ORCHA DETAILED REPORT

FROM REVIEW OF APP
PAIN TOOLKIT, VERSION 2.1.3 FOR ANDROID, ON 05.08.2016

ORCHA Review Summary

Pain ToolKit

By ADI Health

Rated by ORCHA on the date of 05.08.2016

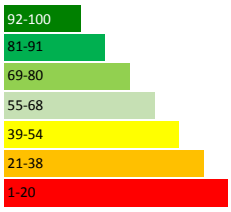
Version 2.1.3

Source: GOOGLE PLAY Platform: ANDROID

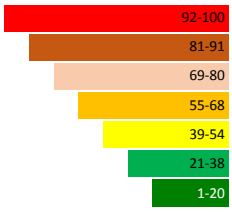
Level:

3

Professionally Led



Value	Risk
47	40



Functions:

✓	Education and Information		✓	
✓	Self Monitoring		✓	
✓			✓	Professional Guidance

PRODUCED BY ORCHA
THE ORGANISATION FOR THE REVIEW OF CARE AND HEALTH APPLICATIONS
05.08.2016

Review reference PTK05082016SLv3.2

INTRODUCTION:

WHO ARE ORCHA AND WHY ARE THEIR RATINGS SIGNIFICANT FOR USERS, CLINICIANS AND DEVELOPERS:

ORCHA is the Organisation for the Review of Care and Health Applications. ORCHA's main purpose is to carry out independent and impartial reviews of health related apps and to present this information clearly to the public, professional and app developer community. ORCHA has created an interactive platform that enables people to easily find and compare potential apps to help find the best for their needs.

The results of all our app reviews are presented on the ORCHA website for users, and ORCHA powered clinical platforms which provide professionals the ability to find and recommend apps to their patients. Our reviews are summarised with two main scores - Value and Risk. We also identify key functional capabilities of the app. The scoring and function system makes it easier to identify and compare the best apps, so that the right apps are used for the best outcomes, and identifiable risks are better understood.

Through this process ORCHA plans to revolutionise the uptake and associated benefits of using great apps for health and care purposes, giving users clarity to identify the best apps for their needs, clinicians the confidence to incorporate this key resource to into their patients treatment plans, and to help developers produce safer and better apps that get deservedly more visibility. Our mission is to inspire confidence in using better health and care related apps that can radically benefit the user and the health and care economy.

The 111 point review process has been developed to provide an objective measure of the app, taking into account the current regulatory standards and guidance that is available. It has been developed with health and care professionals at a clinical and managerial level and also with support from academics focused on this fast moving environment. We have also consulted widely with app developers and publishers.

This report is intended to help you to understand more about the review process, the scoring methods utilised, and the specific results the app has achieved, as well as identifying areas of potential risk which we have highlighted. We also help identify areas for improvement to help increase the overall Value of your app, reduce its risk factors, and therefore improve the associated ORCHA scores.

ORCHA helps drive improvements in the value, safety and user experience for all health and care related apps and is a catalyst to improve visibility and usage of great apps, as well as offering specialist support and opportunities for collaboration.

ORCHA – Promoting better apps, for better outcomes.

Read on for further detailed information on the assessment of the app
Pain ToolKit

WHAT IS THE RELEVANCE OF ORCHA TO ME?

The Health and Care App market currently consists of over 165,000 apps (IMS Institute for Healthcare Informatics, September 2015). It has the potential to create a massive contribution to improved health and care outcomes. However, the quality of these apps vary massively, and with little in place to regulate or review them, the threat of exposing end users to risky apps that could give poor health information or advice, undermines confidence and momentum in this emerging landscape. It can be a challenge to find useful apps specific to a particular health or care need, with generic searches presenting potentially hundreds of matching apps. ORCHA's more concise and user friendly platform of assessed and rated apps fills this gap.

I'M A DEVELOPER:

ORCHA helps you identify areas where you can improve your apps and highlights risks that you might wish to further consider and mitigate through future updates. ORCHA helps to give you feedback and confidence that your app is hitting the mark and should be embraced by the market. It also offers you a benchmark with which to compare yourself with other apps in the same arena, and to inspire further improvements to raise its visibility and uptake.

Whether you simply register for membership with ORCHA, partner with ORCHA consulting services to help optimise your App, or sign up interest in the ORCHA taskforce as an affiliate to help find innovative solutions to industry needs, you can get different levels of feedback, engage with opportunities to further develop your apps, or collaborate with health and care needs in your specialist sector where unmet demands are recognised. Registering or working with ORCHA demonstrates a commitment to high quality low risk apps for greater user benefit, and an interest in the greater potential that apps have in shaping the future of health and care.

ORCHA offers you:

- A dedicated online environment that enables targeting of health and care app users, professionals and communities
- A robust review process providing reassurance and guidance around solution quality and the ability to differentiate and elevate app quality, vasibility and associated uptake.
- A unique online community providing access to resources, standards, and protocols for wider interoperability and integration.

I'M A MEDICAL PROFESSIONAL:

ORCHA offers a streamlined and easy way of finding great apps that you can more confidently recommend to your patients to help them manage, monitor or report on their specific health conditions or goals, which can in turn support you in defining and delivering the most efficient and appropriate treatment plan. If used with a large health population, there is potential for apps to show measurable impact on patient outcomes. ORCHA provides tools to measure usage and modes of use by patients.

As a registered professional user ORCHA will keep you up to date with critical updates on apps you've recommended that we think you should know about as well as your patients. We'll also help keep you informed of new apps relevant to your fields of application that we think you or your patients might find useful.

I'M A USER:

ORCHA makes it easier than ever to find, compare and really benefit from using the best apps for your health and care needs. These can help improve day to day health, or deal with specific conditions.

By registering, users can be kept up to date with updates, and new and complimentary apps that they might want to consider. They can also contribute feedback on their views, suggestions and any concerns to help developers protect users and get the best out of future app developments.

ORCHA™

ORCHA Review Certificate

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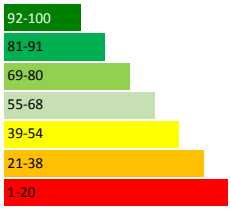

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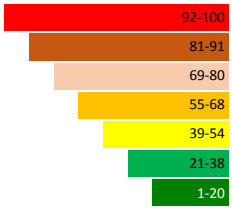

Functions:

✓	Education and Information			
✓	Self Monitoring			
		✓		Professional Guidance

ORCHA, the Organisation for the Review of Care and Health Applications, has assessed the application 'Pain ToolKit' on 05.08.2016 and can confirm that the app has been reviewed as a Level '3', 'Professionally Led' app, and has received the above summary rating.

The app has received a value rating of '47' out of 100, which takes into account a standardised assessment of the Data handling, Design & Testing, Clinical Assurance & Efficacy, User Experience and User Feedback. This score can be compared with other apps in its field on the Orcha register at www.orcha.co.uk

According to the platform source from which it was downloaded, the app had enjoyed 1,000 - 5,000 downloads at the time of review. It also reflected 9 user reviews, giving it an average rating of 2.2 out of 5.

The app has received a risk rating of '40' out of 100, with higher scores representing higher risk. This is based on a standardised assessment of typical risks associated with Data handling, Design & Testing, Clinical Assurance & Eficacy, and User Experience.

This detailed report is intended to help you understand more about the scoring methods utilised, and the specific results the app has achieved, as well as identifying areas of risk and potential areas of weakness which could be improved to increase the overall value of the app and therefore the ORCHA score.

The ORCHA review is based on a standard assessment regime and on a typical user profile for this type of app, and does not take into account other specialist or clinical needs or associated risks. Users should verify that it meets their specific needs and requirements, or seek specialist medical advice if they have concerns or are aware of medical conditions or other particular requirements that may lead to a higher level of risk to them specifically. It is the users responsibility to independently research and assess the app or seek third party advice to satisfy themselves that it meets their specific needs and is of an acceptable level of risk to them. Users should raise any concerns with their medical professional and should report safety concerns to the developer and via the feedback option at www.orcha.co.uk

For full terms and conditions of use please go to:
http://app.orcha.co.uk/Home/LegalStatement

www.orcha.co.uk

ORCHA proudly works with:

TSA The voice of technology enabled care services

ECHAlliance

Information shown correct at time of review based on source information. Orcha reserves the right to withdraw or change data published by them at any time.

Certificate Reference: PTK05082016SLv3.2

HOW DOES THE ORCHA REVIEW PROCESS WORK:

MONITORING THE APP MARKET PLACE

ORCHA constantly monitors the app market place looking for good potential apps to review. Our automatic scraping algorithms continually cycle data gathering on the 165,000+ apps out there. We use a process of elimination to start making our task more manageable, by applying a screen or filter that removes the apps that in our opinion, Did Not Qualify (DNQ) for initial review to satisfy the mass UK market. This uses a number of fundamental criteria such as the app being available in English, the developer being active and able to respond to problems and updates, and the app being maintained so that it is compatible with recent software platform updates. From this point we have a live and more manageable filtered list of qualifying apps like yours to focus on. We prioritise our reviews from this list based on a number of factors, including requests from our healthcare and professional users, apps that we have identified as being of good potential, and apps from developers who have commissioned an express review. The ORCHA Review Queue awaits our team and one by one they are allocated to a reviewer.

THE REVIEW BEGINS WITH THE AUDIT STAMP

At ORCHA we are committed to total quality management, so the review process starts with some fundamentals. A reviewer is appointed to the App. All our reviewers have been carefully selected and highly trained to be able to expertly interrogate and review apps, using a process that receives regular audits and has been demonstrated as being able to produce consistent results between different reviewers. An 'Audit Stamp' is applied to the review. This is critical data that we can use for full traceability of such things as who the reviewer is, the primary device used, software version etc. We ensure all our devices are running the latest software for reviews.

APP DOWNLOAD AND INFO COLLECTION

We record full details of the App at point of download - source, version, date, time again for full traceability. The reviewer then familiarises themselves with the app, and gathers information from freely available information in the public domain including the developers website, Google Play, I-Tunes, or other download sources, MyHealthApps portal, the developer’s website, and general information from the app itself. This information is used in answering a standard set of questions that makes up the ORCHA Review.

Note that an app may have a particular feature (eg. data stored securely), but a positive score will only be given if there is a statement to this effect. Similarly, ORCHA reviewers do not generally validate any information provided by the developer (eg. if you say data is stored securely, we do not undertake tests to prove whether this statement is correct). The app could be reviewed on a number of different devices, with all these details recorded and specific to that review.

WHAT DOES THE REVIEW LOOK LIKE

The actual review process involves the reviewer interacting between the app and a digitised roadmap of 111 questions that guides the reviewer on a carefully choreographed and comprehensive assessment of all key areas of the app. No questions can be missed, and only those that apply to the functionality and level of the app are applied so scoring is always fair.

Each of the questions has been devised by our management panel of specialists including clinicians, academics, mhealth & data specialists, drawing on recognised principles, standards and NHS guidance in each of the sections we consider. The review questions have been thoroughly tested as being capable of being objectively answered, and each is allocated an appropriate weighting for scoring normally low, medium or high, in each section, and whether it contributes to the value or risk score, or both.

VALUE AND RISK

Some questions in each section contribute to the section Value score, and some contribute to the Risk score, and some, contribute to both. Value questions are defined as those that measure quality of the app, and which contribute to a good user experience, and how beneficial the app might be to users. Put simply, on our scale, the higher the Value score, the better the app in terms of how it satisfied our Value questions. Risk questions are associated with such things as how reliable the content and operation of the app are, and how safe the users data is and the user by using it. Put simply, on our scale, the higher the risk score, the riskier the app could be based on our Risk questions.

It should be noted, that our assessment largely looks for statements or evidence in the app to satisfy our questions around risk. Much like medicines, if we are looking for statements and evidence within the app that information it contains on a condition has been validated by a clinician or appropriate specialist, and the app fails to clearly state this, we must assume that it hasn't and therefore the risk would be higher. It doesn't necessarily mean that it hasn't been clinically verified, but you wouldn't take a tablet on the assumption that it had been through clinical trials unless you could see a statement that it had within its enclosed documentation.

WHAT AREAS DO WE REVIEW

We interrogate apps by answering the questions to gain objective data to thoroughly understand the app and assess the following main sections of our review:

Level Assessment - This assesses the main purpose of the app from 4 levels ranging from fitness and wellbeing, up to apps intended only for clinical use by professionals and clinicians.

Function Assessment - This assesses the main functional capabilities of the app. For example;

Education and Information	Care Support
Self Monitoring	Personalised Guidance
Auto Monitoring	Professional Guidance

Data - this is about the data collected, how it is utilised, managed and the policies and security in place that help to protect the users data.

Design and Testing - this looks at how clearly the developer has demonstrated the users interests during design, development and testing and compliance with recognised standards.

Clinical Assurance and Efficacy - critically this is how clearly the developer has demonstrated within the app that any information, guidance, methods and functions of the app have been proven to be valid, of benefit and maintained so the user or clinician recommending the app can count on the content.

User Experience - this is a measure of the attempts made to make the app clear and easy to use, and how accessible it is to a range of different users. It also considers some the key points raised in research around the benefits in goal setting and sharing information or buddying with like minded users.

User Feedback - uses a careful analysis of user reviews and download statistics to get a consensus from the existing user base. This makes up only an element of the overall score, but does give apps that have demonstrated high reviews and high download figures the opportunity to differentiate themselves from lower scoring or unreviewed apps. The scale has been carefully developed so that new apps with only a few reviews, and those with high downloads and mediocre reviews still get a fair contribution to this element of the score.

Further details on each of the sections, and how the app scored follows in the review results sections.

REVIEW RESULTS PAIN TOOLKIT

LEVEL ASSESSMENT PAIN TOOLKIT

ORCHA has devised 4 different levels of apps, assessed based on the following fundamental principles which define each level. It should be noted that level 3 and 4 apps, are subject to third party assessment and approval as detailed below;

1 Wellbeing – These are generally keep healthy apps available to everyone who might wish to use them.

2 Self Managed – These apps tend to be aimed at people with an existing or potential health condition to help support them manage or monitor the condition and support independence.

3 Professionally Led – The patient and professionally-led apps in this level include those that are essentially prescribed by a health care professional. These apps tend to encourage a collaborative approach (between patient and healthcare professional) to managing or treating a particular condition, and may also need to fulfil other regulatory or industry related test standards. *See note below

4 Practitioner / Professional Use – These apps tend to be more heavily restricted, controlled and regulated by legal and regulatory standards as they might be liable to dangerous misuse. The clinically led apps in this level are normally developed by health professionals for use by health professionals, to aid immediate clinical decision making with the capacity for significant impact on patient outcomes. *See note below

*NOTE ON CE MARKING AND THE MHRA

If your app provides individualised recommendations to a user (eg. instructs the person how much insulin to take based on blood glucose values entered), it may need to be CE marked. This usually will apply to apps in level 3 or 4, but could also apply to some level 2 apps. An app does not need to be CE marked if it simply provides generalised advice (eg. advises the user what is the normal range for their blood glucose and suggest they should seek medical advice if outside of this). ORCHA does not provide an assessment of whether an app should be CE marked, as only MHRA Notified Bodies are accredited to do this. However, we will advise if we think the app may need to be CE marked and suggest you take specialist advice.

THE RESULTS OF THE LEVEL ASSESSMENT ON THE APP PAIN TOOLKIT VERSION 2.1.3 FOR ANDROID, CARRIED OUT 05.08.2016, IS AS FOLLOWS

The app was assessed against the levels outlined above and was deemed, based on the information available, to be a level 3 - Professionally Led App.

ORCHA has devised 6 key functional capabilities which we look for during our assessment of the app;

Education and Information:

Apps with this function offer general information in an attempt to give users generic background information, knowledge or potential action related to specific health issues or objectives. They may also report on environmental variables that may have an impact on health, such as Air Quality for information purposes. This type of function might often be compared to a health leaflet.

Self Monitoring:

Apps with this function will often allow the user to manually enter data related to their health issue or objective, summarise this data, and may offer reminder or alert functions that are manually set up by the user.

Auto Monitoring:

Apps with this function allow some means to automatically record data for the user related to their health issue or objective. This may be via built in capability within the device (such as location information) or via attached devices (such as FitBit or other measurement devices).

Care Support:

Most frequently this function is associated with the ability to link into forums associated with the condition or health objective where the user may be able to gain support or become part of a community with common challenges or objectives. It may also indicate the potential for sharing information with family, friends or others in an informal caring capacity.

Personalised Guidance:

These apps might offer personalised alerts, guidance or recommendations calculated and suggested based on the user information enterred or recorded. Depending on the type of advice given they may be level 3 apps which are professionally led and because of the importance of correct guidance being given, they may be subject to CE marking or more extensive testing by the developer or third parties.

Professional Guidance:

These apps tend to offer guidance to professionals only relating to the diagnosis or treatment of conditions, and these apps are most likely to be level 4 apps, requiring extensive testing and CE marking, having been developed by clinicians for clinicians.

THE RESULTS OF THE FUNCTION ASSESSMENT ON THE APP PAIN TOOLKIT VERSION 2.1.3 FOR ANDROID, CARRIED OUT 05.08.2016, IS AS FOLLOWS

The app was assessed against the functions outlined above and was deemed, based on the information available, to offer the following key functions:

✓ **Education and Information**

✓ **Self Monitoring**

✓ **Professional Guidance**

REVIEW RESULTS: DATA	PAIN TOOLKIT

THE RESULTS OF THE DATA SECTION ASSESSMENT ON THE APP PAIN TOOLKIT VERSION 2.1.3 FOR ANDROID, CARRIED OUT 05.08.2016, IS AS FOLLOWS

Data scoring questions focus on three main areas under the Data heading; Data Collection, Data Utilisation and Data Management. This section of the review focuses on the apparent efforts of the developer to help mitigate risks and add value in certain areas by clearly indicating their policies around Data and whether they have followed best practice, certain standards and legal requirements in order to protect and enhance the User experience. The Data section scores contribute to 40% of the overall Risk Score, and 15 % of the overall Value Score.

DATA	**VALUE:**	**29%**
DATA	**RISK:**	**58%**

The review process identified questions for the developer to consider to help identify possible areas for development to reduce potential risk, and increase value. Some areas have an inherent risk associated with functionality, but which may be reduced by looking at the other areas highlighted as follows;

If the user is required to enter data to access all areas of the app, this carries a base amount of inherent risk to user data, the degree of which can be mitigated by the developer through various means of good practice.

Is it necessary to collect 'sensitive' data as defined by the Data Protection Act 1998.
Is it necessary for the app to store any information that is personally identifiable?
Value may be added with apps that automatically attempt to collect data from or share user data with other apps, however significant data risks exist here which should be carefully considered.
Value may be added with apps that automatically collect user data from externally connected devices, however it is also important to carefully consider the associated data risk.

Value may be added with apps that automatically collect user data from measurement capability built into the device (eg location, motion etc), however it is also important ot carefully consider the associated data risks.

Is there functionality within the app to allow the user to set their own individual preferred privacy controls?

Does the Data Privacy Policy, or Statement, provide detail about where the data collected by the app will be stored (i.e. on the app or in an external data warehouse, cloud server etc.)?
Does the Data Privacy Policy, or Statement, state whether personal data is stored using recognised secure data storage technologies?
Does the Data Privacy Policy, or Statement, state that no data will be shared with other parties without explicit user consent?
Does the Data Privacy Policy, or Statement, state that all personally identifiable data will be encrypted in transit between the device and any developer host storage? (eg using FTP protocol)

Does the Data Privacy Policy, or Statement, contain a process for managing Data confidentiality breaches?

Does the Data Privacy Policy, or Statement, state its compliance with recognised International Data Management Standards (ISO, BSI etc.)?

Does the Data Privacy Policy, or Statement, state its compliance with recognised NHS Data Standards (e.g. NHS IG toolkit)?
Value may be added with apps that contain features allowing the app to share data with with other users (e.g. Clinician / Carer / Family Member / Forums / Buddies), however it important to carefully consider the associated data risks.
Is there functionality within the app to allow the user to set their preferences for sharing the data collected within the app for other purposes (clinical research etc)?
Value may be added where the app sends push notifications.
Value may be added where the app sends email notifications.

REVIEW RESULTS: DESIGN AND TESTING — PAIN TOOLKIT

THE RESULTS OF THE DESIGN AND TESTING SECTION ASSESSMENT ON THE APP PAIN TOOLKIT VERSION 2.1.3 FOR ANDROID, CARRIED OUT 05.08.2016, IS AS FOLLOWS

Design and Testing looks at evidence within the app that the developer has followed good practice during development, compliance with established standards and compatibility with other health 'kit' applications. The Design and Testing scores contribute to 10% of the overall Risk Score, and 15 % of the overall Value Score.

DESIGN AND TESTING	**VALUE:**	**36%**
DESIGN AND TESTING	**RISK:**	**0%**

The review process identified questions for the developer to consider to help identify possible areas for development to reduce potential risk, and increase value. Some areas have an inherent risk associated with functionality, but which may be reduced by looking at the other areas highlighted as follows;

Is there a statement within the app or store about user feedback during design and/or development?
Is there a statement either in the app or store about user involvement in testing?
Is there a statement within the App outlining compliance with any currently recognised App Design Standards (eg W3C, BSI, ISO etc)
Has the app been designed to integrate its Data with Google Fit?
Has the App been designed to integrate its data with Microsoft Health Vault?

REVIEW RESULTS: CLINICAL ASSURANCE AND EFFICACY — PAIN TOOLKIT

THE RESULTS OF THE CLINICAL ASSURANCE AND EFFICACY ASSESSMENT ON THE APP PAIN TOOLKIT VERSION 2.1.3 FOR ANDROID, CARRIED OUT 05.08.2016, IS AS FOLLOWS

Clinical Assurance and Efficacy focuses on evidence within the App that the guidance, information and any recommendations within the app have been verified or where appropriate tested to ensure guidance provided is valid, beneficial and subject to review. The Clinical Assurance and Efficacy scores contribute to 30% of the overall Risk Score, and 15 % of the overall Value Score.

DESIGN AND TESTING	**VALUE:**	**50%**
DESIGN AND TESTING	**RISK:**	**55%**

The review process identified questions for the developer to consider to help identify possible areas for development to reduce potential risk, and increase value. Some areas have an inherent risk associated with functionality, but which may be reduced by looking at the other areas highlighted as follows;

There may be both added value, and reduced risk where the app demonstrates evidence that it has been through clinical trial and received a positive outcome?
There may be both added value, and reduced risk where the app states the developers commitment to how frequently any advice or guidance will be reviewed?
Value may be added where the app identifies a list of review or accrediting bodies or individuals?

REVIEW RESULTS: USER EXPERIENCE	PAIN TOOLKIT

THE RESULTS OF THE CLINICAL ASSURANCE AND EFFICACY ASSESSMENT ON THE APP PAIN TOOLKIT VERSION 2.1.3 FOR ANDROID, CARRIED OUT 05.08.2016, IS AS FOLLOWS

User Experience considers the interface, cost, enhanced functionality to aid accessibility to certain user groups, functions that can improve the likelihood of succesful outcomes, and bugs. The User Experience section scores contribute to 20% of the overall Risk Score, and 35 % of the overall Value Score.

DESIGN AND TESTING	**VALUE:**	**56%**
DESIGN AND TESTING	**RISK:**	**0%**

The review process identified questions for the developer to consider to help identify possible areas for development to reduce potential risk, and increase value. Some areas have an inherent risk associated with functionality, but which may be reduced by looking at the other areas highlighted as follows;

Can the user change the font type within the App or does the app respond to font preferences in the device?

Can the user change the font colours?
Can the user change the presentation theme?
Does the app provide support options for users with poor sight?
Does the app provide support options for users with hearing difficulty?
Does the app contain a HOME function button to aid navigation?
Does the app contain a SEARCH function to aid information finding?
There may be added value if the app gives opportunities to link with other users (buddying, forums or group education).
There may be added value if the app sets goals for the user.
There may be added value if the app allows the user to set goals for themselves.

THE RESULTS OF THE USER FEEDBACK ASSESSMENT ON THE APP PAIN TOOLKIT VERSION 2.1.3 FOR ANDROID, CARRIED OUT 05.08.2016, IS AS FOLLOWS

User Feedback uses a special mathematical function which considers not only the average user rating reported at time of download, but also the number of downloads and the number of user reviews. This helps to reduce uncertainty and bias, and ensure scoring is more reliable. Because of the large potential variances in the data, we also use logarithms in our logic to help reward newer apps with less downloads and emerging success, while still able to differentiate those with higher downloads and reviews where they are more established and the feedback is more reliable.
The scoring method uses a neutral starting point – an app with no downloads or ratings automatically starts with a score of 10 out of 20, so as not to discriminate against what might be perfectly good, new apps. Scores are then enhanced where an app has demonstrated higher download figures resulting in a good number of positive ratings, or reduced where there are a higher number of downloads resulting in large numbers of poor user ratings. A reliable and 'ideal' range has been set such that full scores can be achieved when an app reflects 50,000 downloads or more, with 10% or more resulting in reviews which give an average user rating of 5 out of 5.
Please note. For Appstore we use an approximation for the number of downloads based on typical statistics and the number of reviews. The User Feedback section contributes to 20 % of the overall Value Score.

At the time of review, the contributing factors available from GOOGLE PLAY which contributed to this user feedback scoring section were;

Downloads (of current version)	1,000 - 5,000	No. of user reviews (of current version)	9
		Average user review score (of current version)	2.2 out of 5

USER FEEDBACK SCORE	**10 / 20**

SUMMARY

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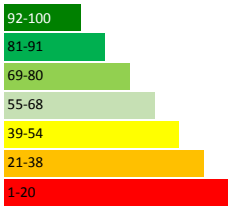

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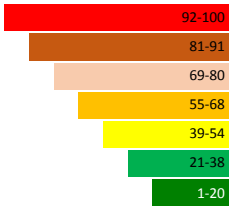

Functions:

✓ **Education and Information**

✓ **Self Monitoring**

✓ **Professional Guidance**

SUGGESTED ACTIONS

Its up to you to decide whether you want to improve your app using some or all of the guidance offered within this report. ORCHA currently has thousands of professional users looking for the best of apps like yours to recommend to patients in the vast health and care environment, along with thousands of registered users that use ORCHA as a trusted resource to find validated and reviewed apps they can trust. Optimising your score and making sure your app sits in a good position on the ORCHA portals gives your app enhanced visibility to a potential audience of 40 Million Smart Device Users.

Improving your score can often be a case of a minor update to dot the I's and cross the T's, through to gaining clinical validation of the great benefits your App offers, or engaging ORCHA consulting to help get the best out of the work you've already put into it.

Either way, we encourage improving apps for the best outcomes for users, professionals and developers. Once you've updated your app, you'll want to make sure that your efforts don't go unnoticed. A new version of your app will be picked up by our automated monitoring system, and providing it continues to meet our minimum criteria, it will be enterred into our review queue for an updatedd review. Alternatively to make sure you get immediately visibility of your efforts, you can request an EXPRESS REVIEW for updates or new apps by registering and logging into your 'MyORCHA' home page:

app.orcha.co.uk/MyOrcha/

APPENDIX: NOTES ON STANDARDS

ORCHA value and risk assessment is derived from a number of standards and guidelines, which were used to develop their review process. These are discussed below;

DATA

There are a number of important standards and legislation relating to information security, data protection, data and information sharing. These inform some of the questions in the Quality and Safety theme:

Freedom of Information Act 2000 http://www.legislation.gov.uk/ukpga/2000/36/contents

Data Protection Act 1998 - Principle s 3, 4, 5, 6, 7 & 8. See ICO Summary of Data Protection Principles
https://ico.org.uk/for-organisations/guide-to-data-protection/data-protection-principles/

ISO/IEC 27001 - Information security management Data protection Act
DD ISO TS 25237, Health informatics – Pseudonymization
GREAT BRITAIN. The Data Protection Act 1998. London: The Stationery Office.
GREAT BRITAIN. The Consumer Protection Act 1987. London: The Stationery Office.
SNOMED Clinical terms. Available from: http://ihtsdo.org/snomed-ct/

HEALTH & SOCIAL CARE INFORMATION CENTRE. UK Terminology Centre (UKTC). Available from:
http://systems.hscic.gov.uk/data/uktc.
HEALTH & SOCIAL CARE INFORMATION CENTRE. HSCIC interoperability toolkit (ITK). Available from:
http://systems.hscic.gov.uk/interop/background/itk/faqs
National Information Board Interoperability guidance
http://www.isb.nhs.uk/about/publications/interoperability.pdf
See also standards for risk - BS EN ISO 14971, Medical devices – Application of risk management to medical devices. This standard was used in the design of the ORCHA risk methodology.
And PAS 277:2015: Health and wellness apps – Quality criteria across the life cycle – Code of practice and the Medical Devices Directive (CE mark for medical devices): Council Directive 93/42/EEC relevant to all sections

QUALITY AND SAFETY

This important area is where most key standards occur. The following standards are relevant:

THE MEDICAL DEVICES DIRECTIVE (CE MARK FOR MEDICAL DEVICES): COUNCIL DIRECTIVE 93/42/EEC.

ORCHA uses this standard to indicate to developers whether an app may need to be CE marked. We have also used it to inform us on what we think is best practice in design, development, risk management and post-launch monitoring.

CE marking is regulated by the Medicines and Healthcare Regulatory Authority (MHRA) in the UK. Companies need to engage one of the accredited 'Notified Bodies' to do assessment and auditing. ORCHA is not a Notified Body to assess and advise on CE marking, but we do have links with BSI who can provide this service.

This directive was originally developed for hardware medical devices (including things like X-Ray or MRI machines, prosthetic limbs etc). Over the years, software has been incorporated and there are implications for apps.

Relevant links

The directive text is at http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices/index_en.htm

MHRA GUIDANCE ON CE MARKING FOR SOFTWARE AND APPS

https://www.gov.uk/government/publications/medical-devices-software-applications-apps

Related to the Medical Devices Directive are some other important standards. These are discussed very fully and clearly within the recently produced advisory note PAS 277:2015: Health and wellness apps – Quality criteria across the life cycle – Code of practice, which includes full discussion of the key guidelines. PAS277 can be downloaded free from http://shop.bsigroup.com/forms/PASs/PAS-2772015/ .

If you wish to get a CE mark for your app, you need to demonstrate that there are quality management processes in place in your company. One relevant standard is ISO13485 – Medical Devices: Quality Management Systems: Requirements for Regulatory Purposes. This is a version of ISO9000 applied specifically to medical devices. The other one to consider is BS ISO/IEC 90003, Software engineering – Guidelines for the application of ISO 9001:2000 to computer software. This has ongoing operational implications – the company must maintain its certification through annual audits by a Notified Body.

BS EN ISO 14971, Medical devices – Application of risk management to medical devices. This standard was used in the design of the ORCHA risk methodology.

There are a number of important standards and legislation relating to information security, data protection, data and information sharing. These inform some of the questions in the Quality and Safety theme.

ISO/IEC 27001 - Information security management Data protection Act

DD ISO TS 25237, Health informatics – Pseudonymization

GREAT BRITAIN. The Data Protection Act 1998. London: The Stationery Office.

GREAT BRITAIN. The Consumer Protection Act 1987. London: The Stationery Office.

SNOMED Clinical terms. Available from: http://ihtsdo.org/snomed-ct/

HEALTH & SOCIAL CARE INFORMATION CENTRE. UK Terminology Centre (UKTC). Available from: http://systems.hscic.gov.uk/data/uktc.

HEALTH & SOCIAL CARE INFORMATION CENTRE. HSCIC interoperability toolkit (ITK). Available from: http://systems.hscic.gov.uk/interop/background/itk/faqs

National Information Board Interoperability guidance http://www.isb.nhs.uk/about/publications/interoperability.pdf

USER EXPERIENCE

ORCHA evaluates user experience based on best practice from a range of sources. Not only should an app use best practice, but it is also important that a statement is made to this effect (in Terms & Conditions, About or somewhere else on the app).

The most useful guidance is that provided by Google Play and the Apple Store guidelines. As ORCHA only reviews apps that have been approved through these two app stores, developers are likely to already be familiar with these sources, but we would recommend careful scrutiny before publishing.

OTHER USEFUL STANDARDS

BS EN 62366:2008, Medical devices – Application of usability engineering to medical devices

Web content accessibility guidelines http://www.w3.org/WAI/intro/wcag

ENDORSEMENTS

ORCHA proudly works with

PRIVACY AND COPYRIGHT POLICY

LEGAL STATEMENT

All information given in the ORCHA register, reports, website or other media is for guidance only based on openly available information on the app detailed at the time of review and based on the reviewer's opinion and standard review regime in place. Users, developers and professionals should use the information only as part of their own assessment as to the relevance and suitability of the app and take necessary caution to ensure that the details are correct and that the app is suitable for their purposes, particularly where multiple or complex conditions do or might exist and where medical advice is advisory. For full terms and conditions of use please go to: http://app.orcha.co.uk/Home/LegalStatement