App Development and Governance Policy

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Governance or Assurance Committee	Clinical Effectiveness
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CONTENTS

CONSULTATION AND DISTRIBUTION RECORD	
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Consultation Process / Stakeholders:	• Clinical Effectiveness Group • App Governance Group • Digital Solutions Group • • • • • • • •
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CHANGE RECORD			
Date	**Author**	**Change**	**Version No.**
April 2024	A Minns	Changed outline of what is covered and merged apps built from scratch and those adapted sections	2
April 2024	A Minns	WhatsApp info or removed as no longer relevant	2
April 2024	A Minns	Appendice 1 taken out and link added in place	2
April 2024	A Minns	Update to App definition	2

1.   INTRODUCTION

This policy sets out how NHS Lanarkshire manages the development and governance of Apps across NHS Lanarkshire. It will outline the required standards for: -

1. Designing new Apps
2. Adapting existing Apps
3. Using clinical /patient apps on NHSL/your own device

Recommending Apps from third parties to patients/staff has separate guidance and should be referred to in addition to this policy.

A **Quality Assurance Framework** governing the production of Apps has been developed on behalf of the Right Decision Service, managed by the Digital Health Institute on behalf of the Scottish Government. This framework has been adapted for local use and will be applied to any App we commission/endorse for use in the NHSL (Appendix one).

Definitions

- What is an App?

'*An app, which is short for "application," is a type of software that can be installed and run on a computer, tablet, smartphone or other electronic devices. An app most frequently refers to a mobile application or a piece of software that is installed and used on a computer.*'[1]

It is important to note that this policy does not cover desktop 'applications'. 'Applications' refers to software programs normally associated with desktop computers (workstations) and laptops. Applications are usually installed from media such as:-
- DVD disk
- USB "thumb drive"
- devices and/or over the internet
- directly from the suppliers web site and

They often require the user to run a separate installer software program.

"Apps" refer mostly to software programs developed specifically for mobile device use, primarily smart phones and tablets. They may also be able to be used on desktop computers and laptops depending on their technical design.

Most "Apps" tend to be primarily installed using an "app store" such as the Apple Store for mobile apple devices and Google Play for android devices.

- Apps as medical/clinical devices

MHRA defines an App as a medical device as: -

'Apps, stand-alone software, or diagnostic devices that gather data from a person, such as diet, heartbeat, or blood glucose levels — and then analyse and interpret the data to make a diagnosis, prescribe a medicine, or recommend treatment — are classified by MHRA as medical devices'[2]

This policy does not cover the development or use of Apps as medical devices. If a team wishes to use an App that is classed as a medical/clinical device they must check it:-

- Originates in the UK/EU. Those outside the UK/EU pose a significant risk.
- Apps that are medical devices that originate outside the UK/EU should not be used without prior approval. If you wish to use and medical/clinical device App that fits the above description, please submit a one page SBAR to Director of eHealth/IMT. Please see information below for government guidance on medical devices as Apps.
- Has appropriate certification (check for UKCA logo/kite-mark)
- Accuracy of information. It the responsibility of the team using/recommending to ensure App is appropriate and up-to-date.
- DPIA required in all cases – see Information Governance team

National Guidance -
https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/999908/Software_flow_chart_Ed_1-08b-IVD.pdf

It is essential in all the above to utilise any national tools such as the **Quality Assurance Framework** and **Clinical Risk Assessment tools** (included in the references). This will ensure compatibility between locally and nationally approved applications.

Please contact Graham McCurrach within the medical physics team for more info on medical devices in NHSL Lanarkshire.

2.   AIM, PURPOSE AND OUTCOMES

The purpose of this policy is to provide a guide to the development and use of Apps in NHS Lanarkshire.

Mobile only websites are out with the scope of this policy. This policy defines a mobile website as content that can be accessed on a mobile device (e.g. Ipad, iPhone or Android Mobile Phone) but doesn't not require installation of software to your device from an App store like ITunes or Google play store.

This policy will outline the responsibilities of managers, team leaders and employees when using/designing/recommending Apps for both clinical/non-clinical/staff and patient use.

This policy will outline the agreed processes for: -

1.   Designing new Apps
2.   Adapting existing Apps
3.   Using clinical /patient apps on NHSL/your own device

Recommending Apps from third parties to patients/staff has separate guidance and should be referred to in addition to this policy.

- ALL guides/forms can be found on the App Governance page on the internal NHS Lanarkshire website, FirstPort.

3.   SCOPE

3.1   Who is the Policy intended to Benefit or Affect?

This policy is intended for all staff, partner agencies, members of the public, students, contractors'/data processors and any others that develop/recommend App resources throughout the board. It should also be used by staff seeking to develop new Apps either in NHSL Lanarkshire, with partner agencies/groups or with external third parties.

This policy covers use of Apps on either NHSL devices (laptops/computers/iPad/iPhone) or personal devices of staff. See below for further guidance.

3.2   Who are the Stakeholders

All Staff
Students
Partner agencies i.e. North and South Lanarkshire Council, UWS, Universities etc.
Contractors and data processors
Anyone living or working in Lanarkshire using NHS Knowledge Services
Other NHS Boards

NHS Lanarkshire takes care to ensure your personal information is only accessible to authorised people. Our staff have a legal and contractual duty to keep personal health information secure, and confidential. In order to find out more about current data protection legislation and how we process your information, please visit the Data Protection Notice on our website at www.nhslanarkshire.scot.nhs.uk or ask a member of staff for a copy of our Data Protection Notice.

4.   PRINCIPAL CONTENT

This policy is divided into 3 sections each covering the principles of design and governance standards for particular aspects of App use/design.

When seeking approval to proceed with an App in NHSL you are required complete the checklist in appendix 1. This includes a full description of support for the App such as staffing, financial support and ongoing maintenance. All sections of this form must be complete before proceeding to the approval stage.

Section 1 - *Designing a new App/ Adapting an existing Apps for NHSL use*

This section should be referred to when designing an App from scratch or adapting one that already exists. This includes designing an App that will be:-

- o be badged/will include the use of the with NHS Lanarkshire logo
- o is fully or partly funded by NHS Lanarkshire
- o NHS Lanarkshire staff are partly or fully responsible for the updating/upkeep of the information on the App.

When we are creating or designing an App, it is important that we ensure minimum standards have been adhered to.

Step1: The app checklist should be completed and submitted to the App Governance Group (AGG) for consideration. This form outlines the processes that you are required to consider when designing/adapting your App. If you need help completing the checklist, please get in touch with the appropriate dept. outlined on the form.

Once this form has been fully completed and submitted, it will be considered at the AGG and a recommendation made to the submitting team. You may also be required to attend that meeting to talk to your submission. No Apps will be approved for design outside this process.

NHSL is aware that Apps have been developed outside this process. You may be required to submit a form retrospectively and ensure that all aspects of the design follow the standards outlined. No new Apps should be developed without following the above process.

You are responsible for how you use an app on a work mobile device. There are a number of caveats on the use of Microsoft 365 Teams and Email/Outlook and this guidance should be followed. Social networking/ messaging apps are NOT approved for the recording of any personally identifiable patient or staff data, and that includes text, photos, videos and audio.

Staff can request Apps by requesting through the IT Service Desk portal available on first port and the app will be reviewed, and if approved added to the Comp Portal.

Section 2 - *Use of third party Apps by staff/using Apps on your own device/NHLS devices*

Many NHSL staff will have access to an NHSL owned phone/iPad. Apps on these are controlled and can only be downloaded with prior approval. If you have an App you want to be able to download on NHSL devices, please follow the process outlined below.

- Raise an IT service request for the application requested along with a business case on why the application is required.
- Telecoms will then review the request and see if the application has already been requested or is a new request.
  - Existing approved applications can be pushed out or downloaded provided that the use of the app is compatible with the original approval. Apps previously approved but requested by another dept./team for a different use, may have to complete governance process again.   A standard operating procedure should be in place by the service on how they are using the app.
  - Existing declined applications – users will be advised that the application has been declined in the past.

Apps that contain personal identifiable information (PII) including staff and patient data cannot be downloaded onto personal devices for work purposes.

Staff can download Apps on their own device if the App does not store any personal identifiable information or commercially sensitive information.

Other help in the policy: -

Appendix 1 – A guide to mobile enabled website vs apps
Appendix 2 – Flow chart on governance process
Appendix 3 – Outline of governance process

Section 3 - *Recommending Apps from third parties to patients/patient information*

When we are referring patients to Apps to help with their care, we are responsible for ensuring that the information on that App is appropriate and accurate. As an individual or a department, it is vital that you are fully aware of all the information on the App being recommended and not just particular sections of it.

General considerations
- Who has recommended this? Is it other NHS/Council/third sector? Why are they recommending it/what checks have they already done?
- Consider why you have picked this App over others to ensure you are not favouring one provider over another.
- Who has made the App? Are they trying to sell something?

- Advise individuals to read the privacy notice and permissions. Be aware of what is being signed up to.
- Don't encourage people to sign up to apps with in-app purchases.
- Does the App have push notifications? Can these be switched off?
- Check where the data goes and whether or not the developer uses it. Make sure individuals signing up are aware of that.
- Avoid the risk of reputational damage for the board.
- Is the App downloadable from App Store/Google Play/NHSL portal? If it is outside these sources, have you checked them?

Accuracy of Information
- Does the information come from a validated information source?
- How often is the information updated?
- Is there anything surprising/unusual in the information?
- Is the information at an appropriate level?

Other
- What Instructions have you given on downloading/use of App
- What support is available for those who need it?
- What alternatives are available to the App?
- Does the App meet accessibility guidance?
- Risks – do you need to register any risks?

Central Repository

All approved Apps that complete the governance process will be kept in a central repository list. This will record the date of approval, review dates and responsible person/team.

NHSL Guidelines App

NHS Lanarkshire Guidelines are to be stored in one centrally managed App. Clinical guidelines are not to be held on any other 3rd party Apps or on Firstport. All NHS Lanarkshire guidelines should only be stored on the NHS L guidelines App and website. This can be downloaded from the App and Google Play store. See clinicalguidelines@lanarkshire.scot.nhs.uk for further help.

User Interface Design

All new apps must conform to Scottish Government accessibility standards. Further guidance is available here. In addition, all new apps should follow the NHS Scotland web interface design guidelines where possible.

5. ROLES AND RESPONSIBILITIES

Clinical Effectiveness Committee – Will oversee the work of the App Governance Group ensuing timely reports are submitted through which the work of the Group is monitored. Approval of App Governance policy.

App Governance Group - Will ensure that the governance process for App development are agree and implemented across NHS Lanarkshire.

Head of Digital Transformation– Will chair the App Governance Group and ensure the delivery of the work plan and duties as set out in the terms of reference.

Head of Evidence – Will deputise for the chair of the Apps Governance group as required. Will liaise with staff on the development of Apps and maintain a registration of Apps centrally.

Department Managers/Teams – To ensure that the agreed processes for the development and approval of Apps are followed. To ensure that the appropriate paperwork is submitted accurately and on time

NHS Lanarkshire Telecomms Manager – To ensure that the processes governing the deployment of Apps to NHSL devices are followed.

NHS Lanarkshire Security Manager – To ensure that security best practices are followed in the development and maintenance of new Apps.

Senior Evidence Staff – To contribute to the management and development of Apps

NHS Lanarkshire staff – to observe process and governance for Apps as outlined in this policy. Use supporting documents and seeking clarification where needed when developing Apps. Ensure applications are completed timeously.

Information Governance - To ensure processes for the development and approval of Apps are in line with current data protection legislation and NHSL Information Governance Policies

6. RESOURCE IMPLICATIONS

Education/training

This approval of Apps is a new process for staff and a degree of education will be required. This will be delivered with the help of the communications department.

Financial

All apps will require a degree of resourcing and this will mostly come from local teams. Apps will require ongoing funding and this should be agreed before approval of Apps are

given. All developments should ensure they follow the NHSL guidelines for procurement purchasing

Staffing

Management of the Apps process is coming from the App Governance Group. This work will increase for all members of the group as the demand for more App use develops in the board. This will be monitored and reported through to Clinical Effectiveness Group.

Further help is available on our Firstport page

7.   COMMUNICATION PLAN

The policy will be available on the public website

The Clinical Effectiveness Committee will be made aware of this as the reporting group for Apps

Communications dept. will be employed to help with raising awareness of policy to staff and members of the public and any partner agencies.

Copies of policy will be given to partner agencies as required

NHS Education for Scotland (NES), Universities, North and South Lanarkshire Council as and when required.

Highlighted within the PULSE

West of Scotland Development Group.

8.   QUALITY IMPROVEMENT – Monitoring and Review

The policy will be reviewed every 3 years with the Clinical Effectiveness Committee

Feedback from stakeholders will be sought.

App requests will be monitored and a central register of Apps maintained by the Evidence Team

9.   Equality Impact Assessment

This policy meets NHS Lanarkshire's EQIA

X

(tick box)

10. Summary or Frequently Asked Questions (FAQs)

To help staff understand long or complex polices, please ensure you send a summary or a frequently asked questions list with your completed policy

11. REFERENCES

- The Right Decision Service available at The Right Decision Service (scot.nhs.uk)

- The Right Decision Manual: this manual includes the processes and requirements for the development of internal apps, the principles should be adhered to e.g., market research prior to the approval of the app: Right Decision Manual Home (scot.nhs.uk)

- NHS Scotland Quality Assurance Framework: Online version available here: Survey Powered by Webropol: Quality Assurance Checklist for Decision Support Resources (webropolsurveys.com) ; Word version here: https://scottish.sharepoint.com/sites/PMO2/_layouts/15/Doc.aspx?OR=teams&action=edit&sourcedoc={6FF00A66-DC62-4CAF-B63D-26303BBAD976}

- Clinical Risk Assessment: Risk management (scot.nhs.uk)

12. CHECKLIST

To be sent to Corporate policies: -

Copy of completed policy
Copy of EQIA
Copy of Assurance process document for all renewed policies

Appendix 1 -   Mobile Enabled Website vs App – which approach should I use?

There are a few issues that have to be considered around these competing platforms. Info below may help you decide.

Issue	Mobile App	Mobile Website	Hybrid App
Price	Relatively expensive. You also need to pay a small fee to register to submit an app to the correct marketplace (Google and Apple usually) and they have to be maintained.	A mobile website is developed and maintained in a similar way to a website. There are on-going costs for hosting to consider.	Cost less to develop than a native app. Also enables use of the same codebase across multiple platforms saving money. Fees for submitting to 'app stores' still apply as would on-going hosting costs. Maintenance costs are less as developers only maintain one codebase.
Online versus offline	Once downloaded and installed, can deliver content off-line (without internet access). This is an advantage for the consumer of the product if they have limited internet access via their mobile phone.	Requires internet access.	It's possible to develop an app that works entirely offline or one that connects to a remote server for 'live' content.
Compatibility and accessibility	An app has to be developed for each platform that it is accessible from. If it is to be available on Apple, Android (Google) and Blackberry, it will have to be developed	Mobile websites are available on a wide range of devices.	Hybrid apps are generally cross-platform compatible and can be published to multiple 'app stores.'

	separately for each of these.		
Interactivity	Lends itself to computer application type of functionality. Especially when the interactivity is personalised and expected to be used repeatedly.	Possible but not as focussed as with an app.	Interactivity is good with hybrid apps. It's possible to make use of the native features of the device, such as, Camera, File Storage, GeoLocation, Accelerometer etc…
Search	Not searchable via online search engines.	Google or other search engines can be used to find this content.	If the app is published as part of your mobile website then it may be possible to find its content via search engines.

Appendix 2 – Flow Charts –

The purpose of the App Governance Group is to ensure that all governance processes for apps has been followed appropriately. The process involves multiple teams and process and can take some time to complete i.e. DPIA, procurement check, copyright etc. Please plan this appropriately to ensure your development is not held up. No apps will be approved without a completed checklist.

Flowchart 1 - Original App
Flowchart 2 - Adapting pre-existing Apps
Flowchart 3 – Third Party Apps

Appendix 3 - App Approval Process

Apps will be reviewed for:-

- Technical suitability
- Compliance & governance
- Branding

The App Governance Group (AGG) reviews submissions at bi-monthly meetings working with teams/stakeholders to arrange for additional information/modifications as needed. You may be required to present an SBAR on your App to the group. To ensure there are no delays with approval, please seek guidance from the Chair or Vice-Chair of the AGG before your submission. Please ensure all paperwork is submitted correctly.

All new Apps must follow this process. Any App already published before 2022 will be required to complete the paperwork and approval process in retrospect.

What will be considered?

1. The AGG checklist will take approx. 10 minutes to complete and will ask questions about the app, the development stage, the target audience, evidence, information governance funding and communications plan.

2. If you have supporting documentation for your App, please also provide this with your submission i.e. contract or design outline

3. Areas to think about before you submit the form:-
   o **Governance** – have you considered all the areas in this policy and completed all the appropriate paperwork?
   o **Risk management** – who is responsible for the review that an app? How will it be kept up-to-date. Are there significant risks if the information goes out-of-date?
   o **Branding** – Communications dept. must be consulted on appropriate branding and the use of NSH Lanarkshire name and logo.
   o **Clinical Device – outside the remit of this group – see above**

4. The AGG will review the checklist and communicate back to the App lead on approval status and/or further steps.

5. All Apps and content of Apps remain the responsibility of the team developing the app. The AGG is a governance group which will provide reports to the Clinical Effectiveness Group on the development and funding of all Apps in NHSL

References

1. What Is an App? Types of Apps and Examples https://www.indeed.com/career-advice/career-development/what-is-an-app

2. MHRA Explains Whether Or Not A Health App Is A Medical Device. https://www.meddeviceonline.com/doc/mhra-explains-whether-or-not-a-health-app-is-a-medical-device-0001