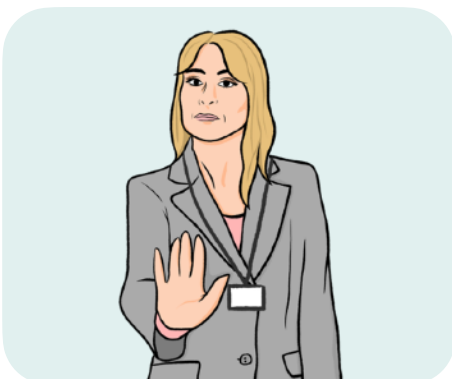
Safety should come first whenever AI is made, chosen or used.



Healthcare staff should be able to ask questions and report mistakes or problems.



If something goes wrong, people should find out why it happened.

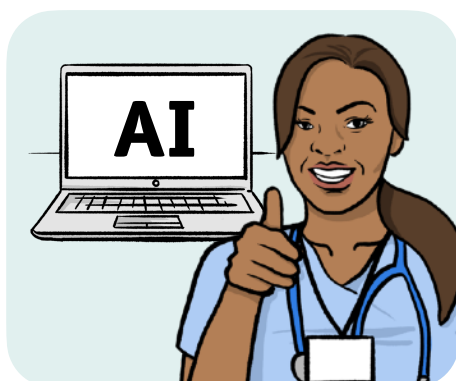


They should use what they learn to help stop it happening again.

Getting ready to use AI



Healthcare organisations should get a guide to help them check if they are ready to use AI.



The guide should help healthcare organisations check that staff:

- Understand AI and how to use it.

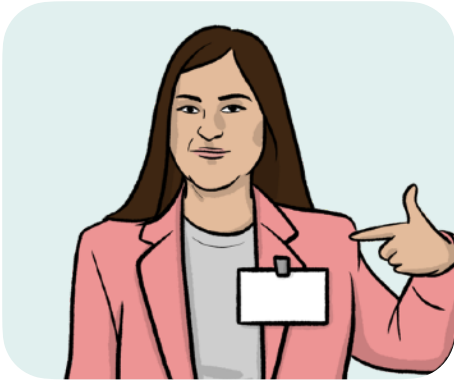


- Know what to do if something goes wrong.

Knowing who should do what

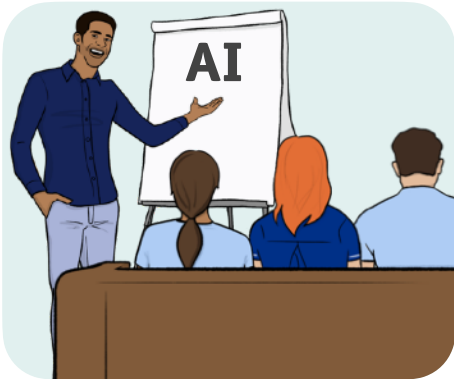


Clear rules should explain how each person and organisation should help make, choose, use and check AI safely.

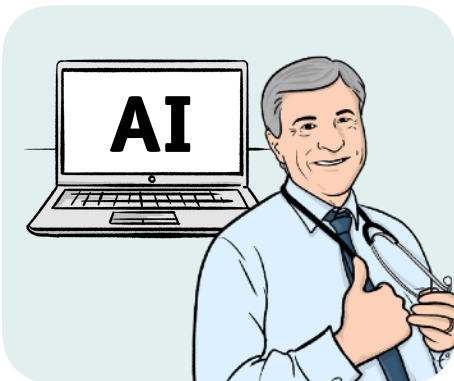


It should also be clear who will deal with any problems and put things right.

Helping healthcare staff understand AI



Healthcare staff should get training before they use AI.



They need to understand how to use the AI correctly and what to do if it makes a mistake.



Healthcare staff should still use their own knowledge when making decisions about care or treatment.

Choosing, using and checking AI safely



Healthcare organisations need clear information about choosing and using AI.



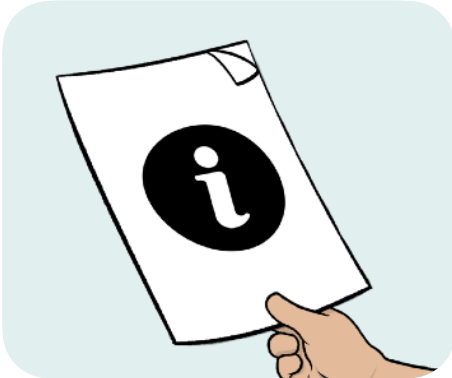
Before buying AI, they should check that it is safe and right for the job.



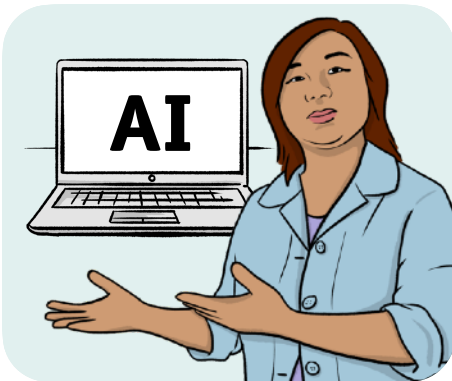
They should plan how staff will start using the AI safely.

They should keep checking that the AI works safely.

Clear information and rules people can trust



People need clear information before they can trust how AI is used in healthcare.



They need to know when AI is being used and what it is being used for.



Companies that make AI also need clear rules so they know what they should do.

Telling people when AI is used



Patients should be told when AI has an important part in their care.



They should be told how it has been used and what will happen if there are any problems.



Healthcare organisations should keep clear records about which AI they use and what they use it for.



Patients should know how to raise concerns and ask for help if they think AI has affected their care.

Involving patients and the public



Patients and the public should be involved in making decisions and rules about AI in healthcare.



This should include people from different backgrounds and with different health needs.

Making AI that is easy to use



Companies that make AI should speak to patients and healthcare staff while they are making it.

This will help them make AI that is easy for people to use.

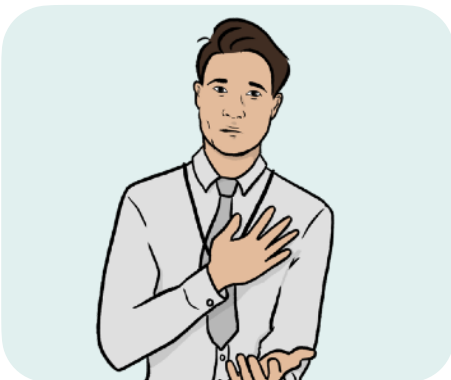
Sharing information about safety



Patients and healthcare staff need to be able to speak up about mistakes and safety problems with AI.



If a safety problem is found, patients and staff who use the AI should be told.



They should be told what the problem is and what they need to do.

Clear help for companies that make AI



Companies that make AI should understand the rules and checks for AI in healthcare.



They should get clear guides that explain:

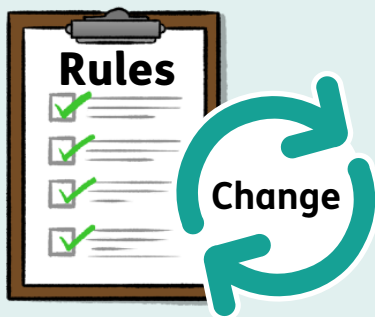
- What they need to do.
- How to ask for help if they have any questions.



What the changes will mean for people



These changes will create clearer rules and checks for AI in healthcare.



The rules and checks can change as AI changes and we learn more about it.

Patients and the public



The changes should help patients and the public feel sure that AI is safe, fair and checked properly.

People will be told when and how AI is used and have clear ways to speak up about problems.

Healthcare staff



Healthcare staff will get training and support to help them use AI safely.

They will understand what they should do and how to speak up about mistakes or problems.

Healthcare organisations



Healthcare organisations will get tools to check whether they are ready to use AI and keep checking it.

Companies that make AI



Companies that make AI will get clear rules about what they should do at every stage.

The government



The government will learn from how AI works in healthcare.

They will change the rules if needed.



They will also help the UK become a world leader in making and checking AI for healthcare.

Find out more



You can read the full report on this website:

<https://www.gov.uk/government/publications/national-commission-into-the-regulation-of-ai-in-healthcare-recommendations-for-a-future-regulatory-framework>



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