



British Cardiovascular Society

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The Future of Cardiology A Paper Produced by the British Cardiovascular Society Working Group on The Future of Cardiology August 2020

'The Voice of UK Cardiology'

Affiliated Societies

Arrhythmia Alliance (AA)

Association for Inherited Cardiac Conditions (AICC)

British and Irish Hypertension Society (BIHS)

British Association for Cardiovascular Prevention and Rehabilitation (BACPR)

British Association for Nursing in Cardiovascular Care (BANCC)

British Atherosclerosis Society (BAS)

British Cardio-Oncology Society (BCOS)

British Cardiovascular Intervention Society (BCIS)

British Congenital Cardiac Association (BCCA)

British Heart Rhythm Society (BHRS)

British Heart Valve Society (BHVS)

British Junior Cardiologists' Association (BJCA)

British Nuclear Cardiology Society (BNCS)

British Society for Cardiovascular Imaging (BSCI)

British Society for Cardiovascular Research (BSCR)

British Society for Heart Failure (BSH)

British Society of Cardiovascular Magnetic Resonance (BSCMR)

British Society of Echocardiography (BSE)

Cardiovascular Care Partnership (UK) (CCPUK)

Society for Cardiological Science and Technology (SCST)

UK Maternal Cardiology Society (UKMCS)

1.0 Background

The COVID pandemic has presented the NHS with a unique set of challenges and forced a managerial, financial and clinical focus on the rapid re-purposing of large sectors of secondary care to accommodate an anticipated deluge of patient with severe respiratory illness. Immensely disruptive as this has been it has also allowed a speed of decision making, adaption, adoption and transformation that has never previously been possible in the NHS. In the space of a few weeks primary care and outpatient secondary care have moved to a largely virtual service with telephone consultation the norm and video consultation developed or developing fast. MDTs and other meetings requiring multiple participants are conducted via Microsoft Teams or other digital platforms and many trusts have provided their clinical staff with the means to work effectively from home. Behind the scenes some of the blocks which prevented effective data sharing within the NHS have to a large extent been removed and the power that this has unleashed is evident from the nationwide analysis of diabetes as a risk factor for adverse outcomes with COVID-19.

The pandemic has also led to the temporary shutdown of non-emergency primary, secondary and tertiary care services and the suspension of the identification and surveillance of chronic conditions in primary care. Furthermore, the footfall of patients presenting to primary care fell dramatically resulting in a delay in identification of serious or significant disease, reduction in out-patient referrals and primary care generated hospital admissions for non-COVID related illness. There was also a significant reduction in patients self-presenting to emergency departments. At the time of publication, outpatient referrals are significantly lower than pre-pandemic levels. We are now entering a phase of restoration as these services gradually restart but it is clear that the “new normal” will be significantly different from before the pandemic and will take time to evolve. Social distancing and the need to segregate COVID free facilities from those used to treat COVID positive patients mean that practice will need to adapt and evolve and the productivity of diagnostics including echocardiography lists, catheter lab sessions and face to face clinics will be substantially lower than previously, at least for the duration of the pandemic.

2019 saw the publication of two extremely important documents, the [Topol Report](#) on equipping the NHS workforce for the digital future and the [NHS Long Term Plan](#). Many of the changes that have been put into place during the pandemic are already present as recommendations in these documents. The Getting It Right First Time, GIRFT, report on cardiology will be published later this year. The overriding theme of the report will be that cardiology services must be delivered on the basis of functional networks, and this too has been a major theme emerging from the COVID experience, especially in those areas worst affected.

It is essential that we are able to embed the positive changes emerging from the COVID crisis into routine practice to achieve the goals set out in the Topol Report, the Long Term Plan and the forthcoming GIRFT report. Equally it is important that we develop services that will be resilient to any future pandemic peaks. To facilitate this, the BCS set up a Working Group on the Future of Cardiology with the brief of capturing service developments that have been forced on us by the crisis which should be adopted across the NHS in a new model of cardiovascular care. We are grateful to BCS members who have provided examples of innovation within their units.

2.0 Principles of Service Delivery

1. Cardiology services should be delivered on the basis of networks or systems of care that are fully and seamlessly integrated from community to tertiary care
2. Systems of care should be designed with a patient-centric approach with an emphasis on the use of technology to facilitate diagnostics, monitoring and communication at all levels
3. Systems of care should be value based, outcome focused learning organisations. No patient should be disadvantaged and the inequality gap should be narrowed and not widened
4. Primary / community care identification, coding and surveillance of cardiovascular patients should be standardised and improved
5. Virtual consultation should become the norm in both primary and secondary care for those who do not require a face to face attendance
6. Patient visits to hospital should occur only when necessary for patient care and should occur at the right time in the right environment with the right people present
7. As a default, diagnostics should be delivered in an integrated community diagnostic hub run by secondary care in partnership with the primary care network and by staff rotating through secondary and / or tertiary care
8. All patient pathways should be streamlined and agile to avoid duplicate investigations and referrals and take into account patients with multiple co-morbidities
9. The system needs to be resilient to further outbreaks of COVID or other threats and access to all services needs to be protected

3.0 Referrals from primary care

In many areas there is a lack of a ready means for primary care clinicians to contact secondary care for advice about patients so that referral for an outpatient appointment has become the default. A lack of clear protocols mean that inappropriate tests may be requested or patients under investigated. A lack of robust triage of referrals means that patients may wait a long time for an appointment at an inappropriate clinic and then undergo a further wait for investigations. Many problems can be dealt with via Advice and Guidance or by similar mechanisms of direct virtual contact between primary and secondary care without the need for an appointment. Potential interactions between primary and secondary care are summarised in figure 1.

To resolve these issues all referrals to a cardiology service should be made electronically through a single triage portal informed by agreed local protocols for advice on referrals, arrangement of investigations and management advice of common conditions. Where investigations are requested directly from primary care as part of these pathways, results should be accompanied by a clinically relevant report that provides advice on further management. All referrals should be triaged and allocated to a pathway. There are a number of potential models of triage but it is essential that those performing this role are appropriately job planned to do so and are able to request appropriate investigations. Triage can be performed by a secondary care clinician, either a cardiologist, a specialist nurse, or a GPWSI. Whilst the precise mechanism can vary the aim to is to reach a definitive identification of disease, appropriate coding and safe management plans in the most efficient way with

the minimal number of hospital attendances. It is essential that all communications between clinicians become part of a mutually accessible electronic record of care.

The output of the triaging process could take a number of forms:

- a. Advice in an auditable and electronic format to the GP without the need for further consultation or investigations.
- b. Advice in an auditable and electronic format to the GP following triage service initiated investigations, delivered via a community diagnostic hub, without the need for consultation
- c. Virtual consultation with the GP or other HCP regarding the patient when more information and primary/secondary care discussion is required either with or without preceding community diagnostic hub delivered investigations.
- d. Virtual or face to face consultation with the patient, graded by urgency and need for investigations.

4.0 Maximising the Potential of Virtual Clinics and Remote Follow Up

Virtual consultations are a mainstay of the redesign of cardiology out-patients. The underlying principle is that physical attendance at clinics is minimised without compromising the quality of care and patient experience. Phone clinics are technically less complex and may be suitable for patients who are less comfortable with use of technology but video consultations offer the advantage of mutual visualisation of the patient and clinician, the use of images in explanations of procedures and potentially the recording of consent. They also facilitate the participation of family members or other patient advocates and open the possibility of multi-disciplinary consultations without the need for all clinicians to physically be in the same location. However, it is important to recognise that neither phone nor video clinics shorten the time taken to interact with patients and may potentially increase it as may appropriate triage. This must be recognised in job planning.

A good example is device follow up clinics. Patients with implanted devices are increasingly being followed up remotely. Although there is an added cost for this capability, for bradycardia devices at least, the advantages outweigh this cost and remote device follow-up should become the default to minimise the requirement for travel and face to face attendance.

Maximum use should be made of the skills of the wider heart team including specialist nurses, pharmacists and cardiac physiologists running virtual and face to face clinics. There are significant national shortages of key staff, particularly cardiac physiologists which will have an impact on service provision in some areas.

Virtual consultations can be scheduled as a formal outpatient appointment arranged, where necessary, around the need for investigations such as ECG, echo and other non-invasive investigations which may be required or be part of an agreed symptom based pathway.

Virtual consultations should have a structured format with patients advised in advance of the structure, including the need to ensure certain information is readily available such their past medical history, a list of the patient's current medication and any known allergies. Ideally there should be electronic access to the full primary care record.

Some patients, especially those who are not working, may be willing to have an appointment within a given timeframe without a specific slot being allocated such that they can be contacted when a clinician has time. This would work best with those triaged as suitable for a pooled, team based waiting list.

For a number of patients, there will still be the need to have a face to face consultation so that essential clinical examination can be performed. Where required, face to face clinics will need to be conducted in an environment that minimises the possibility of COVID [or other infectious agents] transmission. The number requiring face to face consultation will need to be determined but is likely to be relatively small. These will include:

1. Heart failure patients, especially complex patients or some new referrals. Once a treatment plan has been initiated these patients may be able to have virtual follow up and integration into the community heart failure nurse service or primary care to minimise the need for future face to face consultations. Note, that it would be recommended, where possible, that any face to face consultation be scheduled at the integrated community diagnostic hub.
2. Complex valve disease patients where clinical examination is required in addition to non-invasive investigation. N.B. It may still be possible in future, to undertake such examination remotely via the integrated community diagnostic hubs, using electronic stethoscopes with digital transfer.
3. Complex congenital heart disease
4. Additional complex patients as defined on an individual basis.

Virtual consultations also allow the flexibility of staff to work from home, in existing hospital facilities or another suitable environment plus the flexibility to perform consultations outside of conventional clinic hours and with housebound patients and those without transport or in care homes. Most clinicians no longer have their own private office and so purpose built facilities will still be necessary to support both privacy for virtual consultations and for the patients who still require to be seen on a face to face basis.

There will be a requirement for training of staff to utilise the digital platforms for virtual consultations and also a need to ensure that supervision and training of junior staff is integrated into the system to comply with the recommendations of the cardiology training curriculum.

For a small number of patients, attendance for investigations at the community diagnostic hub, or as a consequence of the virtual consultation will result in a recommendation for immediate hospital admission e.g. left atrial myxoma identified at echocardiography, or severe, uncontrolled heart failure identified during virtual consultation. This highlights not only the need to ensure rapid image sharing and review of images from the community diagnostic hub but also clear pathways to arrange urgent/immediate hospital admission where necessary.

5.0 Availability of Records

Lack of access to records from other hospitals and from primary care is a frequent source of delay in the management of complex patients and can lead to treatment

errors and to treatment against patients previously expressed wishes. Availability of all patient data including ECGs, ambulatory recordings, non-invasive imaging and procedural images such as angiography is an essential part of a comprehensive electronic record and will greatly facilitate management of patients across institutions.

6.0 Integrated Prescribing with Primary Care

Many patients who have outpatient consultations have recommendations for alteration of medication, including new medication requests or adjustment of existing medication. These are actioned via a request to the GP either by letter or, where more urgent, by paper request via the patient. In a small number of patients, where very urgent medication is required this can be prescribed and dispensed at the hospital appointment. Redesign of outpatient services allow opportunities for more integrated electronic prescribing with primary care. Whereas non urgent prescription changes can still be achieved via electronic communication with primary care, urgent prescriptions may need to be addressed by hospital based electronic prescribing linked to home delivery of dispensed medication or integration with primary care systems. This is not specific to redesign of cardiology outpatients but should be considered as part of whole system service redesign.

7.0 Cardiac rehabilitation

Traditional cardiac rehabilitation has been severely curtailed by the pandemic as many of the patients most likely to benefit from rehabilitation are those at highest risk from COVID. This has led to the rapid development of home based rehabilitation facilitated by the use of social media, smartphone apps and wearable activity trackers. Some services are also running remote group sessions. Western Health and Social Care in Northern Ireland have transformed their programme by incorporating:

- Multidisciplinary assessments by video
- Weekly virtual interactive group sessions
- On-line educational videos
- Remote monitoring using wearable activity monitors
- Optimising medications and medical risk factor management through liaison with primary care

<https://westerntrust.hscni.net/service/ourheartsourminds/virtual-programme/>

Virtual rehabilitation also opens new possibilities for those for whom English is not a first language

8.0 Networks / Systems of Care and Community Diagnostic Hubs

Traditionally most diagnostic investigations in cardiology have been provided in secondary care with a substantial number of GP practices having no direct access to even a 12 lead ECG. Where secondary care provision has been successful it has enabled one stop clinics but this still requires hospital attendance and for those patients requiring for instance both echocardiography and Holter monitoring has usually required multiple visits. Some trusts had managed to place a proportion of their diagnostic capability within the community pre-COVID but the drive to provide off-site cardiac physiology investigations during the pandemic has accelerated this process and led to the proposal to develop community diagnostic hubs.

The location and size of community diagnostic hubs will be determined locally based on population need and linkages to other services, especially respiratory medicine and stroke where there are important synergies, but they must be fixed locations of sufficient scale to support a range of services.

Principles

1. Services within a community hub will need to be delivered by staff linked to, and often rotating from secondary care services. This will allow
 - a. Governance
 - b. Quality Assurance
 - c. Training
 - d. Integration
2. Fast, secure connectivity to hospital servers to ensure rapid transfer of investigations, including images and reports for clinic review and integration into the patient record. Upload should be automatic requiring no additional steps
3. For most adult cardiology patients the community diagnostic hubs will provide investigations based on predefined symptom referral pathways such as breathlessness, palpitations and syncope or via medical staff grading of referrals. This will allow patients to have the following investigations
 - a. Blood tests including NT-proBNP
 - b. Digital 12 lead ECG
 - c. BP
 - d. Oxygen saturation
 - e. Spirometry and pulmonary function tests (once possible due to infection risk)
 - f. Chest x-ray
 - g. Echocardiography
 - h. Ambulatory rhythm monitoring – by a combination of Holter monitoring and ‘patch’ devices
 - i. Ambulatory BP monitoring
 - j. Device monitoring for those patients in whom remote monitoring is not practical
 - k. Potentially, insertable cardiac monitors
4. Depending on co-location with other specialties it may also be possible in some instances to incorporate CT scanning including CTCA and CT-FFR into community diagnostic hubs
5. Community diagnostic hubs should also include facilities for both video and face to face consultation.

9.0 Secondary and Tertiary Care Activity – Resilience and Systems of Care

It is impossible to know how long the constraints of social distancing will be present but secondary and tertiary care services need to be organised to be resilient to ongoing infection risk, second peaks of COVID and new threats. Services need to be planned across networks or systems of care and this is aligned with the main theme of the GIRFT report.

Six principles should apply:

- a. Services should be organised to minimise the frequency and duration of attendance at hospital sites. So far as possible diagnostics and pre-admission

clinics should be performed in community settings. Where face to face clinics are essential these should be organised such that all relevant investigations can be performed beforehand or on the same day. Where possible outpatient CT coronary angiography +/- CT-FFR should be utilised in place of invasive angiography for patients on valve disease pathways. Elective admissions should take place on the day of the procedure unless precluded by travelling distance and early discharge planned and facilitated.

- b. For the foreseeable future services need to be organised such that there is separation between acutely admitted patients who may be infected and those admitted for elective procedures who have been screened for infection and who should be admitted only to a 'green zone'. This may require designating some sites or sections of sites as emergency only and others as elective only. The traditional separation of non-day-case elective patients into surgical and cardiology wards may need to be abandoned in favour of combined 'green' wards with separate joint facilities for inter hospital transfers or other patients who have not been able to isolate prior to admission.
- c. Except in periods of extreme crisis all hospitals admitting cardiology patients must maintain access to a coronary care unit or equivalent high dependency unit or must make clear arrangements for the immediate transfer of all acute patients requiring monitoring or specialist treatment to an alternative site.
- d. Trusts will need to further develop agile collaborative working such that facilities such as catheter labs, CT and CMR scanners are fully utilised and can remain operational during future crises. This may require redistribution or consolidation of activity across sites. There is a strong case for 'passporting' such that clinical staff are able to work across secondary / tertiary care as well as in community diagnostic hubs. Similar arrangements may be required to ensure 24/7 consultant cardiologist cover at all hospitals admitting acute patients, 24/7 access to urgent echocardiography and temporary pacing plus 7/7 access to permanent pacing.
- e. Clinicians within heart teams should not routinely be responsible for the management of general medical patients if this is not part of their pre-COVID job plan. Their expertise should be directed towards the management of cardiac conditions where their skills are best utilised. The corollary is that cardiologists need to provide prompt senior decision making to support other services including acute medicine and critical care and this may require greater consultant input closer to the front door of the hospital. This will need to be factored in to job planning.
- f. Access to specialist tertiary services must be protected. This includes TAVI, electrophysiology, cardiac surgery and other specialist interventions as well as specialist outpatients that may require face to face appointments. Such protection will require planning on a regional basis to ensure that these services are not immediate casualties of a second peak and that cardiac surgical ICU beds, in particular, remain ring fenced.

10.0 Inter-hospital referrals

Inter-hospital referrals are frequently required in cardiology and can be time consuming as well as being performed on an informal and ad hoc basis with no robust audit trail. There are a number of systems: e.g.

<https://www.youtube.com/watch?v=APvgHwev4Js>

<https://www.referapatient.org/Home/Index>

that enable structured referrals that ensure accountability and an audit trail that becomes part of the patient record.

11.0 Virtual MDTs

The GIRFT cardiothoracic surgical report promoted the idea of virtual MDTs as a means both of ensuring that patients could be discussed without long waits for a weekly meeting and of enabling the participation of referring clinicians. A Joint Working Group of the BCS, BCIS, SCTS and ACTACC is currently drafting updated guidance for joint cardiology / surgical MDTs.

Virtual MDTs should now become the norm and there should be a mechanism for the formal discussion of urgent patients on a daily basis, along with disease based structured MDTs such as aortic valve disease, mitral / tricuspid valve disease, endocarditis, revascularisation, heart failure and device implantation.

Virtual MDTs can provide a potential mechanism for patient involvement, possibly with pre-recorded videos of patients as part of the assessment process. Where relevant, they also allow the involvement of primary care and of multiple specialities, even if not co-located, for instance for an ICC MDT.

There is also an opportunity to use the ability to perform regular virtual MDTs to facilitate the redesign of disease specific patient pathways within a cardiology network. This will require a number of steps:

- Clear referral pathways from primary to secondary care coupled with ongoing education
- Structured assessment and surveillance by / overseen by secondary care clinicians
- Clear pathways for onward referral to a single common point of entry to a relevant disease specific network MDT for consideration of intervention
- Clear communication across all stages of the pathway
- Systematic review of outcomes

All of these steps will require the integration of patient records outlined elsewhere in this document.

12.0 Education

Cardiology education has been transformed by COVID. The principal scientific meetings have all been cancelled or postponed and in their place a multitude of initiatives have been developed. The programme of Zoom based webcasts on BJCA-TV produced initially by London deanery specialist registrars has been of very high

quality and has achieved an international audience. Web based education is more economical, more accessible and more equitable than attendance at fixed meetings. It allows registrants to view content in their own time and for repeat viewing as required. It also facilitates multidisciplinary involvement – for instance joint cardio-metabolic-renal education on the management of diabetes in cardiovascular patients. For many aspects of teaching and training it will become the norm.

Some essential elements of training, such as hands on simulation, cannot be delivered on-line and there will still be a place for physical scientific and educational meetings which also provide valuable networking opportunities. It is likely that fixed meetings will in future be hybrid with fewer on-site attendees and all appropriate material available on line. Options for a virtual conference experience are already available and are likely to develop rapidly.

Although on line content will be in principle be accessible at all times it is also important that clinical staff are able to interact with speakers and discussants and ‘virtual study leave’ will need to be built into training programmes and job plans to allow this to happen.

13.0 Patient Education

The rapid move to on line education provides opportunities for patient education. This could take the form of a programme of national education webinars provided jointly by professional societies and patient groups. Many patient groups, e.g. Arrhythmia Alliance, have already developed virtual patient education events and on line materials. Patients and carers could be provided with an electronic suite of information on diagnosis or discharge to facilitate compliance with medication and life style alterations, focussing in future on relevant apps.

14.0 Staff Well Being – An exemplar from Oxford

Staff well-being has not traditionally been high on the NHS agenda but has taken on a new focus during COVID. In March 2020 the Oxford Heart Centre Staff well-being Team was formed, the aim of which was to support staff through the anticipated personal, professional and moral stress of the pandemic and to do this by integrating well-being into our daily practice.

The Core Well-Being Team consists of a Cardiology Consultant, two Cardiac ICU nurses and three Clinical Psychologists. A network of well-being leads covering each domain of the Heart Centre (junior doctors, medical students, physiologists, cardiac intensivists and nursing representatives from each ward) were subsequently recruited and the core team meet with each of them on a regular basis to help address the specific well-being needs of their team.

The team aim to provide support which is both psychological and practical. Psychological support initiatives include twice-weekly webinars with the psychologists to discuss topical issues (e.g. sleep disturbance, managing uncertainty, parenting, death and dying); regular psychological support sessions for those medical students facilitating communication with relatives; and daily well-being huddles on Cardiac ICU in which staff perform a short mindfulness exercise and share examples of good practice they have observed on shift. Practical support initiatives include arranging

overnight rest facilities for junior doctors; introducing a 'buddy' system pairing junior with experienced nursing staff; and swapping the standard issue masking tape on which you write your name for colour-coded tape to make it easier to identify different staff groups in level 2 PPE.

Whilst some of the detail of the well-being service is COVID specific, the ethos is not and this is something that could be adopted for the longer term.

15.0 Registries, Audit and Research

One of the key achievements during the pandemic has been the removal of many of the obstructions that previously inhibited the flow and linkage of clinical data within the NHS. This has been essential in identifying the reduction in hospital activity that occurred as a consequence of the crisis and also to provide a measure of the pace of the restoration of services. This type of analysis requires close to real time data analysis. Cardiac teams have made considerable efforts to upload data to the NICOR registries on a weekly basis to facilitate this activity and it is something that should be continued post COVID with appropriate resourcing both of audit teams and of the infrastructure of the registries themselves. This will ensure that contemporaneous data is available to answer important clinical, quality improvement and quality assurance questions for a wide range of stakeholders including PCNs and ICPs.

From the research perspective the power of the linkage of routinely collected data and systematic registries has been exemplified by the analysis of diabetes as a risk factor for adverse outcomes with COVID

[https://www.thelancet.com/journals/landia/article/PIIS2213-8587\(20\)30272-2/fulltext](https://www.thelancet.com/journals/landia/article/PIIS2213-8587(20)30272-2/fulltext).

There will be an ongoing need for this type of analysis.

Therefore four requirements need to be met;

- Resourcing of hospital audit teams and IT infrastructure to allow weekly upload of registry data to NICOR
- Resourcing of NICOR to allow cleaning, validation and processing of submitted data
- Seamless data flow from NICOR to NHS digital and NHS England and NHS Improvement
- Ready access for researchers to linked datasets without repetitive information governance barriers

16.0 Apps and Related Technologies

A full discussion of Apps and their potential role in the future provision of cardiology services is given in Appendix 1.

17.0 Summary

Cardiology, like other specialties needs to assimilate and act on the lessons learned during the pandemic. This will require a restructuring of the way that we all work and

deliver clinical services and will be neither easy or comfortable at all times. This paper has focussed on adaptations that have already been introduced or are planned and it is evident that there will be further evolution of practice as the future landscape of healthcare in the UK emerges with more clarity. What does need emphasis is that while many of the changes we describe do not in themselves come with a substantial cost they will not be achieved without a substantial investment in IT infrastructure and diagnostic capacity. The NHS will also need to recognise that all clinical staff will in future need to organise their time in different ways and must build this into job planning and contract discussions.

Glossary

ACTACC	Association for Cardiothoracic Anaesthesia and Critical Care
AECG	Ambulatory ECG
BANCC	British Association for Nursing in Cardiovascular Care
BCIS	British Cardiovascular Interventions Society
BCS	British Cardiovascular Society
CCP-UK	Cardiovascular Care Partnership United Kingdom
COVID	Coronavirus disease
CT	computed tomography
CTCA	CT coronary angiography
CT-FFR	CT fractional flow reserve
GIRFT	Getting it Right First Time
ICC	Inherited cardiac conditions
ICP	Integrated care partnership
ICU	Intensive care
MDT	Multidisciplinary team
NICOR	National Institute for Cardiovascular Outcomes Research
NT-proBNP	N-terminal pro brain natriuretic peptide
OOH GP	Out of hours GP
PCN	Primary care network
RAAC	Rapid access arrhythmia clinic
RACPC	Rapid access chest pain clinic
RAHF	Rapid access heart failure
SCTS	Society of Cardiothoracic Surgeons
TAVI	Trans catheter aortic valve implant
TLOC	Transient loss on consciousness
TTE	Transthoracic echocardiogram

Working Group Members

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Appendix 1

Useful Apps for the Cardiology Team

Document for the Future of Cardiology Working Group, August 2020

Author: Sarah Hudson, Cardiology Registrar, Bristol Heart Institute and Topol NHS Digital Fellow.

- 1. Introduction**
- 2. App Regulation**
 - 2.1 Apps as medical devices**
 - 2.2 Classes of medical devices**
- 3. App Assessment**
- 4. The future of cardiology: Which apps could be recommended at present?**
- 5. Conclusions**

1. Introduction

For many, apps have become a part of everyday life. Research shows that 77% of the UK population owns a smartphone, and the average number of apps used per month is 34¹. This app use includes healthcare apps, with one survey suggesting 20% of smartphone users use health apps². Doctors also increasingly use apps to support and improve patient care. A 2015 Royal College of Physicians (RCP) survey showed 54% of doctors used apps to support their clinical work³ and a 2019 Austrian

paper quoted 74% of doctors using medial apps on a daily basis⁴. Internationally there is an increasing drive for doctors to ‘prescribe’ apps to help their patients. An example of this is the new Digital Care Act (Digitale-Versorgung-Gesetz) in Germany⁵. This Act means that in the future German statutory health insurances funds will reimburse the costs of health apps under certain conditions.

However, given the vast numbers of apps available and the non-robust nature of the current regulation system it is difficult for doctors to know what apps to use in their clinical work or which would be appropriate to recommend to patients. The Future of Cardiology working group identified this as an area for review, and this document aims to provide background information to help inform this. It covers background on app regulation, app assessment, suggested apps that may be useful to cardiologists in clinical work and suggested apps that may be ‘prescribed’ to patients.

2. App Regulation

2.1 Apps as Medical Devices

The regulation of healthcare/medical apps is poorly understood, partly because whether there is any statutory regulation involved depends on whether they are classed as medical device, and if they are classed as a medical device the degree of regulation depends upon the class of medical device they are classified as. This range of regulation makes sense since the label ‘healthcare and medical apps’ covers everything from apps that are essentially just electronic versions of paper reference guides to apps which help calculate what dose of insulin to take based on food consumed. Clearly the risks associated with these two examples are vastly

different, and so appropriately the regulation is different too, with the former app unlikely to be classed as medical device whilst the latter app would be. It is important to note that even if an app is not classed as a medical device it may still need to conform to other regulations, for example regarding data protection.

The current relevant regulations in the UK are the UK Medical Device Regulations 2002⁶ (amended 2008)⁷. These define a medical device as:

“an instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application—

a) is intended by the manufacturer to be used for human beings for the purpose of-

i. diagnosis, prevention, monitoring, treatment or alleviation of disease,

ii. diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,

iii. investigation, replacement or modification of the anatomy or of a physiological process, or

iv. control of conception; and

b) does not achieve its principle intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,

and includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device”

Medical Devices in the UK are regulated by the Medicines & Healthcare products Regulation Agency (MHRA) and they have guidance to help work out if an app is classed as a medical device⁸. Examples given of apps likely to be classed as a medical device included those that influence treatment by advising on dose of medication, size of implant or time of treatment. An example given of an app which ‘may be’ a device was described as one which provided a risk score tailored to a specific patient based on entered data for that patient.

The complexity of ‘is it or is it not’ a medical device is further complicated by the concept of ‘intended purpose’. ‘Intended purpose’ is determined by what the developer states in the apps description, chosen category in app store, instructions and promotional material. To illustrate this the MHRA document described an app which was intended to magnify text. If it was advertised as an app that magnified text but did not mention visual impairment, it would be unlikely to be a medical device, whilst if it was advertised as for people with visual impairment it would be classified as a medical device.

2.2 Classes of Medical Devices

If an App is a medical device, it must achieve a CE mark and then be registered with the Medicines & Healthcare products Regulation Agency (MHRA). Registering with the MHRA is a straightforward self-declaration process which can be done online⁹.

Achieving a CE mark indicates that the product has been assessed to meet high safety, health and environmental protection requirements.¹⁰

There are 4 categories of CE marks:

Class I – generally regarded as low risk

Class IIa – generally regarded as medium risk

Class IIb – generally regarded as medium risk

Class III – generally regarded as high risk

Medical devices which fall into Class I can be self-declared to meet CE standards, whilst those in other classes require external validation.¹¹

Which class a medical app falls into will depend on what it does. The main applicable section from the EU Medical Devices Regulations is Rule 11, which states:¹²

Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

– death or an irreversible deterioration of a person's state of health, in which case it is in class III; or

– a serious deterioration of a person’s state of health or a surgical intervention, in which case it is classified as class IIb.

Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

All other software is classified as class I.

Realistically this means that most healthcare apps that are classified as medical devices will fall into class IIa and thus require external validation.

A guidance document¹³ was issued in 2019 to give further advice to try and rationalise which software was classified as class IIa. This clarified that apps that only perform a ‘simple search’ to retrieve records by matching record metadata against record search criteria do not qualify as a medical device, and so do not require a CE mark.

It also provides a 5 step decision model to determine if the software/app counts as a medical device. Step 4 of this is a critical question about whether the action is for the benefit of individual patients (and would be counted as a medical device) or generic diagnostic or treatment pathways not directed to individual patients (and would therefore not be counted as a medical device).

It additionally adds the words “reasonably likely” to rule 11, changing it from “have an impact that may cause” to “reasonably likely to have an impact that may cause”.

This guidance document also contains a table to help to assign risk class based on a combination of the significance of information provided by the app to a healthcare situation related to diagnosis/therapy and the state of healthcare situation or patient condition, using International Medical Device Regulators Forum (IMDRF) classifications.¹⁴ A version of this combining the IMDRF details with the EU guidance version is shown in figure 1.

		Significance of information provided by app to healthcare decision		
		Treat or diagnose To treat/prevent or mitigate by connecting to other devices etc to provide therapy, or to diagnose/screen/detect using sensors, data or other information	Drives clinical management Will be used to aid treatment or diagnosis, or to guide next diagnostics or interventions	Informs clinical management Will not trigger an immediate or near term action
State of healthcare situation or condition	Critical Type of disease or condition is: <ul style="list-style-type: none"> • Life-threatening • Requires major therapeutic interventions • Sometimes time-critical Intended target population is fragile with respect to the disease or condition	Class III	Class IIb	Class IIa
	Serious Type of disease or condition is: <ul style="list-style-type: none"> • Moderate in progression, often curable • Does not require major therapeutic interventions • Intervention is normally not expected to be time critical in order to order death, long-term disability or other serious deterioration of health, whereby providing the user an ability to detect erroneous recommendations Intended target population is not fragile with respect to disease or condition	Class IIb	Class IIa	Class IIa
	Non-serious Everything else	Class IIa	Class IIa	Class IIa

Figure 1: Apps as Medical Devices – CE Classes

Overall, these regulations show that many medical apps are likely to be classified as class IIa medical devices and therefore require a CE mark and formal external validation- requirements that at the moment are not necessarily as widely recognised as they should be. It should be noted that currently there is no central register or easy way to check if an app has a CE mark.

3. App Assessment

Various companies and bodies now exist that specialise in assessment of Apps and can help minimise the need for individuals to understand the various nuances discussed in section 2.

The NHS has launched its App Library¹⁵ which is backed by a comprehensive and thorough assessment process prior to apps being included.¹⁶ However, it currently includes only a small number of apps and only 1 cardiology-specific app. It also does not include apps it might be expected to list, such as those produced by Public Health England.¹⁷

Another source of assessed Apps is ORCHA. ORCHA is a private company which describes itself as leading app evaluation organisation. It works with multiple companies and agencies, including NHS Digital and NHS England¹⁸. Its review

process includes looking at an apps functionality, data and security, clinical assurance and user experience in a structured manner¹⁹.

Both of these sources are useful in determining the validity of apps.

4. The future of cardiology: Which apps could be recommended at present?

In an ideal future all members of the cardiology team would have access to a menu of verified apps from which they could pick those which would support their clinical work and be reassured they are safe, validated and supported by regular updates. They would also have a library of apps from which they could prescribe to their patients, such as is the plan in Germany⁵ and the small-scale version available in the UK to GPs using the EMIS clinical system²⁰.

At present this area is a void and thus there is the opportunity for the British Cardiovascular Society to provide constructive leadership. However, section 2 demonstrated how there are multiple legal pitfalls in apps actually being medical devices but not correctly registered as such, and while section 3 outlined sources to aide recommendation many relevant apps have not yet been assessed. In order to limit the liability of the society it therefore makes sense to limit recommendation of apps to be suggested to patients to those produced by Public Health England and relevant apps already in the NHS App library. This gives a list of 9 possible apps (table 1) and covers many of the key areas cardiologists might wish to 'prescribe' an

app for, such as smoking cessation. It also includes the AliveCor Kardia, which is listed at the bottom of the table as it is slightly different, in that it is an app used in conjunction with a small device to allow patients to record medical grade ECG traces to their smartphone.²¹ It can be incredibly useful for detection of arrhythmias but requires the patient to purchase the device.

Name	Domain	Description	Supplier/ Sponsor	Price	NHS app
Active 10	Fitness	Add regular bursts of brisk walking to daily routine	PHE	free	no
Couch to 5k	Fitness	Support to run	PHE	free	no
Drink free days	Decrease alcohol intake	Practical support to decrease alcohol intake	PHE	free	no
Easy Meals	Healthy eating	More than 150 healthy recipes	PHE	free	no
iPrescribe exercise	Fitness	Exercise plan and support	Private company	Free (?during COVID only)	yes
NHS App	Logistics	View medical record, order repeat prescriptions, book GP appointments	NHS	free	yes

NHS Smoke Free	Quit smoking	4 week programme to aide smoking cessation	PHE	free	no
My mhealth: my heart	Management of condition	App to store information about health condition	Private compa ny	£39.99	ye s
Kardia	Rhythm analysis	App which works with a device to provide medical- grade ECG traces on smartphones	Private compa ny	Basic app free. Requires purchase of device	no

Table 1: Apps that could be recommended to patients

Recommending apps that may be useful to members of the cardiology team in their clinical work has greater risk in terms of falling foul of the app being an unregulated medical device. This means that many potentially useful apps, such as the Valve in Valve apps or the HCM SCD risk calculator, cannot be recommended as they should be registered as medical devices but there is no evidence on the apps that they have been. Apps that are essentially electronic versions of paper references from reputable sources (such as the ESC pocket guidelines or the BNF) can be recommended, as can apps that are educational (such as MedShr, which the BCS already promotes). The Cardiosmart/CS explorer app by ACC which provides clinicians with visual aides to explain conditions to patients, could also be recommended. In total 7 apps could be considered to potentially be recommended (table 2).

Name	Domain	Description	Supplier/ Sponsor	Price	NHS app
British National Formulary	General medicine	BNF in electronic format	Royal Pharmaceutical Society	free	no
CardioSmart Heart Explorer	General cardiology	Graphics and animation to help explain cardiac problems to patients	ACC	free	no
CMR guide	Imaging	CMR reporting support	ESC/EACVI	free	no
EACVI Recommendations	Imaging	EACVI recommendations and expert consensus papers in electronic form	ESC/EACVI	free	no
EchoCalc	Imaging	Echo reporting support	BSE	free	no
ESC Pocket guidelines	General cardiology	ESC guidelines in electronic format	ESC	free	no
Med Shr	General medicine	Clinical cases for clinician education	Private company	free	no

Table 2: Apps that could be recommended for use by the cardiology team

5. Conclusions

Apps have the potential to have a positive impact on patient care. However, it is important to ensure that they are fit for purpose and fulfil any required legal obligations. At present the body of apps that are potentially suitable to recommended is therefore small but could be nonetheless be impactful, particularly in helping patients address risk factors.

Moving forward, education of clinicians regarding assessing apps will be needed to ensure they are equipped to assess the validity of apps, and are aware of pitfalls such as ownership of data fed into apps.

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