Oxford
Academic Health
Science Network

Oxford Academic Health Science Network Report:

App Development Roadmap

Contents

Executive Summary

App development can be daunting for the uninitiated, and a challenge for NHS organisations to respond to the increasing demand to develop and support mobile apps within their environment. NHS staff are increasingly seeking to tap into the potential informatics benefits associated with mobile devices. They join a steady stream of individuals, organisations or professional bodies developing apps to target local or national unmet needs.

This mobile app roadmap has been developed by the Oxford Academic Health Science Network (AHSN) in conjunction with NHS Innovations South East, and is intended to provide the uninitiated with some basic guidance on app development and commercialisation of the app using current approaches. This field of innovation is constantly changing, so comments and viewpoints expressed reflect current practice as of January 2014.

Key considerations for app development include an overview of factors that need to be considered before committing to any app development and the app development process. As with all projects, good preparation will help manage the app development and increase the likelihood of a more successful outcome. The development process is facing a number of changes as many of the emerging clinical apps may require approval from a regulatory body such as the UK Medicines and Healthcare products Regulatory Agency (MHRA).

The increasing use of healthcare apps has created concern amongst clinical commentators and professional bodies with regard to the quality of many published apps. NHS organisations seeking to develop healthcare apps should ensure that appropriate processes are put in place to check for clinical risk, security, information governance, integration with existing infrastructure and that the app is fit for purpose.

Business justification remains important. Regardless of internal or external development the funding and resourcing of apps will remain a challenge – therefore there is a need to fully understand the opportunities that an app may provide for a given organisation, its staff and ultimately its patients.

There is no single commercial model that is relevant for apps created in conjunction with the NHS to meet an unmet need, and a number of factors will influence the approach. Different approaches may be required depending on whether the healthcare app is targeting an NHS user or health conscious consumer. App value should be determined by the outcome. If there is clear value in the outcome, then it should be paid for in some form. What we have come to expect from apps as a consumer is and may be quite different to what we expect from a medical app in the future.

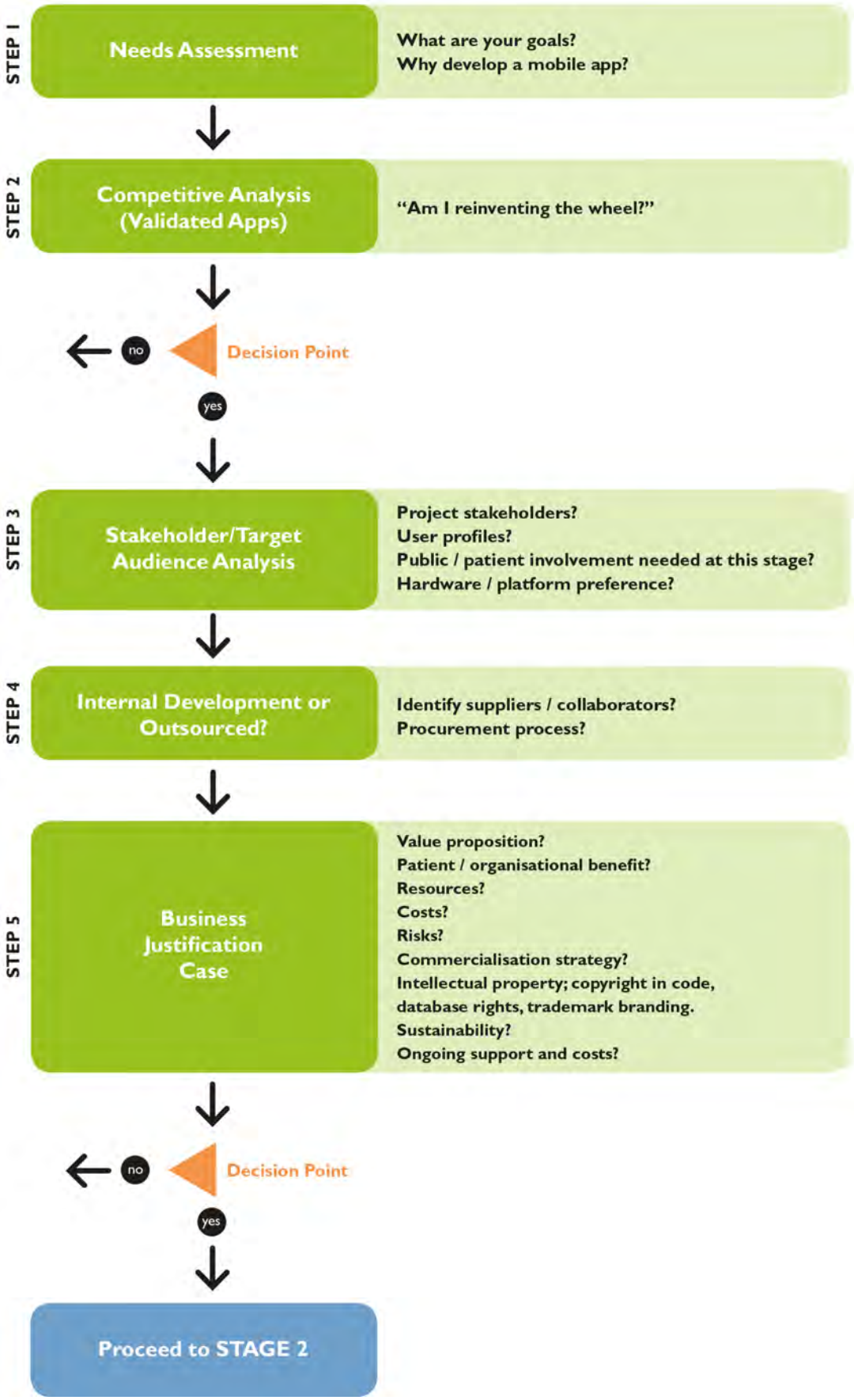
NHS England recognises the benefit of proven healthcare apps both from a patient perspective and benefits to an ever changing NHS. The emergence of the NHS choices app store (currently for lifestyle apps, but investigating expansion into more clinical apps) in 2012 is one of several peer-review routes allowing healthcare apps to be showcased to a target audience.

Autumn 2014

Mobile App Road Map Stages

** Subject to nature of mobile app*

STAGE 1: Pre-Development



The widespread adoption and use of mobile technologies have the potential to provide new and innovative ways to improve health care delivery and the health of individuals.

Clinicians have increasingly embraced the use of both smartphones and tablets in their professional capacity over the past three years. A survey conducted by the GMC demonstrated that in 2011 30 % of doctors used a smartphone app. (Visser,BJ and Bouman, J. 2012) Another study concluded that this number would rise in 2012 and predicted that 83% of medical doctors would use a smartphone in their work (Baumgart DC, 2011).

The use of healthcare apps is not limited to clinicians using such tools at work. Apps also provide an empowerment mechanism for patients so that they can take greater responsibility for their own diagnosis and treatment. Apps for patients are being developed to support healthier living, help manage a long-term condition and to provide initial advice on an emerging medical problem. Employers are also experimenting with how smart phone technology can improve patient safety and outcomes, while simultaneously driving higher efficiency.

In their third Global Mobile Health Market Report published in March 2013, Research2Guidance predicted that the market for mobile health (mHealth) app services will reach $26 billion by 2017. Evidence was found that the long-expected mobile revolution in healthcare is set to happen with both healthcare providers and consumers embracing smartphones as a means to improve health and healthcare. Top mHealth publishers have generated more than 3 million free and 300,000 paid downloads in the USA on the iOS platform. The reach on other platforms and in other countries differs but the trends are similar. They found more than 97.000 mHealth applications listed on 62 full catalogue app stores. The majority of these applications were general health and fitness apps which facilitated the tracking of health parameters by individuals and provided users with basic health and fitness related information as well as guidance.

Needs Assessment

All needs assessment starts with an understanding of a current or baseline position and what an organisation is trying to achieve. Put another way what is the goal? There are a variety of tools and techniques which are typically used in value management or change management processes to identify goals. The simplest tool to support a needs assessment is a gap analysis which identifies what needs to be done in the gap between the current position and a future end point or goal. If applied fairly, does the needs assessment support the development and creation of a mobile health app to achieve the goal or facilitate a change in service or process towards that goal?

Why Develop an App?

Smartphone and tablets are hybrid devices with components and functionality more closely resembling a computer. The range of functionality enables efficient communication in a clinical setting independent of the patient's location and the potential to support improved decision-making at the point of care resulting in fewer errors and better outcomes. This is particularly important for professionals who are constantly on the move and rarely have the opportunity to sit down in front of a desk with a networked computer.

Apps are software applications which can be downloaded onto smartphones, tablets and e-readers to provide solutions for an individual problem or to satisfy a niche requirement as opposed to huge enterprise IT projects which are very expensive and take a long time to commission. Apps can also be accessories that attach to a smartphone or other mobile communication devices, or a combination of accessories and software.

Medical apps have an enormous potential for improving clinical practice by providing a quick, comprehensive, and up to date overview of current clinical guidelines, making a differential diagnosis, performing useful calculations and looking up a patient's investigations, which could change the way healthcare is delivered in the future. (Boulos *et al*., 2011).

There are two general types of mobile apps, native and non-native. Native apps reside on a mobile device and have been developed specifically for the device software platform. Native apps can use specific coding to utilise mobile device features such as a built in camera or GPS capability. Non-native apps utilize browser interfaces or other gateways to provide the end user with information through a mobile device. A native mobile app typically requires download through a market place associated with the operating system (OS), such as iTunes for Apple OS devices, Android's marketplace for Android OS-powered phones, the Microsoft windows App store and Research in Motion's App Store for Blackberry devices. Non-native apps simply require that the mobile device has the appropriate web browser or other interface enabled.

The increasing capabilities associated with mobile device hardware means that mobile apps are more capable of delivering ever greater functionality and can respond in a quicker fashion than earlier devices. Newer web technologies also mean that non-native apps can increasingly compete with native apps in terms of function.

Alternative approaches to app development

A number of app developers offer packaged software services to avoid traditional app development and management costs. Typically based on a monthly subscription per user model, these services (software as a service (SaaS), and hybrid models) can also include mobile device management and mobile application management infrastructure as part of the overall service.

Developing an app can be a daunting process. There are lots of decisions to be made and each one can have a dramatic impact on the overall cost of the finished app and its chances of success, BUT DON'T BE PUT OFF! Analysis

There are over 97,000 apps (and growing) listed on several app stores ranging from healthy lifestyle apps to apps targeting clinical staff. Many of these apps may be of unknown origin and without any validation or certification from a credible body. Before committing resources to the development of an app, a search should be undertaken to determine similar apps that may:

- Fully address the requirement of the organisation or individual and which could be an alternative to new app development or view as a competitor app
- Address the requirements of the organisation or individual but lack validation by a healthcare organisation or certification by a recognised body.
- Partially address the requirements of the organisation or individual but lack validation by a healthcare organisation or certification by a recognised body.

Any alternative app currently on the market and available in your chosen platform or platforms could be considered a competitor app in the market. In reality only those medical apps that are certified or validated by appropriate organisations for relevant and safe content are likely to be the true competitors longer term, as market forces will favour higher quality medical apps.

Stakeholder / Target Audience Analysis

Who are the stakeholders (individuals or organisations) that need to be involved in the app design and development or kept informed? This may include stakeholder at departmental, divisional, management or executive level. The stakeholders may also be external individuals, organisations or a network of organisations who may have an influence on the app development or who will be impacted on by the development and deployment of the app (or app supported service). Does this app need to integrate into an existing care pathway and how? What do you need to do or communicate to address any identified risks or issues?

Is the target audience fully understood in terms of needs, preferences or expectations? For instance is the target audience platform agnostic or does the app need to run on a specific hardware device or operating system (see below)? Will the target audience pay for the app, want a free app, or expect it to be bundled into an existing service? Does the profile of the target audience lend itself to a particular commercialisation approach?

Choice of Operating System Platform

There are numerous mobile platforms but the two systems that dominate the market are Apple's iOS and Google Android. Other technology companies which also distribute apps are Microsoft Windows, and Blackberry but they only retain a relatively smaller market share. Windows Phone devices have gained significant and increasing market share with Nokia devices in certain countries but this indicates new sales rather than reflecting the existing installed base (existing app consumers).

Mobile devices are upgraded on a regular basis with their operating systems correspondingly being refreshed to take advantage of advances in the hardware technology. Apple and Google currently release newer versions of their iOS and Android mobile operating systems annually with iOS 7 and Android 4.4 KitKat issued in 2013. This should be taken into consideration when selecting the platform, as there may be a need to address backward compatibility or release new updates to reflect newer platform versions.

Microsoft has launched Windows phone 8 with update version 8.1 due later in 2014.

Apple distributes major updates to the iOS operating system for iPhone, iPad and iPod touch devices via iTunes. iOS7 runs on the iPhone 4 and later, second generation iPad and later and all models of the iPad Mini. Apple provides third-party developers with a set of tools and Application Programming Interfaces (APIs) to create apps which take advantage of the technology inside every iOS device.

Apps can only be installed onto an Apple device running Apple's iOS operating system if the software has been 'digitally 'signed' by Apple. This means that for most Apple iOS users the only way to add apps to their device is through the Apple App Store, although a private certification route is available for organisations (See iOS Enterprise licence).

In contrast to Apple, which only licences its iOS on its own devices, Android is open source and Google releases the source code under the Apache License. This open-source code and permissive licensing allows the software to be freely modified and distributed by device manufacturers, wireless carriers and enthusiast developers. Manufacturers that use Android include Samsung, Nexus, Motorola and HTC but the process for rolling out OS updates across the range of manufacturers is not as efficient as Apple's. This can also present challenges to the app developer in terms of the way in which the app functions from one device to another eg screen resolution.

Windows Mobile is an operating system that was developed by Microsoft. This OS is used in smartphones and other mobile devices. Windows Phone 7 and the latest Windows Phone 8 are currently the more popular OS versions. Microsoft may take an approach that's similar to Apple's App Store, where tablet specific apps don't run on the phone, but phone apps scale to run on a tablet. Microsoft has expressed commitment to a common app platform between the two operating systems so in due course all of the Microsoft apps may become available on all Microsoft supported devices. Windows phone 8 is a major step towards convergence with Windows 8. A comparison between Windows 8 and Windows phone 8 can be found at http://msdn.microsoft.com/en-us/library/windowsphone/develop/jj681690(v=vs.105).aspx

A number of sites have offered comparisons between the various mobile operating platforms including:

http://www.pcmag.com/article2/0,2817,2416521,00.asp

http://www.macworld.co.uk/news/apple/ios-7-vs-windows-phone-8-which-mobile-platform-right-you-3471624/

An increasing number of developers are developing or redesigning apps based on a multi-device web app format which can also make use of newer HTML5 scripts and more capable mobile devices. Open source tools such as PhoneGap (phonegap.com) and Appcelerator (appcelerator.com) permit easy creation of apps ("web wrapping") using web technologies to build apps for both Android and iOS platforms.

http://simpleprogrammer.com/2013/07/01/cross-platform-mobile-development/

Internal Development or Outsourced?

Do you have access to internal resources within your organisation to develop the mobile app? In many cases a supplier or collaborator will be required to support the development and deployment of the required mobile app. Do you plan to go out to competitive tender or single tender action?

Business Justification Case

In many instances a business justification case will be required to secure access to funding and resources associated with the development of the mobile app. The information required will vary between organisations, the nature of the mobile app and its alignment with organisational objectives.

The business justification case or equivalent document should be used to decide whether or not to proceed with app development. Information gathered during this STAGE 1 can also be used to guide requirement captured as an early part of STAGE 2.

Factors to consider in the business justification case include:

Value Proposition

In a brief and clear statement can you articulate what the mobile app is, what need it is addressing and what it means in terms of value to the organisation or to the patient / consumer? This is selling the idea internally and may differ from a value proposition used to sell the app to an external audience. *E.g. For patients with advanced rheumatoid arthritis the iDocstar is a mobile app used by clinicians to radically simplify the complex process of patient assessment for biologic therapies, guide patients onto appropriate treatments, and save the organisation £xxx,000 per annum.*

Patient /Organisational Benefit

Expand on the patient / consumer / organisational benefits with supporting evidence where possible. If there is an appropriate link to organisational priorities, national or regional drivers *eg. Supports Clinical Guidelines 50 (CG50) or project is aligned with the NHS (1.4) and Public Health (4.6) Outcomes Framework.* Other factors may be pertinent such as patient experience, patient safety, organisational efficiency, supports clinical governance or better clinical audit etc

Resources & Costs

Have you fully identified internal and external resources needed to support the development and deployment? How will training be addressed? What about maintenance or updates? What are the risks? Does the organisation have the relevant infrastructure to deploy the solution such as wifi connectivity, mobile device

and application management capability? Will the app need a regular refresh of clinical content? How will you make longer term use of the app sustainable within the organisation?

Risks

How are you managing overall project risk? Do you have appropriate terms with a contracted developer? How are patient safety risk being addressed?. Are there any communication or other technical risks? How are you addressing any data security needs? Does this app need to interact with existing enterprise systems and how will the app impact on this? Who is checking overall quality of the app?

Commercialisation Strategy

Is this being developed for internal use or is there a wider need in the market? Do you understand the market need and size? What is the route to market? Can you protect your app? Who owns your app? Academic institutions and NHS organisations all have access to IP and innovation specialists that can offer support with the commercialisation process.

Intellectual Property Considerations

The development of mHealth apps should be treated in the same manner as any other software developed or commissioned by an NHS organisation. In the UK, the intellectual property rights usually associated with software are copyright and database rights (in the code and database) and design rights (user interface and images, icons etc). This could also include trademarks in instances where a brand or identity is being established. Patenting of apps is more expensive and can be more challenging unless there is a clear "technical character" associated with the app or app-based service.

Intellectual property (IP) created with an NHS organisation by its staff will usually be owned by that organisation. Terms relating to this can be found within the organisation's policy for the management of IP.

NHS parties seeking to explore IP associated with the development or commissioning of apps are encouraged to seek professional assistance at the earliest possible stage, and prior to commissioning of any development work. A list of organizations that can offer assistance and who are within the Oxford AHSN region are shown within the references section.

Reference Costs

The cost of a mobile app varies depending on the complexity, functionality, mobile platform and the app developer used. Total app costs need to take into account product development costs, any regulatory costs, developer licenses with mobile platform operators, and any marketing costs. Some of these may be viewed as one off costs. Ongoing costs may include maintenance and support, upgrades and other annual license fees.

Ballpark costs

Apps can be broken into four major groups, depending on the amount of work involved in developing them.

- Simple Apps - A simple app with perhaps up to 4 screens and serves one basic function can range from £1,000, to £7,000. Simple apps don't store any data about the user or about the previous uses of the app.
- API or Database Apps - app storing information on the mobile device or interacting with a remote server increases complexity. Saving data on the device, device authentication, or syncing data between multiple devices would expect to cost between £5,000 and £30,000.
- Enterprise or multi-feature Apps – Typical business app. Users can access information using the app via any device or web-browser. The app will possess several key features and the user interface will be heavily customised and branded to the organisation or service for an immersive service. These apps can cost £30,000 and upwards.
- Games – Not surprisingly the wide range of game apps can range in price from £7,000 to £200,000.

Android versus Apple versus Microsoft

Whilst there are several platform operators in the market including Microsoft and RIM, the majority of apps being developed are focused on the Apple iOS and Google Android platforms. Unlike the iPhone and iPad, Android runs on a multitude of third party devices each possessing a range of associated hardware components and different versions of Android API. This allows developers to create apps for a varied audience but can create challenges for app functionality due to different coding needs, depending on the aAndroid version and device. The uptake of an app can also be maximised by developing across different platforms.

According to OpenSignalMaps (May 2012), they estimated that there were almost 4,000 different Android devices on the market with many different screen resolutions that apps needed to accommodate to provide the best possible user display. They also noted that the two most popular Android versions made up 75% of the devices surveyed – leaving a significant 25% of devices running out-of-date software to support apps. Depending on the nature of the app and its dependency on the device hardware, reliability issues can be overcome by testing the app on different phones. This can impact on both time and cost and probably reflects that the Android apps are typically 2.5 times more expensive to purchase than iPhone and iPad apps (Canalys, Feb 2012).

Example Costs For Common Features

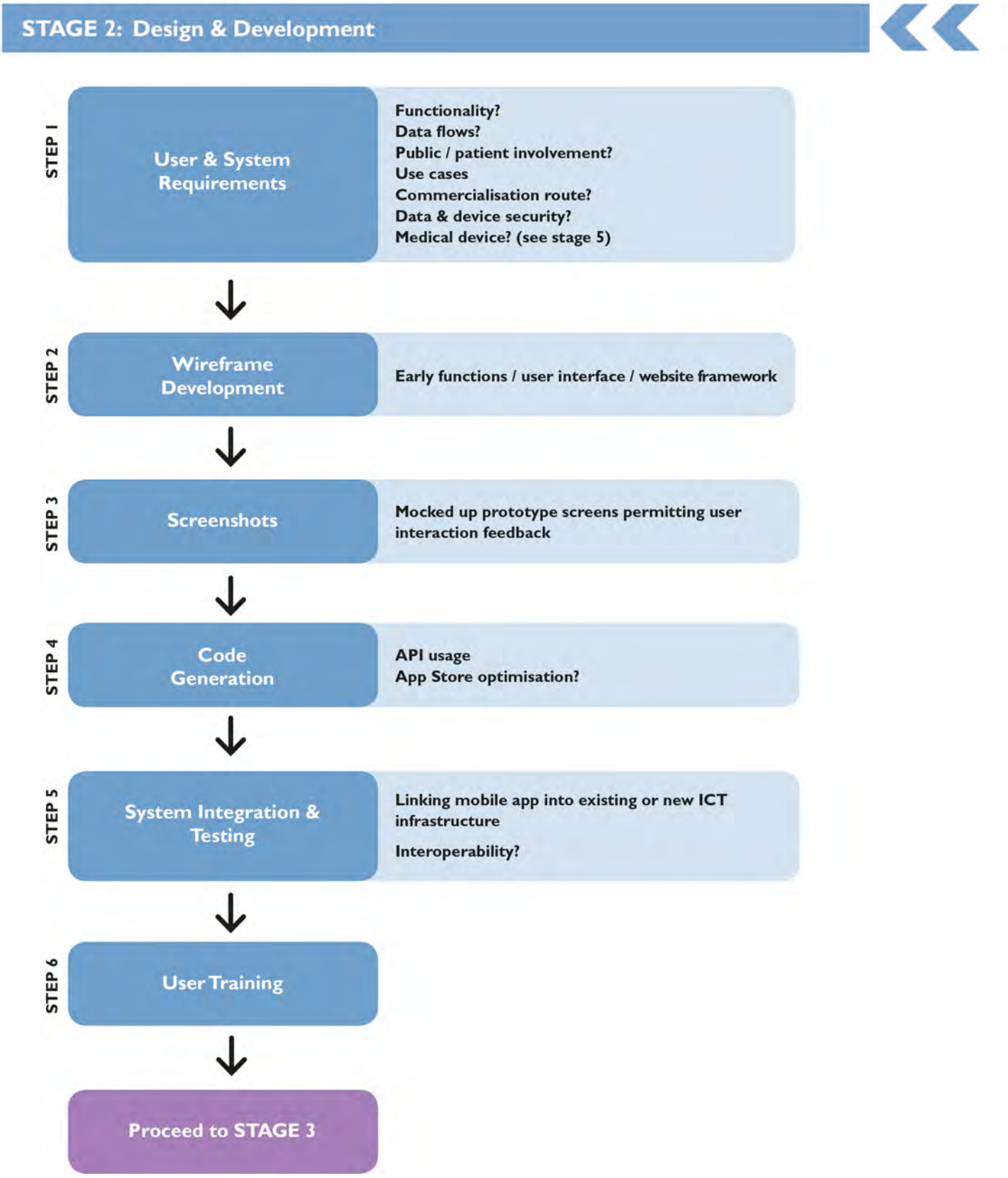
- Social Media Integration - This would include allowing users to Tweet and post to Facebook from within the app, or sign in to your app using their Facebook account - £300 to £1,000
- In App Purchases - Apple lets you charge users for additional downloads and services from within the app using In App Purchases- £1,000 to £3,000

Additional Costs To Consider

- iOS Developer account allows publishing to the Apple iTunes store via its validation process. Cost is an annual fee -$99
- iOS Developer Enterprise account allows self publishing to in-house app store and distribution to employees. Does not permit distribution to other parties and is an annual fee. $299
- Google Play Developer Console account supports development and distribution via Google play and is a one off cost - $25
- Access to Microsoft App developer resources and publish via Microsoft app sites. Cost is an annual fee. £19 for individuals, £65 for companies.
- Servers and back-end support. £100/month - If your app relies on a web server to store your user's data - you should expect to pay around £100/month for server support and maintenance.
- Marketing. Building a great app is a good starting point but you need to market the app or service. Marketing is essential before during and after launching an app and should be factored into any business case. A number of NHS or healthcare communities, forums and networks offer a cost-effective means of communicating your app to a target audience. £1,000 to £5,000

Summary of Key Points

- Medical and lifestyle apps provide a valuable way of sharing information, working more efficiently and supporting diagnosis, treatment and patient outcomes.
- A choice of app platforms is available with many developers currently favouring the iOS platform as this is deemed to be more secure than Android, but this in turn restricts the choice of hardware, and potentially - access to the app.
- The cost of developing an app should take into account all app features, connectivity with third party systems, any ongoing costs and an appropriate marketing budget to support wider commercialisation.
- A business justification case is a useful way to capture necessary information against which an organisation can make a go / no go decision on any required investment (time, effort, money) and value or impact to the organisation or delivery of patient care.



An example of a simple design & development process is shown above highlighting key steps in this stage. Many app developments are typically undertaken using an agile development process. This iterative process offers a rapid and responsive approach to the development of the app and its functionality. The approach undertaken will vary from supplier to supplier with many developers using tried and tested processes and a range of development tools

User & System Requirements

App develop starts with a clear understanding of what the medical app needs to do, for whom , and the environment it needs to operate in. In some instances, internal ICT support within the NHS or academic organisation can develop the user and system requirements documentation to support internal development of the app or inform a tender specification. In almost all cases where the development is outsourced, the external supplier or collaborator will seek to establish clear and unambiguous requirements early into the project, or even in phases depending on the development methodology.

User Requirements Specification or User Requirements Document (URD): This document specifies what the app really needs to do for the customer or end user and what the developer will provide. Use Cases are often used to walk through the user steps or interactions with the proposed app. Construction of the document usually requires negotiation between the customer and the developer and takes into account: the customer's view of what is needed, what the app really needs to do from a software engineering perspective, and the technical and economic feasibility of the proposed development. The URD will usually form part of a contact between the parties and can inform a project plan highlighting key milestones, cost and timescale.

The Systems Requirements Specification seeks to identify understand and plan for the organisation and user impact of the proposed app and the manner in which it will integrate with other systems and the business environment. It will ensure that any technical "shall do" requirements are properly integrated with the needs of the business or user. This will include consideration for functional requirements such as data and device security within the proposed system environment, data rules, app store requirements, user interface, interoperability with existing systems, and other needs such as medical device or clinical safety requirements etc..

Hardware Considerations

Apps can be developed for smartphones, tablets and desktop devices. Key considerations include the purpose of the app and the intended use of the app and device. Smartphones have grown in popularity over the years and have revolutionised the manner in which web services and information provide via a truly mobile and portable solution. Smartphone users tend to want information in a hurry. Desktop and tablet users will tend to interact with their devices in a different manner. Enterprise level apps such as patient record or outpatient clinic solutions may lend themselves to larger portable and desk based devices.

A key consideration between the choices of device such as smartphone versus tablet will be determined by the hardware specification of the device. Clearly a tablet or a mini tablet will have a larger screen size than a smartphone, which means that the app can be designed based on a bigger user interface providing more functionality on the screen, or making navigation easier. Form based apps for instance may benefit from larger screens on tablets compared with a smartphone which would have to be designed differently to optimise the user experience.

Device size does affect how users hold and interact with the device and this may change in different environments such as use on a hospital ward versus use in a home.

Tablets are not necessarily more powerful that smartphones. Some of the lower budget tablets available (providing potential access to a wider app audience) offer larger screen size but may lack communication capability (such as 3G/4G), significant processor power, or other functions such as GPS or cameras now routinely found on most smartphones.

Many apps developed for smartphones with limited screen size can also be configured for work on larger compatible tablet devices eg running iPhone apps on the iPad /iPad mini unless they are a form/control-based app. This consideration can be factored into the design stage of the app development.

Another factor for consideration is the interoperability of the mobile device with existing systems infrastructure or even other desktop devices (a developing area of convergence that Microsoft in particular seems to be pursuing with vigour).

Adaption of the user interface is key to developing an app for a smartphone, tablet or desktop. This will help improve usability, performance and the overall user experience.

Use OF API Components

An API or Application Programming Interface is a process, tool or routine that supports a specific task or interaction with a specific part of the software. Many social network apps and advertisers use API to share information in a seamless way; app user authentication is also often supported by an API routine connecting device to remote server. The use of APIs provides useful building blocks for developers to create powerful mobile apps.

The opening up of APIs is part of the UK government's overall approach to open ICT and user centred digital services and there is an increasing call for suppliers and vendors to open their APIs to third parties.

Security and Communication Considerations

Depending on the use of the mobile app, data and app security should be a major consideration in terms of design and development of the app. Factors to consider include deciding whether information actually needs to be stored on the app, encryption of any data stored on the app and the way that the app interacts with the wider network. Breaches of patient confidentiality, conflicts of interests and malfunctioning clinical decision-making apps could all negatively impact on patient care.

The potential for sensitive data to leave an organisation is exacerbated by mobile devices and wireless networks, which by their nature, allow access to healthcare systems and databases. Securing appropriate access rights from different devices for different users by segregating data is a complex high risk task for any organisation.

A survey by HP suggests that more than 86% of apps tested from the app store showed a variety of security vulnerabilities. Arxan, a data security company argue that a similar problem is associated with Android apps. Indeed Android OS is currently viewed by a number of app developers and ICT companies as less secure than the Apple iOS. For many of these organisations, and depending on the type of app, they would not choose to develop an Android version of the app using the current Android OS.

Samsung has been trying to address this by the development of a secure app solution called Knox (as in Fort Knox). This is available on selected Samsung mobile devices and will allow separation of personal and work activities on the phone. This is of particular use if an NHS organisation operates a Bring Your Own Device (BYOD) policy within the organisation. In Knox mode there are only certain types of applications that can be used. These range from standard Samsung apps to a set of "Samsung Knox" apps that are available for download. Local administrators can also restrict certain device functions (such as capturing a screen shot) and sharing of information.

As mobile devices and their OS are evolving rapidly, attempts to undertake systematic research studies can be superseded by subsequent releases with additional security features. Such a study has been attempted by Jin Han and co-workers (Han, J *et al*., 2013)

New guidance for app developers was launched by the Information Commissioner's office in December 2013. The document, "Privacy in mobile apps: guidance for apps developers" sets out clear guidance to assist compliance with the Data Protection Act 1998 (DPA) and ensure users' privacy. The ICO also clearly states "an organisation based outside of the UK that develops apps for the UK market, should consider that its users in the UK will clearly expect any apps they use to respect their privacy according to the DPA". Further details can be found at http://ico.org.uk.

Wireframe Development

Wireframes are rudimentary visual schematics that represent the framework or layout of an app to accomplish a particular purpose or objective. Lacking detail, the wireframes take into account screen functionality, content layout, behaviour, and priority or sequencing of what needs to happen with the app. Basic wireframes can be created as simple hand drawn sketches. Wireframes can be used in mock up different scenarios for the way in which the app may function.

Screenshots

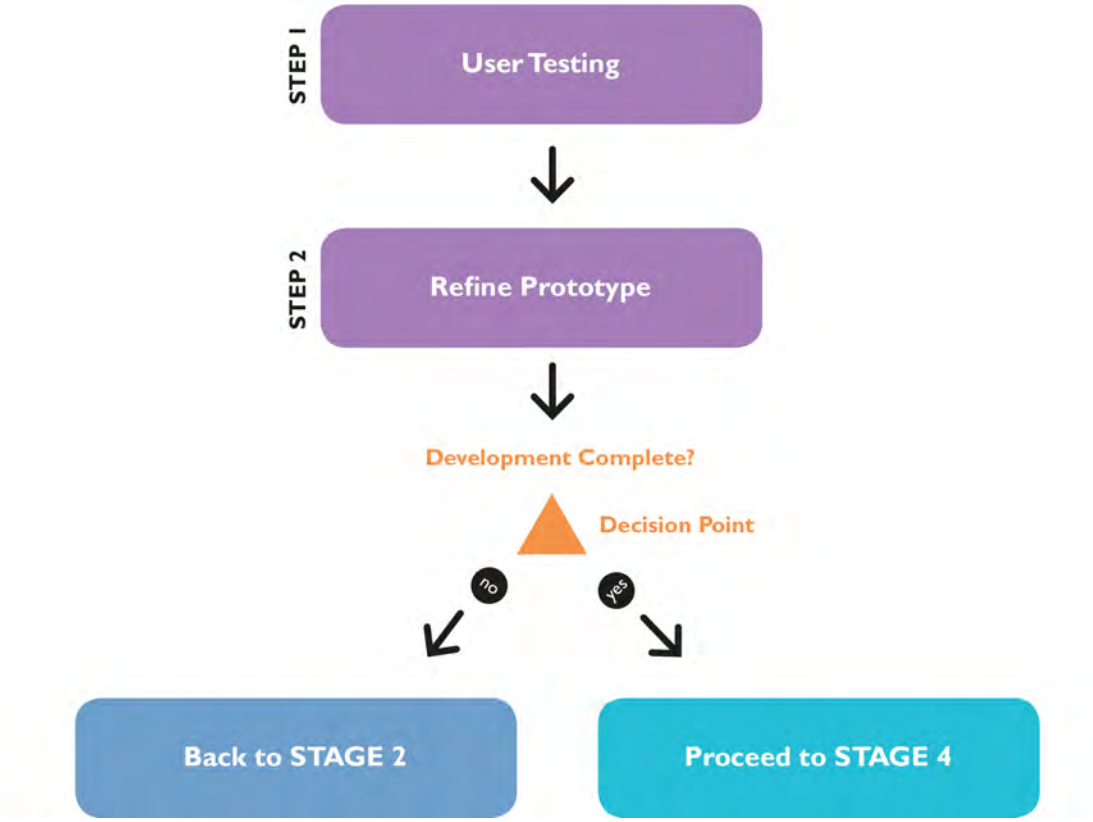
Designers can use the output from the wireframe work to mock up sample screen shots. Unlike wireframes these will give the first indication of what the user interface or app screens could look like. User feedback at this early stage is really useful, particularly with more complex apps, as it can give an early indication of overall usability issues (layout, colours, font size, navigation etc) prior to coding.

Code Generation

Establishment of clear requirements and user interface will allow the developer to proceed with early coding of the app or focus on coding specific functionality components of the app. This may include the use of APIs to permit the app to access or interact with elements of the mobile device eg camera. Consideration can also be given at this stage to coding of other elements (where applicable) such as aAndroid app indexing as part of a digital marketing approach.

System Integration & Testing

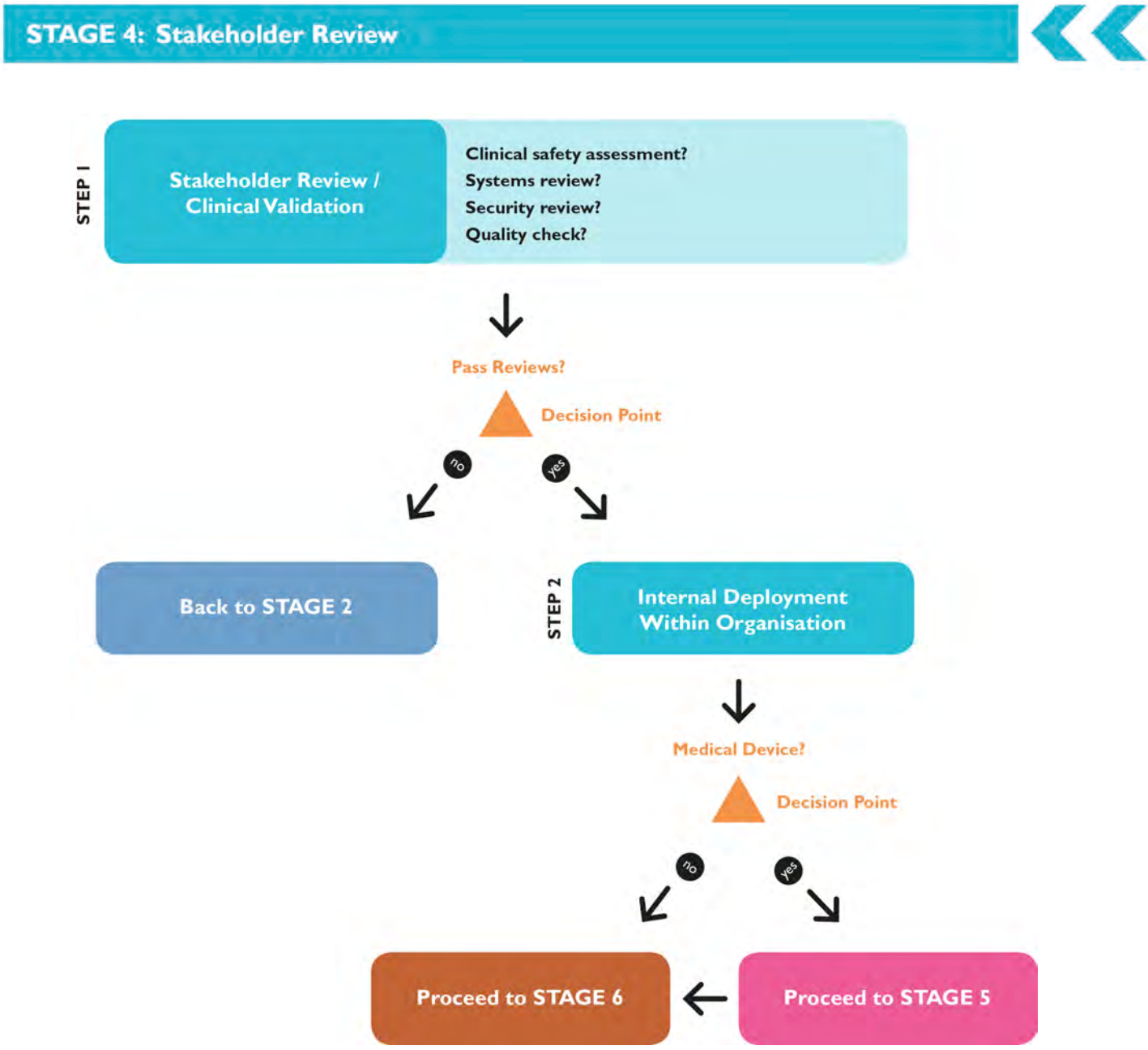
The systems analysis earlier in STAGE 2 will have identified the requirements associated with system integration within the identified business environment. The systems integration step will bring the app together with other components of the business environment to assess the overarching functionality of the mobile app. Depending on the nature and complexity of the mobile app this will usually tested in a “sandpit” or demo environment to test and iron out any glitches.



The user testing phase may be undertaken over several iterative cycles and will usually involve your preferred target audience (this may include job role, age, gender, device and operating system). This phase can focus on specific components within the app such as installing the app, or interaction with specific hardware components. Alternatively it may focus on full app functionality. Issues (or the user experience) arising from the testing phase can be fed back to STAGE 2 to iron out design or coding problems.

A number of dedicated third party user testing companies can also be used to independently assess the human factors associated with a new mobile app eg usertesting.com or userlytics.com.

If the mobile app is deemed to be a medical device then data from the user testing phase can contribute to the technical file required for CE marking (see STAGE 5).



Stakeholder Review and Clinical Validation

The completed app needs to be subjected to a thorough review by relevant stakeholders within (and possibly outside) the organisation. The extent of the review(s) will be dependent on the functionality of the medical app and its intended use.

Relevant Technology Standards

Different types of healthcare apps will require a different approach to manage risk in both the development and use of the app. Mobile medical apps can pose the same risks of failure as other medical devices, including mechanical failure, faulty design, poor manufacturing quality, and user error, among other safety issues.

As an example, a blood-glucose monitor that gives an incorrect reading, whether through a stand-alone glucometer or an integrated mobile medical app on a cell phone, could result in significant harm to a diabetic patient who relies on that reading's accuracy. For this reason governing organisations such as the FDA and MHRA have either created or are in the process of creating technology standards.

In this section we provide a high-level overview of the criteria for qualification focused on IEC 62304, however when considering app development technology standards should be effectively analysed and implemented. It is also important to recognise that medical standards are an evolving aspect of app development that many app developers are still getting to grips with. This will be very much influenced by the type of healthcare app, but should be taken into account by anybody seeking to engage the services of an app developer, or implement the software within their organisation.

Standards for medical device design

Until recently, safety regulations for medical device software, at least officially, were not exceptionally rigorous. In addition, software was not formally classified as a medical product by the Medical Devices Directive. This has now changed. A new regime is in force governing all medical device software development for all classes of device.

Previous software safety standards were best suited to medical devices with low levels of risk, as opposed to products where software failure could be extremely serious and result in death. As more electronic products have become dependent on embedded software, the focus has shifted to the reliability of software systems within the devices and the associated risks at all levels of usage. As a result, the new EN/IEC 62304 standard has emerged as a global benchmark for management of the software development lifecycle.

Risk analysis for hardware and software design

Medical product designers have used risk management techniques to help reduce the risks associated with device hardware. BS/EN/ISO 14971 has traditionally been adopted as the base standard for risk management for medical devices. The current version of this standard is considerably extended from its previous version, and the techniques described are now intended to be applied to both software and hardware systems.

The approach that should be taken is to consider the risks posed by the medical device as a whole, before the software/hardware split is decided. Hardware risk analysis can then run alongside software risk analysis to define the required safety systems for the device.

IEC 62304 is a harmonised standard for software design in medical products adopted by the European Union and the United States. Because the standard is “harmonised,” medical device manufacturers adopting it will satisfy the essential requirements contained in Medical Devices Directive 93/42/EEC (MDD) with amendment M5 (2007/47/EC) as related to software development. This is the least onerous route to ensuring compliance with the MDD. US FDA will also accept ANSI/AAMI/IEC 62304:2006 as evidence that medical device software has been designed to an acceptable standard. This standard is identical to the EN/ISO variant in all essential details.

Designing to IEC 62304 ensures that quality software is produced by means of a defined and controlled process of software development. This process must contain a set of requirements based on the safety class of the software that is being developed.

Clinical Risk Safety Standards

Another important consideration is the protection of patient safety. With the very rapid development of apps in the health environment it has been claimed that there is a need for better safety assurance. The Health and Social Care Information Centre website describes the current clinical risk safety standards. It has also expressed patient safety issues with regard to the way in which healthcare apps may be developed in the UK.

The Health and Social Care Act 2012 states that the following must have regard to an Information Standard published under the Act:

- the Secretary of State for Health
- NHS England
- public bodies exercising functions in connection with health services or adult social care
- anyone providing publicly funded health services or adult social care commissioned by or on behalf of public body

Therefore all NHS organisations and their staff developing mobile applications must manage app development in accordance with relevant information standards.

Information standards underpin national healthcare initiatives from the Department of Health, NHS England, the Care Quality Commission and other national health organisations. They provide the mechanism for introducing requirements to which the NHS, those with whom it commissions services and its IT system suppliers must conform.

The following two standards, relating to patient safety, have recently been revised and approved by the Information Standards Board (ISB). In line with current ISB practice, each standard comprises of:

- a specification, which defines the requirements and conformance criteria to be met by the user of the standard. How these requirements are met is the responsibility of the user.
- Implementation guidance, which provides an interpretation of the requirements and, where appropriate, defines possible approaches to achieving them.

ISB 0129 Clinical Risk Management: its Application in the Manufacture of Health IT Systems

This standard sets clinical risk management requirements for manufacturers of health IT systems. It requires a manufacturer to establish a framework within which clinical risks associated with the design and development of a new health IT system, or the modification of an existing system, are properly managed.

The main activities defined within the standard are the:

- identification of any potential hazards the health IT system may present to patients
- assessment of the severity and likelihood of each hazard and hence the clinical risk
- evaluation of each clinical risk to determine whether it is acceptable against defined risk acceptability criteria
- implementation of suitable clinical risk control measures to reduce or mitigate unacceptable clinical risks.

In undertaking these activities, it is important that their outputs are clearly documented to provide evidence of compliance. The main documents required are:

- Clinical Risk Management Plan, which defines the organisation's approach to clinical risk management for a particular project
- Hazard Log, a mechanism for recording and communicating the on-going identification and resolution of hazards associated with a Health IT System

- Clinical Safety Case Report, a document produced at defined stages that demonstrates the safety of the Health IT System, in as far as it is possible at that stage
- Safety Incident Management Log, which supports the communication and resolution of raised incidents.

The requirements contained in the standard are similar to those in the standards underpinning the Medical Devices Directive. The standard therefore provides a suitable interpretation of the controls needed for health IT systems which are not currently identified as medical devices and not covered under the Directive.

It is recommended that health organisations reference this standard in any procurement or contractual documentation issued to manufacturers. Compliance with this standard ensures that the manufacturer has implemented an effective best practice clinical safety programme during the design and build of a health IT system.

ISB 0160 Clinical Risk Management: its Application in the Deployment and Use of Health IT Systems

This standard requires a health organisation to establish a framework within which the clinical risks associated with the deployment and implementation of a new or modified health IT system are properly managed. In this respect, many of the requirements specified in ISB 0129 are replayed in this standard to ensure consistency in approach.

The requirements combine to establish a Clinical Safety Management System which the health organisation can use to manage the safety of health IT systems throughout their lifecycle.

Additional information on standards can be found at the Health Developer Network (see section: Organisations and Companies Offering Assistance)

Systems & Security review

A proportionate check of the use of the app and its interaction with other systems should be undertaken as part of the review process to ensure that relevant stakeholders are satisfied. Data security relating to the use of the medical app should also be checked at this stage. A small number of data concerns have emerged from within the medical community in both the UK and US recently.

Quality of Apps and Validation

In an overcrowded market where a large proportion of apps are never downloaded, it is always advisable to validate an app idea with a target group of potential early adopters before expending time and money in building a technical solution. By involving end users during the different phases of app development, it is more likely that something is created which users are going to need and are more likely to adopt. Feedback is valuable as it can define which features to include, and which are unnecessary to enable the developer to build the app in a way that these features can be easily incorporated in future iterations as opposed to having to recode the app from the ground up every time something new needs to be added.

The quality of published healthcare apps varies. In many instances public app stores will check apps for compliance with their platform standards but not question the clinical or health content. Discussions with the UK regulator indicate that they are often powerless to act as the geographical jurisdiction associated with a published app is often unclear (MHRA, personal communication). The growing use of healthcare apps has created increasing concern amongst many clinical commentators and professional bodies with regard to the quality of many published apps. In 2013, app developers also started claiming that Apple was restricting the publication of particular types of medical apps. Anecdotal evidence suggests that particular concerns for Apple are those apps that offer drug dosage information independently of the medicine manufacturer.

Recent studies (Visanathan, A *et al.,* 2012; Hamilton, AD and Brady, RR, 2012) have addressed the lack of evidence and clinician involvement in the design and development of medical apps raising concerns about the reliability and accuracy of their content. This has the potential to have a negative impact on patients. It has been proposed that medical experts should peer review the apps although the process is not without some deficiencies. Other scientific validation methods for clinical apps are available and described in detail by (Franko, O; 2012)

Validation methods include:

- **Criterion validity** – comparison against a current gold standard to demonstrate a direct correlation between the new tool and existing standard using an appropriate statistical test.
- **Construct validity** - does the new tool do what it is supposed to do. The test aims to demonstrate an appropriate response against a real-world measure.
- **Intra-observer reliability** – whether there is a highly-reproducible outcome when tested under constant conditions by the same observer.
- **Inter-observer reliability** - reflects the accuracy and precision of a tool when used by various care providers.
- **Content analysis** - the data within an app is compared to a reliable source, such as a gold standard textbook or guideline.

If patient information is used in the validation tests ethical and confidentiality issues must be addressed. Further guidance can be established via local NHS R&D offices.

Internal Deployment Within Organisation

Subject to completion of relevant reviews the medical app should be deemed safe and fit for purpose for wider deployment within the originating organisation. The distinction between internal deployment versus external deployment is relevant for those medical apps that are deemed to be medical devices (see STAGE 5). Apps not deemed to be a medical device can be deployed externally and registered on relevant app stores (see STAGE 6)

Summary of Key Points

- The security of many apps remains a challenge for many healthcare organisations. A recent security audit by one NHS Trust uncovered hidden security breaches associated with bespoke apps developed for that Trust. Appropriate care should be taken with regard to security and the permissions that the app will allow with the mobile device at the time of installation.
- Appropriate standards relevant to the type of app should be applied during development to take into account the level of clinical and patient risk.

The regulatory environment for standalone software is constantly evolving. The regulatory framework governing medical apps in the UK is determined at European level primarily by the Medical Device Directive 93/42/EEC(MDD)8. Individual countries within the European Community transpose the directive into national law which may result in country by country variations. In Europe, the revision of the Medical Devices Directive, which came into effect on 21 March 2010, amended the definition of a medical device to include the reference to standalone software used for diagnostic and therapeutic purposes. This amendment simply clarified the fact that these products were regarded as being medical devices. Medical apps are not specifically mentioned in the Directive at this stage but NHS organisations are advised to seek professional advice before venturing ahead with any non-regulatory app development that may fall within the remit of the MDD. The references section contains a list of organisations that can provide advice in this area.

The Medicines and Healthcare Products Regulatory Agency (MHRA) is an executive agency of the Department of Health and is deemed to be the competent authority for the UK. The MHRA has responsibilities for interpreting and enforcing the relevant UK legislation. Under the Medical Devices Directive, manufacturers who wish to place a medical device on the market must first register the device with their competent authority and label the device with a CE mark.

When is an App a Medical Device Based on MHRA Guidance?

Under clause 2(a) of the Medical Devices Directive, a medical device is defined as follows:

- any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:
    - diagnosis, prevention, monitoring, treatment or alleviation of disease,
    - diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
    - investigation, replacement or modification of the anatomy or of a physiological process,
    - Control of conception;

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

Any mobile app that fits the criteria above could be deemed to be a medical device, although depending on the type of app this remains subject to interpretation in the UK. More recently the US regulatory body, FDA, has issued newer guidance on its interpretation in this area (see section below). Further information is anticipated from European regulators in due course.

NHS organisations are advised to err on the side of caution if there is any uncertainty with regard to the status of a medical app in development.

What if the app is just being used within my organisation or purely for research?

Current guidance allows NHS organisations to be exempt from the Medicines Device Directive and CE marking if the software is being used internally or strictly for research purposes (See MHRA Bulletin 18, February 2011). Other regulations and governance mechanisms, particularly those associated with the conduct of clinical trials will come into force in such circumstances.

What if I want to distribute the app elsewhere and perhaps for free?

Once an NHS organisation seeks to distribute this further afield (outside research) then it is subject to MDD regulation. This is irrespective of whether the app is being made freely available at no cost to the end user. The MHRA refer to a term called "placing on the market" in the context of distribution outside an originating organisation.

- **Placing on the market** means in relation to a device "the first making available in return for payment or free of charge of a new or fully refurbished device other than a device intended for clinical investigation, with a view to distribution, use, or both, on the Community market".

Customer or Developer: who is responsible for compliance with the MDD?

Responsibility for compliance with the MDD rests with the Manufacturer of the device. NHS organisations that either develop a medical device in-house or commission such a device via a third party will be viewed as the device manufacturer. The MHRA defines the manufacturer as follows:

- **Manufacturer** means " the person who is responsible for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party". The obligations of a manufacturer under these Regulations also apply to any other person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name, apart from a person who assembles or adapts devices already on the market to their intended purpose for an individual patient (see Regulation 17).

Outline of MDD Process

The Medical Devices Directive (MDD) has three provisions for medical devices:

- Classification of Medical Device
- Essential Requirements
- Conformity Assessment Route

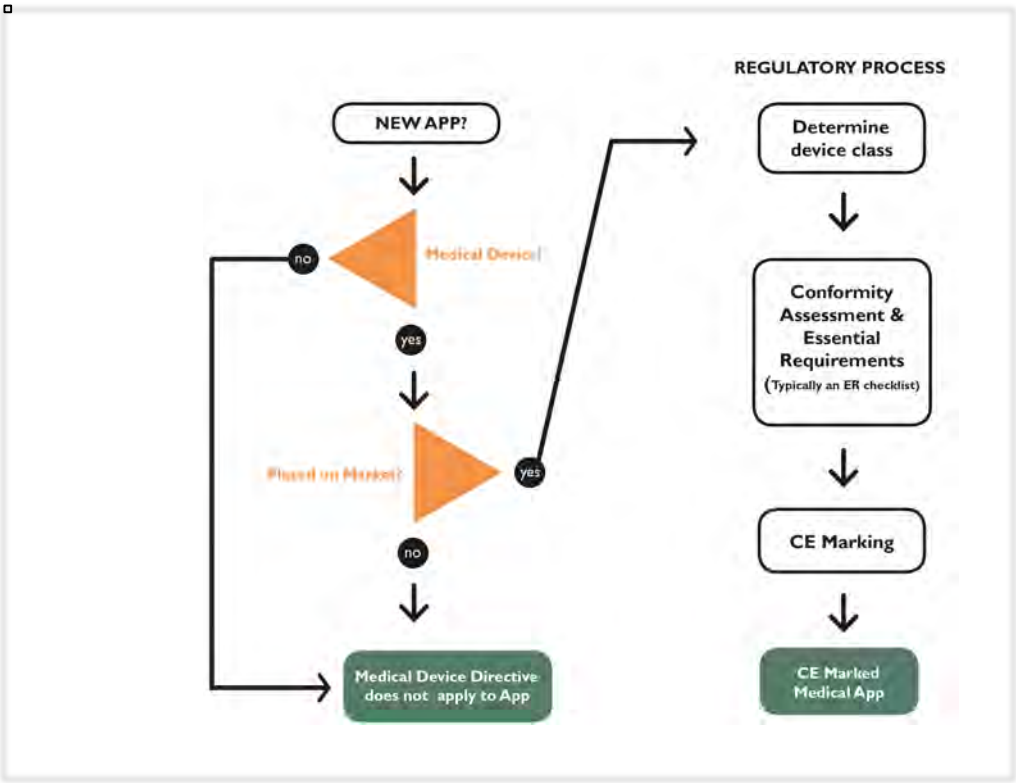


Figure: Decision tree flowchart describing the application of the Medical Device Directive to new healthcare apps

Classification of Medical Device

Medical devices are categorised into classes according to the degree of risk inherent in the device, medical action of the device, duration of use, invasive nature and if the device is powered. Excludes pharmaceuticals.

Class I - generally regarded as low risk. No ISO standard is required. No notified body involved. Can self-certify for CE marking.
For example a standalone clinical decision support app interpreting clinical data, which will influence clinical intervention or interaction with the patient. E.g. Mersey Burns App.

Class IIa - generally regarded as medium risk. Notified body has to be used to confirm compliance with Directive.
For example the Withings Blood Pressure App - direct physiological measurements using smartphone enabled blood pressure cuff or *short term indwelling urinary catheter*

Class IIb - generally regarded as medium risk. Notified body has to be used to confirm compliance with Directive. More clinical data required as part of submission.
For example: Long term indwelling urinary catheter

Class III - generally regarded as high risk
For example: Pacemaker device

The specific class to which a given mobile app is assigned is dependent on the functionality of the app and the manner in which it interacts with or poses a potential risk to the patient. Further information regarding classes see:
http://ec.europa.eu/health/medical-devices/files/meddev/2_4_1_rev_9_classification_en.pdf

Essential Requirements

Annex 1 of the MDD (ref 1993L0042 — EN— 11.10.2007— 005.001— 25) defines 13 “Essential requirements” for the design and manufacture of medical devices as the minimum essential requirements to safeguard patients, users and third parties. These requirements stipulate that the principles of safety should be integral to the design of the product and that the product should be suitable for its intended purpose. In all cases the manufacturer will need to meet the essential requirements. Annex 10 (Clinical Evaluation), Annex 11 (Criteria To Be Met For The Designation of Notified Bodies) and Annex – 12(CE Marking Of Conformity) may also be important for the design of medical apps (Annex 12 is used by default).

Amendments to Annex 1 will expand the list to nineteen essential requirements. The new ER 14. relates to software requirements and has more detail than the current Directive. Compliance with International Standard IEC 62304:2006, "Medical device software – Software life cycle processes," is the Standard that will be expected by Notified Bodies (see Conformity Assessment Route below) as a reference for ER 14.

Many software developers meet the essential requirements through the use of an Essential Requirements Checklist.

"Notified Bodies" are nationally accredited bodies that examine the conformity of the production process completed on behalf of the manufacturers and whose correctness is certified according to uniform assessment factors.

Conformity Assessment Route

Medical device manufacturers are given a choice of routes to meet the MDD requirements; the class attributed to the device will dictate the path that must be followed. The conformity procedures focus on the design and manufacture stages of manufacture.

Manufacturers must provide objective evidence of how the design of the device meets the essential requirements via a technical file. A documented quality system must be in place to ensure that the device continues to comply with the essential manufacturing requirements and is consistent with the information in the technical file.

Routes of conformity assessment are identified in annexes II, III, IV, V, VI, VII and VIII. Many of these MDD annexes contain requirements that the manufacturer's quality system be assessed and be in compliance with the applicable standard, and that those assessments be conducted by a notified body (or through an agreement with another organization) authorized to perform MDD assessments.

FDA Guidance

More recently, in September 2013, the FDA issued its final recommendations (currently non-binding) relating to Mobile Medical Applications. A number of other regulatory bodies including the MHRA are likely to follow with similar guidance or regulations in due course. The forthcoming FDA regulations will be applied to "only those mobile apps which are medical devices and whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended" and these have been termed Mobile Medical Apps. These apps are defined as those that meet the FDA definition of device and either intended as:

- to be used as an accessory to a regulated medical device;
- or to transform a mobile platform into a regulated medical device.

"Software applications that run on a desktop computer, laptop computer, remotely on a website or "cloud," or on a handheld computer may be subject to FDA device regulation if they are intended for use in the diagnosis or the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man"

All mobile Medical App manufacturers should follow a Quality System regulation (which includes good manufacturing practices) in the design and development of their mobile medical apps and initiate prompt corrections, when appropriate, to prevent patient and user harm.

For mobile medical apps, manufacturers must meet the requirements associated with the applicable device classification. If the mobile medical app, on its own, falls within a medical device classification, its manufacturer is subject to the requirements associated with that classification.

Who is a Mobile Medical App manufacturer?

A mobile medical app manufacturer may include anyone who:

- Creates, designs, develops, labels, re-labels, remanufactures, modifies, or creates a mobile medical app software system from multiple components. This could include a person or entity that creates a mobile medical app by using commercial off the shelf (COTS) software components and markets the product to perform as a mobile medical app;

- Initiates specifications or requirements for mobile medical apps or procures product development/manufacturing services from other individuals or entities (second party) for subsequent commercial distribution. For example, when a "developer" (i.e., an entity that provides engineering, design, and development services) creates a mobile medical app from the specifications that were initiated by the "author," the "author" who initiated and developed specifications for the mobile medical app is considered a "manufacturer" of the mobile medical app.

The FDA notes that software "developers" of a mobile medical app that are only responsible for performing design and development activities to transform the author's specifications into a mobile medical app would not constitute manufacturers, and instead the author would be considered the manufacturer

Who is not a Mobile Medical App manufacturer?

- Manufacturers or distributors of mobile platforms who solely distribute or market their platform and do not intend (by marketing claims - e.g., labelling claims or advertising material) the platform to be used for medical device functions.

- Third parties who solely provide market access to mobile medical apps.

- Providers of tools, services or infrastructure used in the development, distribution, or use of a mobile medical app.

- [Healthcare staff], who manufacture a mobile medical app or alter a mobile medical app solely for use in their professional practice and do not label or promote their mobile medical apps outside that organisation.

- Persons who manufacture mobile medical apps solely for use in research, teaching, or analysis and do not introduce such devices into commercial distribution (covered by other governance protocols and regulations).

As with all medical devices, manufacturers are legally responsible for any adverse patient outcomes associated with the use of their device or app. NHS organisations should seek guidance from the NHS Litigation Authority (NHSLA) to establish their position with regard to product liability cover based on their compliance with any NHSLA risk management standards and internal policies.

Summary of Key Points

- The definitions for standalone software which could be deemed to be a medical device are not explicit and therefore currently open to interpretation. The FDA guidance is the latest set of guidelines to be issued by a regulatory body seeking to address issues arising within this fast moving market.

- NHS organisation should give careful consideration to the MDD and establish early in development whether this is a requirement for wider adoption. No NHS organisation wants to be the first party to establish case law for the consequential use of an unregulated mobile medical app.

- NHS organisations developing healthcare apps that fit the criteria of the Medical Device Directive will be deemed to be the manufacturer even if the commissioned development work is outsourced to a third party software developer.

- NHS organizations not familiar with the MDD process should seek advice, particularly with regard to the appropriate conformity assessment route for their medical device or app.
- CE Mark is not the same as FDA approval. CE marking confirms safety not effectiveness of a product.
- The technical file developed for UK CE marking may contribute in part to an FDA submission but it is likely that US-derived data will be required for any FDA submission

App Stores

As the number of apps created have increased exponentially it has become more difficult for customers to locate relevant apps and for developers to bring apps to the attention of consumers. Generic and medical app stores have proliferated as depositories/collections where it is possible to browse available apps, read reviews, purchase them if a charge is payable and automatically download them on to the relevant device. The apps are normally categorised by subject and genres. Many application stores are curated and regulated by their owners, requiring that submissions go through an approval process where applications are inspected for compliance with certain guidelines (such as those for quality and content), and also require that a commission be collected on each sale of a paid application. (Apple retain 30%).

Apple launched its app store in 2008 and it allowed users to purchase and download new apps for their device through either the App Store on the device, or through the iTunes Store on the iTunes desktop software. To have an app accepted in the Apple app store, app developers will require the originating organisation to hold a "developers license agreement" with the relevant platform operator. Developer licence allows development of code which then needs to be submitted to Apple for approval before publishing on iTunes.

Apple offer several types of licence and charge an annual fee, Google play and Microsoft charge a one off fee and operate a simpler structure.

Apple

https://itunes.apple.com

https://developer.apple.com/programs/ios/enterprise/ for internal self publishing

https://developer.apple.com/programs/ for distribution via the apple app store

https://developer.apple.com/library/ios/documentation/LanguagesUtilities/Conceptual/iTunesConnect_Guide/1_Introduction/Introduction.html

The Apple app store is starting to take an increasing tougher towards healthcare apps. A number of app developers have cited examples of new medical apps that have been rejected due to lack of supporting evidence in relation to the source of medical information contained in the app.

Google

Google Play, formerly the Android Market, is a digital distribution platform for applications for the Android operating system and an online electronics and digital media store, operated by Google.

Google play

https://play.google.com/store/apps?hl=en_GB

Microsoft Windows (requires a windows account)

http://msdn.microsoft.com/library/windows/apps/jj714071 there is a separate windows phone app site but these are likely to be merged in Spring 2014.

http://blogs.windows.com/windows/b/appbuilder/archive/2013/11/06/unifying-developer-registration-windows-and-windows-phone.aspx

Blackberry

http://appworld.blackberry.com

As the number of apps has increased, so has the need for categorisation to help users find relevant apps. On both the Apple and Android platforms there is a distinct category for "Medical" which can be interpreted as aimed at health care professionals, while "Healthcare & Fitness" is often used to describe apps for use by patients and the general public. It is important to stress that the allocation of apps to categories is not closely curated – developers may submit their app categorised as they feel appropriate, and may list the same app under multiple categories.

iMedicalApps is an app store for medical professionals, patients, and analysts interested in mobile medical technology and health care apps. Reviews, research, and commentary of mobile medical technology are written by a team of physicians, allied health professionals, medical trainees, and mHealth analysts.

NHS Choices App Store

In March 2012 NHS England launched the NHS Health Apps Library, a collection of apps that had been reviewed by the NHS to ensure they were clinically safe. The library is a way of offering an NHS stamp of approval to apps so users know which ones are safe.

The apps currently included in the library are aimed at public use rather than clinicians but there are plans to expand the library to include healthcare practitioner apps in the future. Developers can submit their apps for review and inclusion online. All apps submitted to the Health Apps Library are checked to make sure that they are relevant to people living in England, comply with data protection laws and utilise trusted sources of information, such as NHS Choices.

Once an app has met these minimum requirements, it is then checked to see whether the app could potentially cause harm to a person's health or condition, for example, is the app limited to providing information from a trusted source – or might it go on to provide personalised medical recommendations or treatment options? If so then potentially there could be harm caused by improper use of the app. The clinical assurance team – which is made up of doctors, nurses and safety specialists, work with the developer to make sure the app adheres to the safety standards. During this process any potential safety concerns are identified and either designed out or dealt with so that any remaining risk is at an acceptable level, thereby reducing the risk of litigation associated with the use of the app.

http://apps.nhs.uk/

NHS Trust Dedicated App Stores

Another recent development has been the creation of NHS Trust dedicated app depositories, often called app stores. These depositories enable the NHS Trust to have complete control over apps approved for usage. Having this structure in place benefits the Trust by safely distributing mobile apps instantly to clinicians, fostering a mobile culture with high adoption, the assurance that apps being used have gone through a validation process and also the support of employee-owned devices. Typically this requires mobile application management (MAM) system to manage the use of apps, security control, updates etc. Many of these are now combined with mobile device management (MDM) solutions that allow enterprise management of mobile devices within an NHS environment.

Other Routes to Market

In addition to the generic app store there are a number of credible online distribution platforms for mobile apps. Some of these are specific to a device manufacturer, some such as Happtique are focused on healthcare apps.

http://www.happtique.com/

http://apps.samsung.com

http://www.handango.com/Home.jsp?siteId=2218

http://www.amazon.co.uk/

Commercialisation of Apps

The pace of app development targeting NHS services is growing at an exponential rate. In some instances these apps are addressing very specific patient or organisational needs, and that in itself is sufficient justification to commit funding and resources to the activity. In many other circumstances there may be a wider potential for use of the app, and there may be a requirement to pursue a commercial route as a means of generating income and / or offering some financial sustainability to the longer term use of the app.

Like other forms of commercially exploited software, potential income can be derived from:

- The app product,
- Provision of a delivery service in conjunction with the use of the app -eg development of a telereferral service in conjunction with a mobile app for community based monitoring or reporting of a chronic health problem.
- Provision of training and technical support associated with the app. (typically the domain of the software developer).

The following section will focus current commercialisation models associated with the app product.

Current Approaches to Commercialisation of Apps

Consumers are increasingly reluctant to pay for apps, particularly when so many apps are available and appear to be free. Where payments are made, consumers are also conditioned by the market to pay typical mobile app prices for such software (ranging from 99p to £5). This has created a challenge for developers of apps who are seeking to cover the cost of app development and maintenance.

There is no single approach that can be used to commercially exploit this technology. A number of factors can determine the most effective or appropriate route to market. These include:

- Type and nature of app
- Intended audience or end user
- Risk profile
- Sustainability and income need
- Organisational fit / bias

Current app models largely developed for the gaming and entertainment sectors tend to be characterised based on free, freemium and paid.

Free Apps

Gartner (2013) noted that 91% of all apps downloaded worldwide in 2013 will be free. Current commercial models for the majority of "free" apps are focused on app advertising or in-app purchases. Some free apps are also associated with paid for health devices such as the Withings blood pressure monitor which can offer alternative income streams.

Advertising

The mobile app market has paved the way for highly segmented and target oriented advertising. Advertisers will spend a lot for customer engagement with minimal effort. At present mobile applications are basically limited to static banner ads, mostly of dimensions 350×50. In some instances, apps which are strategized to be initially free and later followed by download charges register less than 2% conversion rates; most of the income comes through advertising.

Mobile app advertising revolves around advertising companies such as iAds or AdMob which monitor and drive the ads featured. iAds monitors app ads for iOS devices while AdMob features ads for Android devices. Registration with these companies is required if an app is to generate income through running advertisements.

Deploying a free app will bring potential earnings from the advertisements that appear at regular intervals on the application. Depending upon the ad company's revenue model, the charges are collected from the advertiser and then shared between the ad company and the app owner. It's been shown that a free application is likely to get downloaded more often thus creating greater earning potential through advertisements than paid apps.

Many developers track the income stream from their own apps. There is a burgeoning industry in developing software that tracks the number of downloads and income generated from an app. NHS organisations holding app developer licences with the platform owners such as Apple or Google can also generate reports to track downloads and income generation.

Risks

There is however potential risks associated with the advertising model that needs to be considered and managed. A report from researchers at North Carolina State University (March 2012) found that more than half of apps in the Google Play store contained "ad libraries". Some of the more aggressive ad libraries could download and run code from remote servers with impunity, raising security and privacy concerns. These ad libraries received their permission from when the user first installs the app with the user often unaware of granting such permission. (see Security References: cellular-news.com)

Pay-per-click advertising

The pay-per-click advertising model is very similar to Google Adsense. There are several Adsense-like advertising companies which can be used to embed advertisements into an application:

- Admob
- Brightroll
- Google Adsense
- GreyStripe
- iAd
- InMobi
- Jumptap
- MdotM
- Millennial Media

•MobClix

•ZestADZ

Code from these ad companies is placed into the application during the development process. After the app goes live and is downloaded, it requests to show an advertisement and then places that ad onto the screen.

Google finally introduced AdMob to Windows Phone 8 in October 2013 AdMob will provide a compelling alternative to Microsoft's own pubCenter advertising platform.

Not all of the advertising companies are the same. Some have different pay outs, different advertisements, different conversion rates, and all have different fill rates. A fill rate is the ratio of how many times an application requests to show an application and how many times it actually shows up. It is never 100%. This means, sometimes ads aren't shown when they are supposed to, which obviously affects how much revenue is generated. (Note: this is why it's important to design free applications so that the ads show on top of the screen, instead of having a dedicated blacked out space for it. When a request goes out and it doesn't fill, you don't want a large black rectangle to show up on the screen.) To overcome the fill rate issue, selecting one advertising platform that has the highest pay outs but also has a high fill rate is a dilemma. This can be resolved with a mediation service such as AdMob Mediation. Adwhirl was formerly a frequently used mediation solution for developers but it was taken over and "retired" by Google in September 2013 although its open source code will continue to be available on Google Code.

With a "mediation solution" an app developer can sign up for as many ad agencies as desired and the mediation solution should ensure that there is a 100% fill rate. If an ad request goes through for one agency and it doesn't fill, the mediation solution will immediately go to the next agency and find an ad that is available.

There are a number of benefits of developing free apps

Income can be generated if the smartphone owner inadvertently hits one of the ads. Some users however find the banner ads annoying and intrusive.

There are more opportunities to make money from each person who downloads the app than with a paid app. With a paid app, you only make money on the initial purchase, and that's it (unless you have in-app purchases). With free apps, those advertisements are constantly being shown every time a user loads your application.

Freemium and In-app Purchasing

Free to download

Limited functionality but unlock for more features, functionality or virtual goods

An amalgamation of the words "free" and "premium" that refers to services, software programs or mobile apps that are offered to users free of charge, but typically with limited functionality, advertiser support or additional features that are only available for a premium charge. The freemium software business model originated with shareware software, where users are able to download software and try it free of charge but only for a limited time or with a restricted feature-set.

The freemium software model has become extremely popular recently with the debut of freemium apps and in-app purchases in the Apple App Store following the release of iOS 3.0. Freemium mobile apps are available for download on iOS-powered devices like the iPad and iPhone without charge, but users typically have the option to pay for additional features.

Freemium apps now gross more than paid apps in the Apple App Store, with estimates of more than 65 percent of all revenue generated in the App Store from in-app purchases for freemium apps.

Although we were unable to locate any specific statistics on freemium estimates on health related apps, the common theme in articles reviewed were discussing the games market, suggesting that this is the predominant market. That is not to say that there are no freemium health apps just that the games market appears to offer developers the greatest chance of a strong financial return.

Consideration should also be made to the differing market dynamics. For example, in the United States, where it is widely accepted that healthcare is paid for by individuals the attitude to buying a health app may be different to that of the UK public where healthcare is free at the point of delivery.

Paid for App

A small number of apps (particularly within the gaming sector) charge on a pay to download basis Some offer full functionality for a modest price with the business model dictated by volume of sales via an app store rather than app price. The store will however take a percentage of the app price (Apple takes 30%).

The apple app store encourages paid apps with top suggestions in their listing layout and free ones at the bottom of the page. This is due to the fact that the app store directly benefits from each download made for a paid app. Apple app store works on a revenue sharing model that allots 70% to the mobile app developer/owner and the rest for itself.

Probably the biggest benefit of going with a paid application is the income potential. Although it is possible to make money with free apps, the likelihood of generating huge traffic with money from advertisement clicks is unpredictable. Also, the App Store seems to favour paid apps more than free apps. This makes sense, because Apple doesn't get any money from distributing free applications (except those that incorporate Apple's advertising platform, iAd).

Exposure through an app store is essential in order for an app to do well. This means getting onto the top 200 or top 100 or top 10 lists, getting featured on "New & Noteworthy" and "What's Hot", and getting exposure as a new app in the "All [Category] iPhone Apps" space, which highlights the latest applications approved in that category, and all of this is much easier with a paid application.

Many vendors combine this approach with optional in-app purchasing.

Some app experts suggest that it's the confidence over the app that leads to a paid deployment. If the app is good it will not have to depend on advertisements to generate revenue, instead it will find its customers and generate revenue with every download.

What Does All Of This Mean For The "NHS App"?

Let's assume that the app has been suitably peer reviewed, is fit for purpose and has passed the necessary quality or regulatory process. Lifestyle consumer apps are more likely to be handicapped more by the price sensitive market than an app targeting organisation efficiency or service delivery by a healthcare practitioner. Healthcare professionals are more willing to purchase higher cost solutions that are robust, safe and assisting with the delivery of care e.g. mobile decision support algorithms or clinical protocols. Patients using mobile solutions to support long term or chronic conditions may also perceive greater value associated with an app, but NHS organisations will be keen to ensure that the financial model will not act as a barrier to such users.

An increasing number of NHS organisations are using appropriate advertising to assist with website costs and some are considering app advertising (anecdotal evidence), but this may be limited to apps targeting healthcare professionals rather than patients.

Case Study

Benchmark against apps with accreditation – sale price £1.99

A recent study by Cambridge University computer scientists found that just 20% of paid apps are downloaded more than 100 times and only 0.2% of paid apps are downloaded more than 10,000 times. [*Tech Crunch* August 2012]

Optimistic download of 5,000 apps in first year gives income of £5,000. Realistically this would not even represent a break-even point.

A free App deployment with paid-for advertising may generate significant income. 20% of free apps get 10,000 or more downloads. [*Tech Crunch* August 2012].

Code from an ad companies, such as Google Adsense, is placed into the application during the development process. After the app goes live and is downloaded, it requests to show an advertisement and then places that ad onto the screen.

Depending upon the ad company's revenue model, the charges are collected from the advertiser and then shared between the ad company and the app owner.

Let's assume a typical one of our 5,000 users accesses this app 4 times every month and clicks one ad. This gives us 5,000 ad-clicks which would only bring in revenues of £2 - £3 per month. [*typical pay-outs from various internet sources]*

- 500,000 users would bring in £2,000 - £3,600 pa

- 1 million users would bring in £4,000 – £7,000 pa

For an app that requires advertising and updates, 1 million users would represent less than break-even. This process would also need some serious monitoring/management to keep it optimised.

Summary of Key Points

- There is no single commercial model that is relevant for apps created within an NHS environment to meet an unmet need.
- A number of factors including type of user, risk profile, income or sustainability need and organisation preference will influence the commercial model.
- Different approaches may be required depending on whether the healthcare app is targeting an NHS user or health conscious consumer.
- People have become accustomed to free apps, but some users are also comfortable paying for apps.
- It is difficult to see that freemium will be widely used in healthcare as the business model does not seem to be a good fit.
- App value should be determined by the outcome. If there is clear value in the outcome, then it should be paid for in some form. What we have come to expect from apps as a consumer is and may be quite different to what we expect from a medical app in the future.

Digital Marketing and Adoption Considerations

App Stores are commonly deployed by customers seeking to download/purchase mobile apps and also by developers to showcase market and sell their applications. The likelihood of consumers finding useful medical apps through browsing the overcrowded generic app stores is fairly remote. While the number of apps submitted to the major app stores each day is

enormous, only a minute fraction get recognized by users. Adeven estimated that 60% of the apps in the app stores have never been downloaded. If an app is to be widely adopted then promotion and marketing are essential.

Whether releasing a medical app through the app stores or promoting usage within a healthcare organisation, a successful marketing strategy requires planning, careful research, continuous monitoring, a focused aim and effective/ targeted promotion so that the app is noticed and possibly adopted. If an app is classified as a medical device, developments and marketing must not only conform with the rules of a particular app store but also to the requirements of the regulatory bodies.

The principles for product marketing also apply to apps. Developers should initially establish whether there is a need for the particular app and how it differs from similar apps already on the market. Further research to gain an understanding of what contributes to making an app successful should provide pointers for developers. Strategies to help an app stand out in the marketplace include presenting it from a novel perspective and promotion.

Good end user experience is vital and a successful app must be of good quality and function well. The app should be tested thoroughly and perform consistently even under the most extreme conditions. The app should be updated regularly and accessible to the user at all times. It should work perfectly, irrespective of whether the phone connection is on or off, and ideally consume the minimum possible CPU and battery power. If an app constantly crashes it is unlikely that it will be widely adopted. Interaction with end users and an understanding of the customer experience could be obtained if a feedback mechanism was built into the app or a user was asked to rate the app while still using it, rather than during uninstall.

In the digital marketplace Search Engine Optimisation (SEO) and App Store Optimisation (ASO) are essential. As over 90% of web traffic is driven by search engines, content creation and social media, the benefits of SEO are obvious. An app could also be promoted through building an online presence to drive targeted traffic towards it. Search engines also provide another route to link to the app stores -searching and utilizing keywords and keyword names although they operate in a different environment.

For effective App Store Optimisation an understanding of how the app store ranking and search algorithms function is useful. The algorithms can however be changed without notice with the subsequent effect on rankings as recently seen on iOS6 and in essence app developers have very little control over these algorithms and how they utilise keywords (See reference section for App store Optimisation)

The following should aid App Store Optimisation especially with iOS6:

- Singular form words are handled better with search algorithms and produce better results.
- The category name is automatically saved as a keyword so there is no need to repeat it in the description.
- Keywords are as important as the app name but it is essential to have an app title that reads well and succinctly describes the app.
- Preferable to use single keywords
- The App Store landing page should have an engaging appearance.
- Ratings and reviews are important

As medical apps are a niche market, targeting the medical community would be more productive rather than relying on the saturated generic app stores. Sites that review medical apps, social media, blogs, professional websites, publications and networks and integrating the apps with mobile social networks (for example Facebook) are probably the most productive. Any publicity material could include clear and detailed snapshots and videos of the app.

If an app is compatible with a variety of devices and platforms then the market is potentially larger. An app that offers a secure online environment where passwords and sensitive information are protected should be more attractive to clinicians.

No single method is going to boost the visibility of an app but having reporting metrics in place which record number of downloads, number of new users viewing the app, and how the app was located will provide evidence as to which promotion channel has been the most successful.

Ultimately, success of the app will be determined by the driving need, the usability and value of the solution and accessibility. Success should also be determined by an apps' longevity of use. In this disposable society, particularly with respect to apps, where often the usage of an app may only be over several weeks, the true value of a healthcare app will be found in the duration of use.

References / Resources

References

App Development

http://www.research2guidance.com/the-market-for-mhealth-app-services-will-reach-26-billion-by-2017/

http://www.research2guidance.com/shop/index.php/downloadable/download/sample/sample_id/262/

Baumgart DC. Smartphones in clinical practice, medical education, and research. Arch Intern Med 2011;171:1294-6

Boulos MN, Wheeler S, Tavares C, Jones R. How smartphones are changing the face of mobile and participatory healthcare: an overview, with example from eCAALYX. Biomed Eng Online 2011;10:24.

Visser,BJ and Bouman, J. There's a medical app for that. 2012; BMJ Careers . http://careers.bmj.com/careers/advice/view-article.html?id=20007104

Cost of apps

http://katanacode.com/blog/posts/8-how-much-does-it-cost-to-develop-an-iphone-app

http://appfurnace.com/2013/07/why-do-android-apps-cost-more-to-develop-than-iphone-apps/

http://www.dailymobilereport.com/index.php/mobile-app-development-cost/

http://www.canalys.com/newsroom/android-apps-are-too-expensive

Regulatory considerations

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf

http://www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con114556.pdf

THE MEDICAL DEVICES REGULATIONS: IMPLICATIONS ON HEALTHCARE AND OTHER RELATED ESTABLISHMENTS/ Bulletin 18. MHRA. Amended 11 February 2011

Technology standards

http://rdn-consulting.com/blog/2010/06/05/iso-62304-the-harmonized-standard-for-medical-device-software-development/

http://medicaldevices.bsigroup.com/en-GB/our-services/iec-62304/

http://www.emdt.co.uk/article/developing-medical-device-software-iso-62304

http://www.emdt.co.uk/article/iec-62304-compliance

http://systems.hscic.gov.uk/clinsafety/dscn

See http://www.hscic.gov.uk/standards

Examples of validation studies of medical apps

Gregoski MJ, et al Development and validation of a smartphone heart rate acquisition application for health promotion and wellness telehealth applications. Int J Telemed Appl 2012;2012:696324.

Kubben PL, et al An evidence-based mobile decision support system for subaxial cervical spine injury treatment. Surg Neurol Int 2011;2:32.

Kwon S, et al Validation of heart rate extraction through an iPhone accelerometer. Conf Proc IEEE Eng Med Biol Soc 2011;2011:5260-5263.

Mellone S, Tacconi C, and Chiari L. Validity of a Smartphone-based instrumented Timed Up and Go. Gait Posture 2012 36(1) 163-5.

Qiao J, et al Reliability Analysis of a Smartphone-aided Measurement Method for the Cobb Angle of Scoliosis. J Spinal Disord Tech 2012 25(4):E88-92.

Quality and Apps

http://www.imedicalapps.com/2013/06/apple-rejecting-medical-apps-drug-dosages/

Albrecht, UV *et al,* App-synopsis- standard reporting for medical apps. Studies in Health Technology & Information 2013 **192** (1154)

Buijink, AW; Visser, BJ and Marshall, L. Medical apps for smartphones: lack of evidence undermines quality and safety. Evidence Based Medicine 2013 **18** (3) 90-2

Ferrero, NA; Morrell, DS and Burkhart, CN Skin scan: a demonstration of the need for FDA regulation of medical apps on iPhone. Journal of the American Academy of Dermatology 2013 68 (3) 515-6

Franko, O; Validate an App: How to Design Your Study and Get Published. Journal Mobile Technology in Medicine, 2012 **1** (2) 1-4 www.journalmtm.com

Hamilton AD, Brady RR. Medical professional involvement in smartphone 'apps' in dermatology. Br J Dermatol 2012;167:220

Kreiger, WH Medical apps: public and academic perspectives. Perspectives in Biology& Medicine 2013 56 (2) 259-73

McCarthy, M. FDA will not regulate most mobile apps. BMJ 2013 347 (f5841)

McCartney, M How do we know whether medical apps work? BMJ 2013 346 (f1811)

O'Neill, S and Brady, RR Clinical involvement and transparency in medical apps: not all apps are equal. Colorectal Disease 2013 15 (1) 122

Payne, KF *et al* A review of current photography guidelines in relation to smartphone publishing of medical images. Journal of Visual Communication in Medicine 2012 **35** (4) 188-92

Visvanathan A, Hamilton A, Brady RR. Smartphone apps in microbiology-is better regulation required? Clin Microbiol Infect 2012;18:E218–20

Walsworth, DT Medical apps: making your mobile device a medical device. Family Practice Management 2012 19 (3) 10-3

Security and Privacy in apps

http://ico.org.uk/news/latest_news/2013/~/media/documents/library/Data_Protection/Detailed_specialist_guides/privacy-in-mobile-apps-dp-guidance.pdf

Han, J., Yan, Q., Gao, D., Zhou, J. & Deng, R. Comparing mobile privacy protection through cross-platform applications. The 20th Annual Network & Distributed System Security Symposium, 26 February 2013.
http://www.liaiqin.com/hanjin/papers/NDSS2013Han.pdf

http://www.cellular-news.com/story/53557.php

http://mobihealthnews.com/28165/happtique-suspends-mobile-health-app-certification-program/

http://www.nytimes.com/2013/09/12/your-money/free-apps-for-nearly-every-health-problem-but-what-about-privacy.html?_r=2&

http://www.networkworld.com/news/2013/111813-hp-ios-vulnerabilities-276063.html

http://www.theguardian.com/technology/2013/dec/11/app-hacking-commonplace-warns-security-company

http://www.samsung.com/global/business/mobile/solution/security/samsung-knox

http://www.allthingsknox.com/learn-knox/features/

http://www.samsung.com/my/business-images/resource/white-paper/2013/11/Samsung_KNOX_whitepaper_An_Overview_of_Samsung_KNOX-0.pdf

http://www.parabal.com/parabal-white-papers/

App store

http://mattgemmell.com/releasing-outside-the-app-store/

http://www.zdnet.com/blog/hardware/600000-apps-in-apples-app-store-yet-i-cant-find-anything-i-want/19549

http://www.bbc.co.uk/news/technology-23240971

App Store Optimisation

http://www.integratedchange.net/app-store-optimisation-what-you-need-to-know

http://appleinsider.com/articles/13/12/13/apple-tweaks-ios-app-store-search-algorithms-app-positions-fluctuate-8x-more-than-usual

http://www.shellypalmer.com/2012/08/400000-apps-in-the-app-store-have-never-been-downloaded-says-report/

App deployment (how do you get your app to market)

http://searchconsumerization.techtarget.com/feature/Mobile-device-management-vs-mobile-application-management

http://www.softwareag.com/blog/reality_check/index.php/hot-and-not/byod-strategy-manage-the-device-or-manage-the-data/

http://www.crn.com/news/security/240156399/mobile-device-management-market-wont-last-gartner.htm

http://blogs.forrester.com/category/mobile_application_management

(http://www.zdnet.com/blog/consumerization/10-byod-mobile-device-management-suites-you-need-to-know/422)

Commercialisation of apps

http://www.bluecloudsolutions.com/blog/free-paid-apps-works/

http://techcrunch.com/2012/08/26/how-free-apps-can-make-more-money-than-paid-apps/

http://www.appiction.com/Free-Apps-vs-Paid-Apps

http://bgr.com/2012/09/11/mobile-app-market-analysis-free-apps-dominate/

http://www.appbrain.com/stats/free-and-paid-android-applications

http://locassa.com/free-vs-paid-apps/

http://www.thegeekafterglow.com/2012/12/whats-your-usage-of-free-vs-paid-apps.html

http://www.zdnet.com/in-app-payments-more-profitable-than-paid-apps-7000004110/

http://blog.w3i.com/2012/09/24/the-value-of-free-apps/

http://www.slideshare.net/techahead/inapp-purchases-are-in-paid-apps-are-out

http://www.gartner.com/newsroom/id/2592315

http://news.ncsu.edu/releases/wms-jiang-app-ads/

Organisations and Companies offering guidance and consultancy

NISE (NHS Innovations South East) has been helping its NHS members identify, develop and commercialise innovations designed to improve the quality and efficiency of healthcare services since 2004.

NISE works throughout the South East, delivering a comprehensive range of practical support services to help inventors and their organisations bring bright ideas to reality. NISE is developing alternative business models that will identify and address several current barriers to the commercial viability of medical apps for safe use by a wide range of consumers including healthcare practitioners and patients alike. This will assist the NHS to leverage app technology in the growing global market.

Further details can be found at http://www.innovationssoutheast.nhs.uk

HANDI (**The Healthcare App Network for Development and Innovation**) is a non-profit community interest company that seeks to provide mutual support for developers of health and care apps and others interested in this area. HANDI is supported by a community of clinicians, developers, health informaticians and others who believe that lightweight healthcare apps for patients, carers and health and care professionals provide the key to enabling IT to transform of health and care. HANDI is neutral with regard to platforms and business models for apps.

Further details can be found at http://handihealth.org/

d4 is a non-profit organisation focused on improving patient care by placing modern technology in the hands of doctors, nurses and other health care professionals. An immediate focus is to increase the acceptance and affordability of mobile phones for clinicians in the UK.

Further details can be found at http://www.d4.org.uk

App / mhealth Developers

Oxford Web Applications	http://www.oxfordwebapps.co.uk/
Oxford App Studios	http://www.oxfordappstudios.com/
White October	http://www.whiteoctober.co.uk/
Rare form New Media	http://rareformnewmedia.com/home
Biff Bang Pow	http://www.biffbangpow.com
Electric Studio	http://www.electricstudio.co.uk/
Overpass Apps	http://www.overpass.co.uk/android-application-development/
The Boffin Lab	http://www.theboffinlab.com
Serious Games International	http://www.seriousgamesinternational.com
Black Pear Software	http://www.blackpear.com
MicroStrategy	http://www.microStrategy.com
Maldaba	http://www.maldaba.co.uk/
Commontime	http://www.commontime.com
Cranworth Medical	http://www.cranworthmedical.co.uk/

Evaluation services

HDTI App evaluation service	http://www.coventry.ac.uk/research/research-directory/allied-health/health-design-technology-institute/business-support/healthcare-apps/

Digital Marketng

Integrated Change	http://www.integratedchange.net/mobile-healthcare-marketing

Other sources

MHRA	http://www.mhra.gov.uk/
Health Developer Network	http://apps.nhs.uk/developers/health-developer-network/
Notified body	http://www.bsi-global.com/CEMark/MedicalDevices/index.xalter
Medical Device Consultancy	http://c-m-s.com/,

Websites with Additional Information and Medical App Review Sites

http://www.medicalappjournal.com/index.php

http://www.imedicalapps.com/

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