NHS Lanarkshire

App Development and Governance Policy

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Governance or Assurance Committee	**Clinical Effectiveness**
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CONSULTATION AND DISTRIBUTION RECORD	
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CHANGE RECORD			
Date	**Author**	**Change**	**Version No.**

1. INTRODUCTION

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

1. Designing a new App for clinical/non-clinical use
2. Designing a new App for patient use
3. Apps used in NHS Lanarkshire but owned and provided by third party suppliers
4. Recommending Apps from third parties to patients/staff
5. Using clinical /patient apps on NHSL/your own device

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]

- 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: -

- Designing a new App for clinical/non-clinical use
- Designing a new App for patient use
- Recommending Apps from third parties to patients/staff
- Apps used in NHS Lanarkshire but owned and provided by third party suppliers
- Using clinical /patient apps on NHSL/your own device

ALL guides/forms can be found on the App support page on the internal NHSL 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 for clinical/non-clinical use/patient use*

This section should be referred to when you are designing an App from scratch that will eventually be badged with NHS Lanarkshire logo, is fully or partly funded by NHS Lanarkshire or 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 (Appendix 1) 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 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

Recommending Apps from third parties to patients/patient information

When we are referring patients to Apps to help with their clinical 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.

Use the checklist below to consider what you are recommending and the benefits/risks to consider: -

- Does it come from a validated information source?
- How often is it updated?
- Where does the data go? An App may gather multiple pieces of information on those downloading/registering to use. If the App owners gather data on the individual, you need to let the patient/staff member know about.
- How does the company use the data collected?
- Are there in-app purchases?
- Are there similar Apps on the market? Why have you recommended this one?
- Have you identified all the potential risks? Do any need to be added to the risk register?
- Is PII (personal identifiable information)/other data collected?
- Where is data held i.e. UK/Europe other? Check with the NHSL Information Governance department to review.
- Consider the level and complexity of information you are sharing/recommending? Can it be understood? Is it aimed at patients or health professionals?
- Avoid reputational damage for the board - what do you need to consider in addition to this list?

- Can you easily identify who owns the App and how often the information is updated?

Section 3

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.

Messaging apps such as WhastApp may be available for staff to download to a NHSL device as it is useful for collaboration for on-call purposes for example. However, staff are responsible for how they use the app and WhastApp has not been approved for the recording of any personally identifiable patient or staff data and that includes texts, photos, vidoes and audio.

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 2 – A guide to mobile enabled website vs apps
Appendix 3 – Flow chart on governance process
Appendix 4 – Outline of governance process

Central Repository

All approved Apps that complete the governance process will be kept in a central repository. This will record the date of approval, review dates and responsible person/team and original appendix 1 form submitted to the AGG.

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. All NHS Lanarkshire guidelines should only be stored on the NHSL 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.

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:-

Appendix 2 - Mobile Enabled Website vs App – which approach should I use?
Appendix 3 – Flowchart
Appendix 4 – App Approval process detail

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 – App Checklist

NHSL Checklist and Guidance for App Developments FINAL

Name of App_____

Responsible Lead_____

The responsible lead will be the person to whom the committee will send any questions/queries to

Strategy, Audience and Outcomes

Strategic aims and objectives

Description	Comment
Describe the development. How does this solution align to NHSL strategic objectives/other team objectives?	

Purpose/outcomes/audience/goals/tasks (user centred approach)

Description	Comment
Please state the primary purpose/goal of the App. What is it designed to achieve in terms of need/outcome?	
Identify the targets audience/s for the development. Staff/patients/both/other?	
Is the App based on an existing non-mobile optimized website? What are the most popular and heavily-used sections of the website? This may help you to determine which sections of the website are most appropriate to optimize for an App	

Consider any local issues that your audiences may experience when attempting to access the App, e.g. - Will the primary audience access the mobile site/app from within their workplace/home/other - Speed of internet connections - Do users have full internet access or is some content likely to be blocked by a firewall? - Are there any restrictions on mobile device usage within the audience's workplace/home? - Other accessibility issues?	
Consider the solution end-to-end, i.e. what additional support or processes will you need to put in place e.g. will it increase demand for your services? Do you need others outside your team to help you? Have you secured their resources?	
Is there a strategy in place to implement, evaluate, embed and sustain the solution? Please detail	

General Technical Guidance –

Description	Comment
Technical Solution –Mobile App/Mobile websites Before commissioning a piece of work, the correct technical development approach must be considered. **Website/App/Both?**	
Have you identified a supplier? Confirm you have followed appropriate governance for procurement of services. Please contact eHealth procurement lead for further information.	
Mobile Device Operating Systems (apps) It is recommended that apps should be developed for the following operating systems. Please confirm this has been discussed and agreed with designer/owner. - iOS - Android	

App Development – Specific Guidance

Description	Comment
Which platforms will your App be developed for? What are the cost and support implications ?	
How will your content be managed? Will it use an existing Content Management System (CMS) for dynamic content or static content to be downloaded with new version? If a CMS who will host it? Is this part of the supplier contract?	
Before an App is able to go live for download it has to be accepted by the marketplace for each operating system (Apple, Google, Blackberry etc). It must be stipulated in contracts with external companies that the development timeline does not stop until the App is tested and accepted for download. Confirm this has been considered and agreed	
Supplier considerations? Please contact eHealth procurement lead for a list of supplier/recognised contracts	
Will your App support any transactions? • data passed to and from a server i.e. to buy something? • Will your app collect and store data i.e. observational/audit data/Personal Identifiable Data? See main policy for details	
Push notifications: apps for iOS devices can incorporate a system of push notifications, which allow the developer of the app to send messages to users e.g. to inform them of updates, upcoming courses etc. It should be noted that users have the option of disabling push notifications at any time therefore this should not be viewed as a vehicle to reach all users. It is likely that other platforms employ similar features. These functions are supplied by third parties and inclusion will likely incur an additional cost at the development stage plus there may additional charges if limits on the number of push notifications dispatched per month are exceeded. Confirm this has been considered and agreed	
Branding/Style: All Apps must be designed in line with the NHS L corporate branding and house style or an alternative approved style. Contact the communications department for further help. You will also find general design help at this link - NHS Scotland https://www.nhsscotlandci.scot.nhs.uk/wp-content/uploads/Shared/pdf/identity_guidelines.pdf	
Maintenance and support: Consider how often your App will be updated? Who will be responsible for this, i.e. can you do this yourself using a Content Management System or does it require technical developer input.	

Description	Comment
Ensure that you are clear about any support options and on-going costs associated with maintenance or changes to the App. Confirm this has been considered and agreed	
Consider developing wireframes and testing these with sample users. This will help you understand user behaviour and the overall usability of your solution. Thoroughly test prototypes and releases for bugs. Blank wireframes can be found on the App Support page of FirstPort. The Evidence team can also be approached for advice)	
It's a legal requirement for NHSL to make all of our information accessible. NHS Scotland must follow the Accessibility Regulations 2018 for all of our websites, intranets, apps and online documents. Further guidance on the latter here. Confirm this has been considered and agreed	
Analytics: Apps can incorporate analytics facilities which can be used to evaluate the impact of the app, including the number of downloads, the time users spend using the app and the most-viewed screens. These functions are again supplied by third parties and inclusion will incur an additional cost at the development stage. Flurry/Google Analytics is an example of a mobile analytics tool Has this been considered/asked for in the contact?	

Engaging with External Suppliers – general points to consider

Description	Comment
Confirm NHSL SFI and procurement guidelines has been followed	
External suppliers will offer user requirements analysis, wireframes and prototype development as part of the service, however this will add to cost. Determine how much of this should be undertaken in-house. Who have you approached for help?	

Governance and Authority to Act

No App should be developed without sign-off by the App Governance Group. Completion of this form is the minimum required for consideration. Feedback will be given to the submitting author and further clarification may be needed before you can proceed.

Description	Comment
Alignment with other policies may also need to be considered – e.g. Information Governance/copyright/ IMT? Confirm this has been considered and agreed	

Approval of content. The AGG does not look to approve the content of the App. This should already have been approved by the relevant clinical/non-clinical group of specialist. Please confirm the governance group what has approved this development	

Evaluation

Description	Comment
Evaluation of the app should be incorporated into the initial and future development of the solution. An evaluation of the app should be submitted to the AGG after 1 year (contact AGG for template)	

Internal Contacts and Further Resources

Description	Comments
Before embarking on your development you can seek further advice to ensure that you deliver the best solution. Consider early contact with: • IM&T • Information Governance • Procurement • Evidence team • Telecoms team • Communications team	
Resources to help support development • Testing for the Best : http://www.test4best.scot.nhs.uk/ • Final report on scoping project to inform the development of mobile applications for the education of healthcare professionals (University of Nottingham 2012 commissioned by NHS education for Scotland) – Available from ep@nes.scot.nhs.uk • Guidelines for creating accessible websites should be followed from the Guidelines for NHS Education for Scotland (NES) Websites on the NES intranet. • In addition, the Mobile Web Best Practices (MWBP) is a specific guide for making Web sites usable from a mobile device.	

To avoid delays in launching your app, please ensure you complete and submit this checklist to the App Governance Group at least **3 months prior to launch date** of the

App. All paperwork should be returned to:- **amanda.minns@lanarkshire.scot.nhs.uk**
Only completed forms will be considered.

Appendix 2 -   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.

App Development and Governance Policy
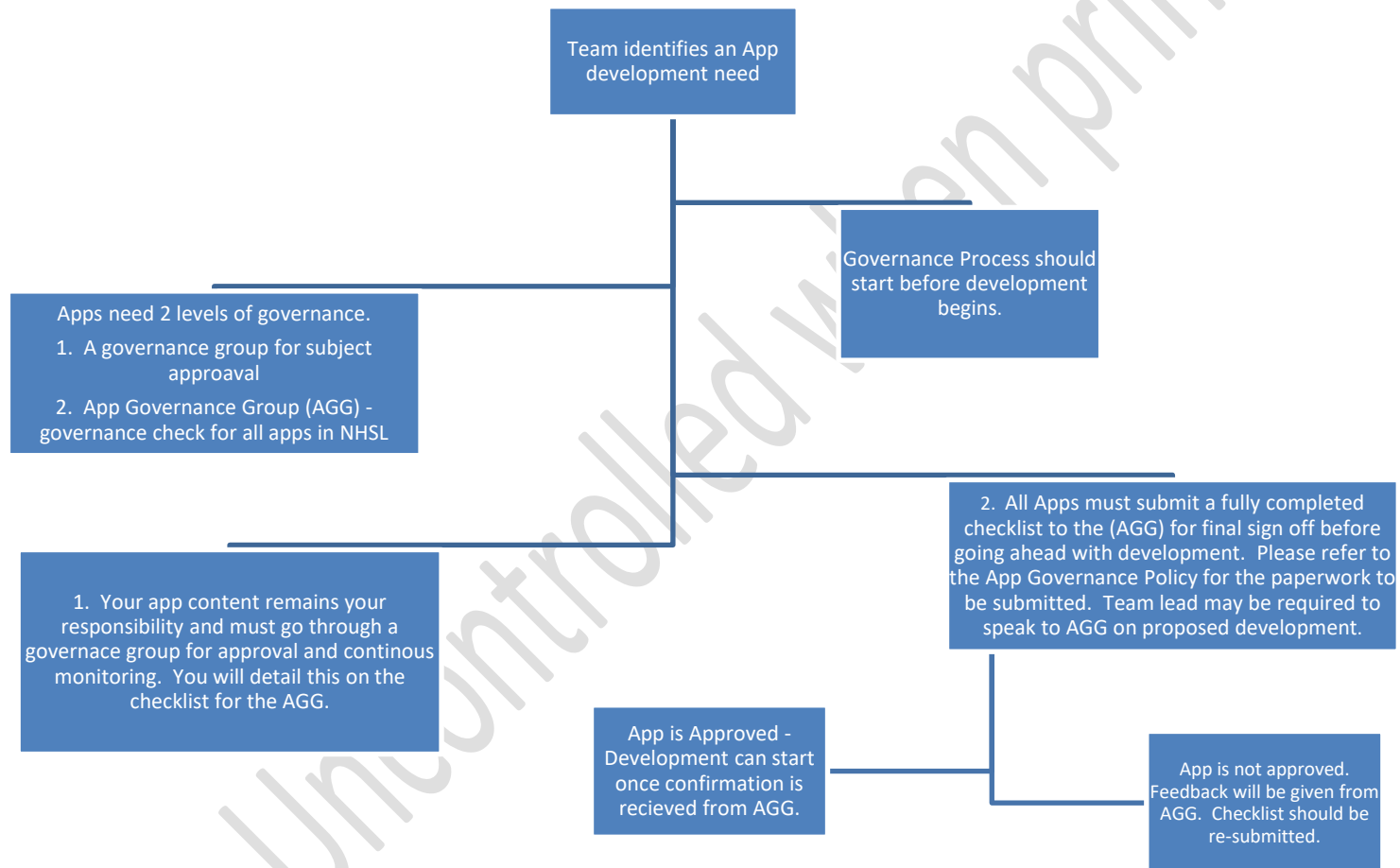
Compatibility and accessibility	An app has to be developed for each platform that it is accessible from. If it is to be available on Apple, Android (Google) and Blackberry, it will have to be developed separately for each of these.	Mobile websites are available on a wide range of devices.	Hybrid apps are generally cross-platform compatible and can be published to multiple 'app stores.'
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 3 – Flow Chart

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

Team identifies an App development need

Governance Process should start before development begins.

Apps need 2 levels of governance.
1. A governance group for subject approaval
2. App Governance Group (AGG) - governance check for all apps in NHSL

2. All Apps must submit a fully completed checklist to the (AGG) for final sign off before going ahead with development. Please refer to the App Governance Policy for the paperwork to be submitted. Team lead may be required to speak to AGG on proposed development.

1. Your app content remains your responsibility and must go through a governace group for approval and continous monitoring. You will detail this on the checklist for the AGG.

App is Approved - Development can start once confirmation is recieved from AGG.

App is not approved. Feedback will be given from AGG. Checklist should be re-submitted.

Appendix 4 - 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. 30 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