

## **ORCHA Review Process**

#### **INTRODUCTION:**

WHO ARE ORCHA AND WHY ARE THEIR REVIEWS 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 is heling 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 helping 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 that apps achieve, as well as identifying areas of potential risk which we have highlighted. We also help developers identify areas for improvement to help increase the overall Value of their 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.

#### 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, and efficiencies. 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, visibility and associated uptake.
- A unique online community providing access to resources, standards, and protocols for wider interoperability and integration.

#### I'M A MEDICAL PROFESSIONAL or HEALTH & CARE PROVIDER:

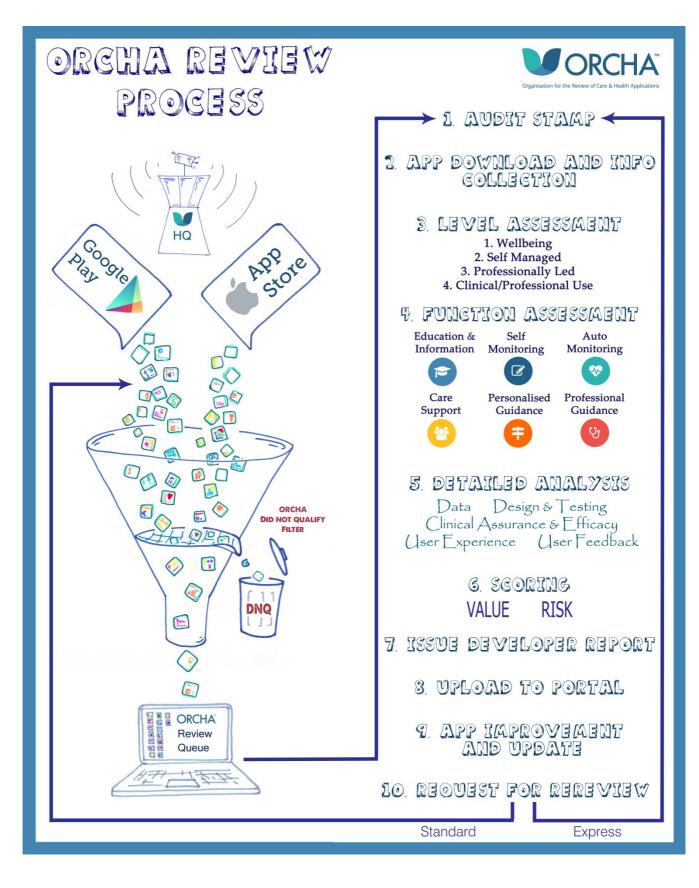
ORCHA offers a streamlined and easy way of finding great apps that you can more confidently recommend to your patients or population. These apps can help manage, monitor or report on their specific health conditions or goals, which can in turn assist you in defining and delivering the most efficient and appropriate treatment plan or level of support. If used with a large health population, there is potential for apps to show measurable impact on patient outcomes and efficiencies. 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. It might also help you consider important factors around apps that you may not have even considered, such as how the developer uses your personal and health data, whether the content of the app has been verified by a relevant specialist and the commitment of the developer to fix bugs and keep the app up to date.

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.



#### HOW DOES THE ORCHA REVIEW PROCESS WORK:

#### MONITORING THE APP MARKET PLACE

ORCHA constantly monitors the app market place looking for 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 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 or in fields of high demand, 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 etc - again for full traceability.

The reviewer then familiarises themselves with the app, gathering information largely from the app itself, but which may also include other freely available information in the public domain such as the developers website, Google Play, I-Tunes, or other download sources, and MyHealthApps portal. This information is used in answering a standard set of questions that form the comprehensive 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 the developer states data is stored securely, we do not undertake tests to prove whether this statement is correct). The app could be reviewed on 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 either 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 clearly the developer states how reliable and proven the content, advice and operation of the app are, and how safe the users data and user is 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 advice or guidance 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 could be higher. It doesn't necessarily mean that it hasn't been clinically verified, and similarly in the absence of clinical trial and side effect data contained with a medicine, users should be more cautious of risks and seek appropriate advice before using it. As such, the risk score should be used as an indication of 'possible' risk and not necessarily the likelihood of risks occurring. As with medicines, Users and Professionals should always satisfy themselves that risks associated with any app are acceptable to them and their specific needs before use.

#### 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.

- 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, if during our review we identify certain key indicators that the app may need to be CE marked, we will endeavour to highlight this and suggest taking further specialist advice.

We display the results of the level assessment on our web and professional platforms, and in the appreview certificate.

## **FUNCTION ASSESSMENT**

This assesses the main functional capabilities of the app from the following main functions;



# 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 goals or issues. 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 goal 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 entered 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. Some apps that offer a way of transferring user specific information or data to a clinician or NHS Patient Record System, might also reflect this function.

We display the results of the level assessment on our web and professional platforms, and in the appreview certificate.

#### **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.

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.

#### **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.

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.

### 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 more confidently count on the content. 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 advice and 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.

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

## **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.

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.

# **SUGGESTED ACTIONS**

If you're a medical professional, contact us for an informal discussion of the great work we're already doing with organisations just like yours, and how we can support and enhance the services you already offer.

For developers, we offer detailed guidance in our report to allow you to decide whether to make improvements to the app using some or all of the guidance offered. ORCHA currently has thousands of professional users looking for the best apps 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 the app score and making sure the app sits in a good position on the ORCHA portals gives the app enhanced quality, value, safety and visibility to a potential audience of 40 Million Smart Device Users.

Improving the 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 the App could offer.

Either way, ORCHA encourages improving apps for the best outcomes for users, professionals and developers. Once an app is updated, our automated scraper will identify an update and assuming it still qualifies, will add it to the review queue. Alternatively, developers or professionals can request an express review via registration and the request process on their home page.

Still got questions – contact ORCHA for an informal one to one discussion on the process and tools that could help you.

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We would like to thank the following people for their valued time and feedback on the ORCHA Review Process as described above, and for the extensive positive acclaim received;



Richard Harding, of the Innovation Agency, Academic Health Science Network for the North West Coast.



Veronica Southern, of Blackpool Teaching Hospitals, NHS Foundation Trust.



Nick Allen MCIPS, Industry Procurement Adviser at Trustech the North West NHS Innovation Service.



Paul Finch, Business Relationship Manager at TSA – The Voice of TEC (Technology Enabled Care).



Dr Sanjeev Maharaj, Elizabeth Street Surgery.



Simon Leigh, Research Fellow in Health Economics, University of Liverpool.