CONNECTED HEALTH CITIES

A nhsa project

Connected Health Cities IG workshop

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Introductions

- Housekeeping

Agenda

10.00 Introductions

10.05 **Scoping, Landscaping and Terminology**
10.30 **Putting into Practice: Case Studies Session 1**
11.30 **Morning Break**
11.45 **Sorting the Legal Basis and Approvals**
12.15 **Putting into Practice: Case Studies Session 2**
13.00 **Lunch**
13.30 Recap Session 2
13.45 **Timing and Planning Issues**
14.15 **Putting into Practice: Case Studies Session 3**
14.45 **Afternoon Break**
15.00 Questions and Answers Session

16.00 **Close**

Aim of Today's Workshop

To guide you on how to address the Information Governance issues involved in establishing data sharing for research projects.

We will use four case studies from the Connected Health Cities Programme giving you an opportunity to discuss real-life problems.

The Question & Answer session at the end will allow you to raise any issues you have encountered which were not covered earlier.

How the Case Study Sessions will work

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Scoping, Landscaping and Terminology

In this session we will discuss the importance of identifying IG issues early in your study.

Scope the Study

- What is the aim of the study?
- What are the benefits for patients, public, care providers?
- What data is needed?
- Where can the data be found?
- What are the risks to patient confidentiality / privacy

Find Data

- National data sets @ NHS Digital

https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-collections

- Surveys, longitudinal studies, UK census data, etc @ UK Data Service

https://www.ukdataservice.ac.uk/

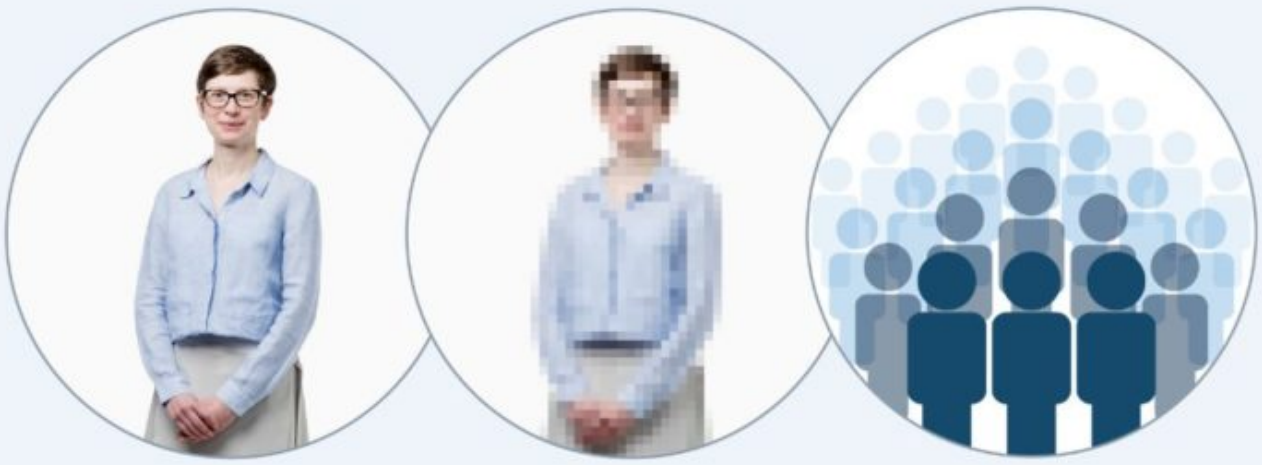
- Data and knowledge Gateway @Public Health England

https://www.gov.uk/guidance/phe-data-and-analysis-tools

- Primary care data linked to a range health related data @ Clinical Practice Research Datalink (CPRD)

https://www.cprd.com/

Spectrum of identifiability



Anonymised

Personally identifiable | De-personalised | Anonymous

More identifiable — Less identifiable

Other words you may see:

Personal data, confidential information, patient identifiable information, confidential personal information.

De-identified, pseudonymised, key-coded, masked, anonymised in context, effectively anonymised, non-disclosive, non-identifiable, de-identified data for limited access.

Aggregated data, grouped data, pooled data, statistics.

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What ‘types’ of data?

Personally identifiable patient data

Personally identifiable patient data: This term describes personal information about identified or identifiable individuals, which should be kept private or secret. It includes the definition of personal data in the Data Protection Act / GDPR, but also includes data relating to people who have died and information given in confidence under the Duty of Confidentiality.

Pseudonymised / De-personalised data

Pseudonym: a unique identifier (sometimes created by scrambling an actual identifier), which does not itself reveal an individual’s ‘real world’ identity but distinguishes between different individuals in a data set

Pseudonymisation: The process of distinguishing individuals in a data set by using a unique identifier, which does not reveal their ‘real world’ identity (see also Anonymisation and De-personalised data).

De-personalised data: This is information that does not identify an individual, because identifiers have been removed or scrambled. However, the information is still about an individual person and so needs to be protected. It might, in theory, be possible to re-identify the individual if the data was not adequately protected, for example if it was combined with different sources of information.

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Aggregated / Anonymised grouped data

Anonymisation: The process of rendering data into a form which does not identify individuals and where identification is not likely to take place (see also de-personalised data).

Anonymised grouped data: Statistical data about several individuals that has been combined to show general trends or values without identifying individuals within the data (see also aggregated data).

Aggregated data: Statistical data about several individuals that has been combined to show general trends or values without identifying individuals within the data (see also anonymised grouped data).

Data Management Plan

- Data Management Plans are best practice
- A DMP helps projects to comply with ethics, funding, and intellectual property regulations
- The University of Manchester now uses DMPOnline, which is free for anyone and provides useful funder templates
- Use is mandated by some funders / identified as useful option
- Also see the Research Data Management Service or the Digital Curation Centre

Identify Stakeholders

- Which organisation(s) will provide the data?
- Where will it be stored and how can you access it?
- Can you / should you involve patients or patient groups?

Engage with Stakeholders

- Ensure key decision makers at the organisation(s) are on-board with your plans
- Consider how to include patient engagement

NIHR Guide to Patient and public involvement in research

- Identify any funding requirements

Understanding the Terminology / the Geek Speak!

- See the CHC Glossary of Terms (to be updated based on your feedback)

- Derived from a number of sources, including Understanding Patient Data and Review of Data Security, Consent and Opt-Outs by The National Data Guardian for Health and Care.

Useful definitions for today

Common Law: The law derived from decisions of the courts and case law, rather than Acts of Parliament or other legislation. For example, the common law duty of confidentiality which applies to data about both living and dead people.

Confidentiality: Ensuring that information is not made available or disclosed to unauthorised individuals, or organisations.

Duty of Confidentiality: A duty of confidentiality (or confidence) arises when one person discloses information to another (e.g. patient to clinician) in circumstances where it is reasonable to expect that the information will be held in confidence. It –

- is a legal obligation that is derived from common law;
- is a requirement established either within professional codes of conduct and/or that must be included within relevant employment contracts. It is also linked to disciplinary procedures through both these requirements.

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Implied consent: an unwritten agreement between the patient and the health and social care professionals that provide their care that allows their data to be shared as long as it is relevant for their care, it is kept confidential and the patient has not objected. It is only valid where a reasonable person would expect it to be shared, such as when there is a legitimate relationship.

Explicit consent: a freely given, specific, informed and unambiguous indication of the individual's wishes e.g. regarding data use. There must be some form of clear affirmative action – or in other words, a positive opt-in. Explicit consent cannot be inferred from silence, pre-ticked boxes or inactivity.

Useful definitions for today

Data Protection Act (2018): The main UK legislation which governs the handling and protection of personally identifiable data relating to living people only. It includes specific rights for individuals, including the rights to know and correct what data is held about them. This Act incorporates the European General Data Protection Regulation.

Data breach: Any failure to meet the requirements of the Data Protection Act, unlawful disclosure or misuse of personally identifiable data and an inappropriate invasion of people's privacy.

Controller: an individual or organisation who determines the purposes for which and the manner in which any personally identifiable data is or will be processed. It is the responsibility of the Controller to ensure that any processing of personally identifiable data is lawful.

Processor: a term used to describe any person (other than an employee of the Controller) who processes personally identifiable data on behalf of the Controller. Controllers must choose Processors carefully and have in place a written contract (detailing the information governance requirements) and effective means of monitoring, reviewing and auditing their processing.

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Useful definitions for today

Individual care: A clinical, social or public health activity concerned with the prevention, investigation and treatment of illness and the alleviation of suffering of an identified individual.

Indirect care: purposes other than individual care of the patient. This includes activities that contribute to the overall provision of services to a population as a whole or a group of patients with a particular condition. It also covers health services management, preventative medicine, and medical research. Examples of such activities would be risk prediction and stratification, service evaluation, needs assessment, financial audit.

Data Sharing: The disclosure of data from one or more organisations to another organisation or organisations, or the sharing of data between different parts of a single organisation. This can take the form of routine data sharing, where the same data sets are shared between the same organisations for an on-going established purpose; and exceptional, one-off decisions to share data for a specific purpose.

Data Sharing Contract and Agreements: a group of documents that sets out the common set of rules to be adopted by the various organisations involved in data sharing. A data sharing contract establishes the rules that will apply to the processing of any data by partner organisations. A data sharing agreement relates to the flow of data between partner organisations for a specific purpose. There is often one data sharing contract and multiple data sharing agreements between partner organisations.

Workshop Session 1

Session 1: Scoping the landscape

- List the kinds of data you will need
- List all the organisations who might hold data relevant to your project
- List key people you need to engage with regarding access to these data, for example experts, regulators, influencers

Sorting the Legal Basis and Approvals

In this session we will identify when you need to identify a legal basis, what approvals you may require and where to find guidance on how to apply for them.

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Key decisions

- Is the study service improvement or research?

  HRA decision tool

- What ‘type’ of data is the **MINIMUM** you require?
  - Personally identifiable data?
  - Pseudonymised / De-personalised data
  - Aggregated / Anonymised grouped data

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Research Studies

- Identify the study sponsor
- Contact the sponsor's research ethics office (or equivalent) for guidance
- Identify if you need REC approval using the HRA decision tool
- Make an application – see the HRA guidance

Lawful Basis

- Different ‘types’ of data have different requirements for lawful basis
  - Personally identifiable data
  - Pseudonymised / De-personalised data
  - Aggregated / Anonymised grouped data

Personally identifiable data

- The ICO provide guidance on what is personally identifiable data
- Falls under GDPR (DPA2018)
  - Requires a lawful basis under GDPR Article 6 (See ICO guidance)
  - Health data is a special category of data and also requires a condition under GDPR Article 9 (see ICO special category data)
  - Processing must comply with the seven key principles in GDPR Article 5
- Requires a lawful basis under the common law duty of confidentiality
  - Consent
  - Section 251 support

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Pseudonymised / De-personalised data

- MAY Fall under GDPR (DPA2018)
  - Requires a lawful basis under GDPR Article 6 (See ICO guidance)
  - Health data is a special category of data and also requires a condition under GDPR Article 9 (see ICO special category data)
  - Processing must comply with the seven key principles in GDPR Article 5

- DOES NOT require a lawful basis under the common law duty of confidentiality

Aggregated / Anonymised grouped data

- It is important to ensure that data is truly anonymised UKAN guidance will assist
- DOES NOT Fall under GDPR (DPA2018)
- DOES NOT require a lawful basis under the common law duty of confidentiality
- If data is reidentified by accident or be design:
  - the data holder becomes a controller
  - GDPR conditions apply
  - The breach must be reported to the ICO

Other guidance

- The ICO provides guidance on the impacts of GDPR on Big Data and AI which some studies will find helpful

- MRC guidance on the spectrum of identifiability

Common Law Duty of Confidentiality

Duty of Confidentiality: A duty of confidentiality (or confidence) arises when one person discloses information to another (e.g. patient to clinician) in circumstances where it is reasonable to expect that the information will be held in confidence. It –

- is a legal obligation that is derived from common law;
- is a requirement established either within professional codes of conduct and/or that must be included within relevant employment contracts. It is also linked to disciplinary procedures through both these requirements.

- There is a breach of confidentiality if personally identifiable data is shared outside the 'care team'
- Can it be avoided by a different approach to data sharing?
- Justification for the disclosure are:
  - where the individual has capacity and has given valid informed consent;
  - where disclosure is in the overriding public interest;
  - where there is a statutory basis or legal duty to disclose, e.g. by court order.
- If not consent you will need Section 251 support

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Section 251 support

- …..in addition to GDPR compliance
- ‘Section 251 support’ is a short-hand term, and refers to section 251 of the National Health Service Act 2006 and its current Regulations, the Health Service (Control of Patient Information) Regulations 2002.
- The controller can disclose the information to the applicant without being in breach of the common law duty of confidentiality.
- Must be for a medical purpose – includes research & service evaluation
- Applications are made to the Confidentiality Advisory Group

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National Opt Out Programme

- The national data opt-out is a service that allows patients to opt out of their **confidential patient information** being used for research and planning

- Patients can find out more and set their opt-out choice at nhs.uk/your-nhs-data-matters.

- Health and care staff can download leaflets, posters and other resources to use when informing patients.

- Advice is provided for organisations on how to implement the technical solution

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Compliant National Organisations

- NHS Digital since May 2018
- Data Services for Commissioners Regional Offices (DSCROs) since May 2018
- Public Health England since September 2018

Future Compliance Timeline

- National organisations: October 2018 - March 2019
- NHS Trusts: February 2019 – August 2019
- GP Practices & May 2019-October 2019
  Clinical Commissioning Groups
- Local authorities & April 2019-March 2020
  Adult Social Care
- Others: October 2019–March 2020
  Pharmacies, NHS Dental and NHS Optician services

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Documentation

- Do you need to complete a Data Protection Impact Assessment –DPIA

Lancashire Care Template* GM Template (Available on request)

*Ensure that you check for the most recent template before completing a DPIA

- You will probably need a Data Sharing Agreement

- You may need a Processor Agreement / Contract

- Data Providers and Recipients may need to update their Privacy / Transparency notices and provide patient information

Workshop Session 2

Session 2: Approvals

- Is your project service improvement or research? Do you need personal data? Will you gather data with consent?
- Based on your answers above what steps do you need to take with

    a) regulators e.g. ICO, HRA, MHRA,

    b) your organisation e.g. university ethics, DPIA,

    c) data provider e.g. NHS R&D/IG, IGARD.

Timing and Planning Issues

In this session we will look at what might delay your study and what to do when you do eventually get the data.

Things that can lead to delay

- DPIA sign off by all stakeholders
- Approvals processes:
  - Ethics Approval
  - Section 251 support
  - NHS Digital approvals
- Getting agreements and contracts signed off

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Getting the Data

- Follow the processes outlined in the DSA
- Ensure appropriate security in place e.g. AES-256 encryption of Secure File Transfer Protocol.
- Validate a subset of data to test that it contains what you requested.
- If there are problems liaise with the Data Provider (if it includes personal data when not expected report to the ICO)

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Analysing the Data

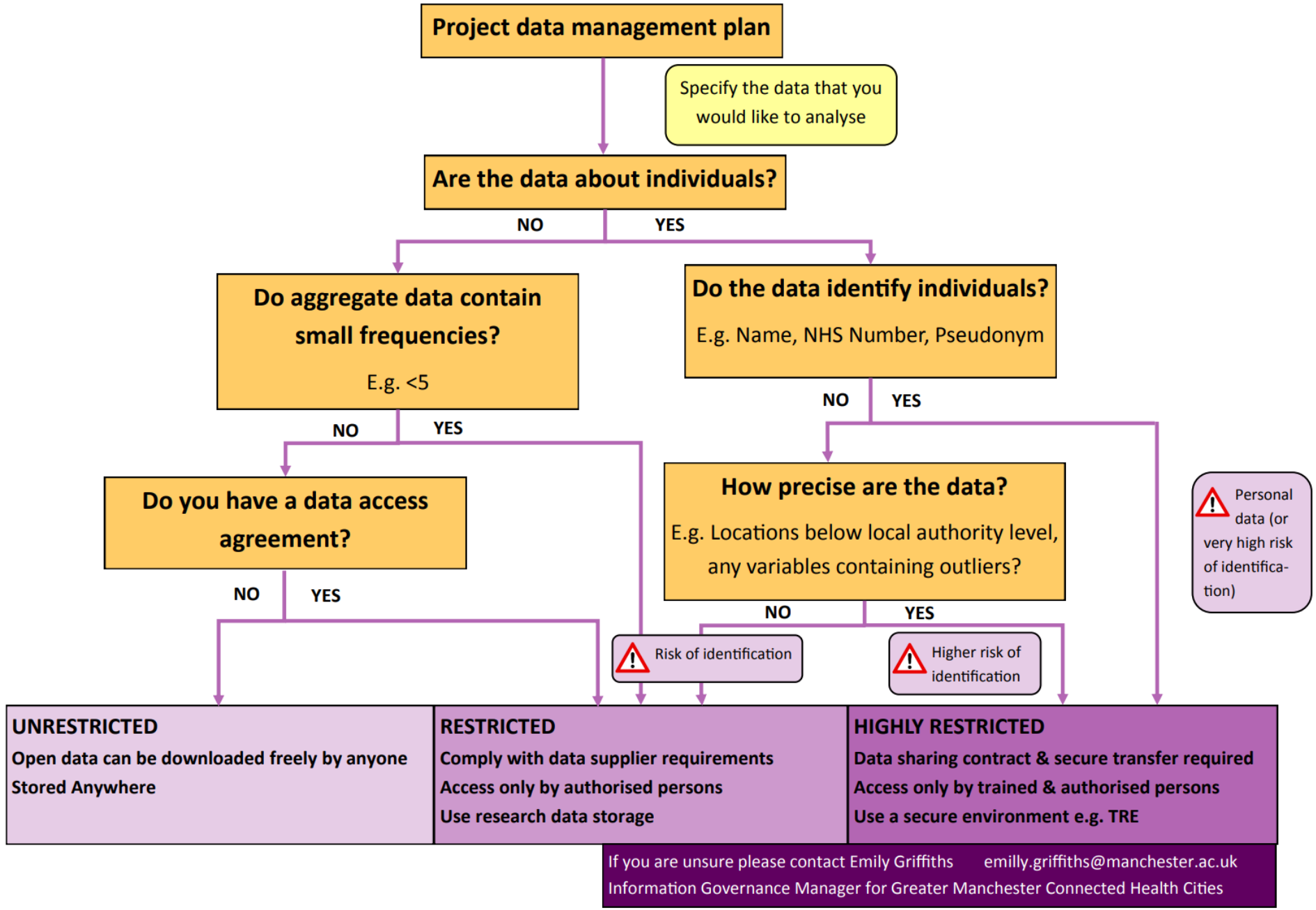
- Produce or add to metadata about what your project holds.
- Comments about data quality or cleaning procedures can be particularly helpful in future.
- Ensure you comply with all agreements with data providers, with university procedures, and with any additional procedures of the environment hosting the dataset.

Research Outputs and publication

- Ensure outputs to be published are anonymised (ICO code of practice, secure data handbook)
- Consult with experts in statistical disclosure control or seek out training as required (many secure environments offer this).
- Draft communications about your project's achievements.

Find Out More about the whole process here

Health data management decision tool



Workshop Session 3

Session 3: Revisiting the plan

- Looking again at stakeholders and approvals identified above:

  a) are there any people or processes you need to add in,

  b) how long do you estimate it will take to get data, and

  c) what order will you approach the necessary steps?

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Thank you for your attention

Questions and Answers