To preserve commercial and confidentiality interests, some elements of this document have been redacted.

Scottish Ambulance Service
Taking Care to the Patient

NHS SCOTLAND

Advanced Life Support Monitor/Defibrillator Unit Replacement Project

Full Business Case

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(Documents that you have linked or referenced to in the text of this document)

Document Title:	Document File Path:
Towards 2020: Taking Care to the Patient, Scottish Ambulance Service (2015)	http://www.scottishambulance.com/UserFiles/file/TheService/Publications/Strategic%20Plan_Online%20pdf.pdf
Initial Results of the Scottish Out-of-Hospital Cardiac Arrest Data Linkage Project, Scottish Government, (August 2017)	http://www.gov.scot/Resource/0052/00523287.pdf
CVD Statistics – BHF Scotland Factsheet, British Heart Foundation, (August 2017)	https://www.bhf.org.uk/research/heart-statistics
Out-of-Hospital Cardiac Arrest: A Strategy for Scotland, Scottish Government, (March 2015)	http://www.gov.scot/Resource/0047/00474154.pdf
eHealth Strategy 2014 -2017, Scottish Government, (March 2015)	http://www.scotland.gov.uk/Publications/2011/09/09103110/0
Advanced Life Support Monitor/Defibrillator Unit Replacement Project, *Initial Agreement,* Scottish Ambulance Service (April 2017)	http://www.scottishambulance.com/userfiles/file/TheService/DefibrillatorMonitorReplacementProgramme2017.pdf

Equality and Diversity Impact Assessment:

15/02/2017 (subsequently reviewed 07/02/2018)

Contents

Section 1: Executive Summary

1.1 Introduction

Purpose

This Full Business Case (FBC) will identify the preferred commercial solution and confirm the affordability of the project. It will also demonstrate that appropriate contractual, commercial and management arrangements are in place to successfully deliver the Advanced Life Support (ALS) monitor / defibrillator Replacement Project.

ALS monitor / defibrillators form a part of the Service's primary response equipment and, as such, is taken to the patient in every emergency and urgent call. The current units utilised by the Service are at the end of their life and as a result an increasing number of faults are arising. In addition, the current unit [redacted] is no longer being manufactured and replacement parts such as batteries are becoming increasingly difficult to source.

Scope

ALS monitors / defibrillators allow clinicians to monitor the patient's heart rhythm and manually intervene if it is determined that a shock is required. In addition to the ability to deliver a shock, ALS monitors are fitted with a number of functions for patient monitoring purposes, including:

- SPO_2 monitoring to observe the oxygenation level of the patient via an external sensor
- Monitoring carbon dioxide levels
- Measuring the patient's blood pressure via a cuff
- Performance of baseline checks such as temperature

The units can be used on a wide range of patients with varying clinical needs and are not for sole use on patients with immediately life threatening conditions; the units will be taken to every emergency attendance. The availability and use of these monitoring functions aids clinical decision making and allows patients to be kept and treated in the home environment where clinically appropriate.

The proposal covers the procurement and vehicle installation of ALS monitors/defibrillator units for operational use in the following areas of the Service:

• A&E Road Crews including PRU Response Cars	540 units
• Air Ambulance	6 units
• ScotSTAR	8 units
• Charity Air Ambulance	1 unit
• Education and Training Department	35 units
• SORT Teams	10 units
Total	**600 units**

This will result in an increase of 55 units from the 545 units currently owned by the Service. This is in accordance with the Service's Strategy *Towards 2020: Taking Care to the Patient* and associated workforce and financial plans which require an increase in vehicles and Paramedics.

There is likely to be an increase in the number of Paramedics and therefore units over the next 3-5 years as the GMS contract is rolled out and the requirement to increase support by Paramedics in

Primary Care. This will be dealt with on a case by case basis as operational delivery expands and changes.

The project includes development of an interface between the new ALS monitors / defibrillators and the electronic patient record (ePR). The disposal and decommission of existing ALS monitors/defibrillators are also included within this project.

Exclusions

The project specifically excludes the replacement of the Automated External Defibrillators (AED, otherwise known as "shock boxes") currently utilised by the Service in Patient Transport vehicles, officer and manager's vehicles and community resilience teams. There will be no detriment to service delivery as the current AEDs do not integrate with the existing ALS monitor/defibrillator unit.

In addition, this project excludes the purchase of replacement mobile phones which are currently paired with the existing ALS monitors/defibrillators to transmit data from ambulance vehicles to the Coronary Care Units (CCUs) in the geographical Health Boards. This facility will be replaced with an IT interface enabling the new ALS monitor / defibrillator unit to transmit the data directly to the CCUs. There is no negative impact of not replacing these phones as the new defibrillator units will transmit via their own SIM or the in-vehicle communications hub.

Investment Decision Process

The Initial Agreement for this project was approved by the Scottish Ambulance Service Board on 19 May 2017 and subsequently by Scottish Government's Capital Investment Group (CIG). Authority to progress to an Outline Business Case was granted on 25 July 2017.

The Outline Business Case (OBC) was approved by the Scottish Ambulance Service Board on 28 March 2018 and subsequently by the Scottish Government's Capital Investment Group. Authority to progress to a Full Business Case was granted on 22 May 2018.

1.2 Strategic Case

Since the approval of the Initial Agreement and OBC for the ALS monitor / defibrillator Replacement Project there has been no fundamental change to the strategic context of the proposal.

The strategic case as outlined in the OBC is still in line with the Service's *Towards 2020: Taking Care to the Patient* strategic framework and the Scottish Government's Out of Hospital Cardiac Arrest (OHCA) Strategy.

Summary of Current Arrangements

There has been no change of material importance to the current arrangements since the approval of both the Initial Agreement and OBC. It is unlikely that the current arrangements will change during the investment process. The Service currently owns 545 [redacted] monitor / defibrillators deployed across the A&E response fleet to respond to patients. The units were originally purchased in 2011.

Summary of Drivers for Change

Driver for Change	Description
To improve patient treatment	The current CPR feedback system is not being consistently used due to the reliance on the equipment being placed in a specific position on the patient. The current machine also has a relatively long analysis time resulting in a longer than recommended hands-off chest time.
To improve staff wellbeing	Staff have raised concerns about the current equipment, namely that it is heavy and awkward to carry, the interface to input patient data is complicated, the telemetry is temperamental depending on the geographical location and the CPR real-time feedback device is very hard and uncomfortable to use.
Ageing technology and equipment	The existing equipment is now over 7 years old and uses outdated Bluetooth technology and mobile phones that are no longer commercially available to transmit patient data. An increasing number of adverse incident reports are being lodged due to equipment issues. A high proportion of these are classified as a risk to patient safety. There are ongoing concerns that product spares and consumables are no longer being developed.
Suitability of current equipment	The existing equipment has been exposed to a wide range of inclement weather conditions. This has impacted upon their resilience and has led to configuration and connectivity issues.
Warranty of current machines	The warranty of the current machines has expired and the Service is therefore incurring increasing expenditure year on year repairing faults.

Summary of Opportunities for Improvement

This project provides the opportunity to connect newly procured ALS monitor / defibrillator units to the communication hub within emergency ambulances. This provides the opportunity to pre-populate patient records with observations and recordings from the ALS monitor / defibrillator unit. Key event data is stored and accurately recorded which is vital for service audit, research and post clinical event feedback. This may provide information on common themes enabling the development of effective training strategies. Additionally, the data can be transmitted in real time to other healthcare professionals within Health Boards, Health Centres and other clinical facilities thereby, improving clinical decision making and patient outcomes.

Summary of Investment Objectives

No	Investment Objective	Baseline Data	Relevant Stakeholders	2020 Priority Area
1	To increase the number of patients that are identified as critically ill and the number of patients who have Return of spontaneous circulation for VF/VT by March 2020	Return of spontaneous circulation for VF/VT Number of patients identified as critically ill and deteriorating from NEWS (National Early Warning Score)	Patients Staff Healthcare Partners	Person Centred Safe
2	To improve the quality of CPR real time feedback, using new and improved technology built in to defibrillator pads by March 2020	% of incidents using the real time feedback device	Staff Patients	Safe
3	To provide a solution which supports access to clinical audit data and research to aid clinical decision	% of clinical data accessible from data warehouse	Patients Staff Healthcare	Safe Effective Quality of

No	Investment Objective	Baseline Data	Relevant Stakeholders	2020 Priority Area
	making and improve training and development of staff by March 2020		Partners	care
4	To deliver a data interface from the hardware solution to the ePR to allow automatic population of clinical data by March 2020	Number of ePR automatically populated with clinical data	Patients Staff Healthcare Partners	Person Centre Safe Effective Quality of Care
5	To deliver hardware which supports wireless communication and data sharing by March 2020	Number of monitors / defibrillators able to wirelessly transit data to the ePR and CCUs	Staff Healthcare Partners	Person Centred Safe Effective Quality of Care
6	To reduce repair costs of the monitors /defibrillators by providing newer, more reliable units by March 2020	Repair costs per annum	Staff	Safe Value & Sustainability

Note - Investment Objective 6 within the OBC included the aspiration to reduce consumable costs. The evidence from the tender responses by suppliers shows that this aspiration is not achievable due to significant increase in unit costs. The Service, will however ensure that consumables are utilised as efficiently as possible to enable cost containment where possible.

1.3 Economic Case

The Economic Case as presented in the OBC has been reviewed to take account of the actual costs provided in the tender. This has resulted in the following change to Option 3 in the Economic Analysis:

OPTIONS	BENEFITS	COSTS	COST PER BENEFIT
	Weighted Benefit Score	Equivalent Annual Charge	EQA £ / Points
	Points	(£)	(£s)
Option 3 as per OBC	786	4,011,773	5,104.04
Option 3 – with final costs	786	3,846,097	4,893.30

The cost per benefit for Option 3 has reduced by £210.74 making it a more robust option. The driver for the reduction is that the unit price of the ALS Monitors / Defibrillators is lower than anticipated.

In addition, the risks and benefits have been reviewed regularly at project team meetings and no significant changes have taken place. Benefits and risks will continue to be monitored throughout the life of the project.

1.4 Commercial Case

The project will be delivered via a commercial framework (NP155/15 Defibrillators Lot 5) awarded by NHS National Services Scotland National Procurement. The framework is in place until February 2020. Additionally, any maintenance contract entered into with a termination date beyond February 2020 will be within the remit of the framework.

Selection of Preferred Supplier

The mini competition was published on PCS-Tender for the four suppliers listed within the Framework. All four suppliers were invited to submit bids. Those suppliers who submitted a bid and met the mandatory criteria were invited to provide ALS monitors / defibrillator units for use in field trials carried out by the Service's operational staff. Bids were received from three out of the four suppliers ([redacted]).

Only two suppliers met the mandatory criteria and subsequently progressed to field trials. The bid from [redacted] failed the mandatory criteria.

The ALS monitors / defibrillators units tendered by the suppliers were as follows:

[redacted]

Scope of Services

The project involves the supply of ALS monitor / defibrillators for use in emergency response vehicles and the air ambulance service. This includes the development of electronic interfaces using wireless communication technology between the defibrillator units and the Service's existing ePR.

The contract also includes the provision of all related goods and services, training materials and support for Service trainers. Further inclusions are the servicing, maintenance and repairs of the devices as required, and the supply of appropriate accessories, consumables, spare parts and user manuals.

Selection Process

Several requirements were highlighted as mandatory and a supplier's failure to meet any of those essential outputs resulted in an unsuccessful bid. Non-mandatory criteria were scored in accordance with evaluation methodology.

The outcome of the tender evaluation is as follows:

Quality	Weighting	[redacted]	[redacted]
Clinical Use	10	9.65	9.36
Communications	20	17.67	16.67
Installation	5	5.00	5.00
Sustainability	3	2.50	2.50
Training	3	2.34	1.56
Warranty, Servicing, Repairs & Business Continuity Planning	10	9.64	9.11
Field Trials	20	20	20
Pricing	30	30	26.25
Total Score (100)	100	96.80	90.45

Lowest Price	£[redacted]
Lowest Bidder	[redacted]
Score	4.00
Weighted Score (30)	30.00

Highest Price	£[redacted]
Highest Bidder	[redacted]
Score	3.50
Weighted Score (30)	26.25

Price Gap	£[redacted]

The winner bidder was [redacted] with their [redacted] unit.

Contract duration

The proposed contract duration is 7 years with the option to extend for a further 3 years. The proposed warranty period for the units is 5 years. This is the standard warranty period for the units and a warranty extension would attract further costs.

1.5 Financial Case

The financial case has been revised using the preferred supplier's tendered costs and this has resulted in the following changes:

Capital Requirements

Option	Total Capital Requirement of Option £	Capital Requirement in Year 1	Capital Requirement in Year 2
3 OBC Estimate	[redacted]	[redacted]	[redacted]
3 FBC Final Cost	[redacted]	[redacted]	[redacted]

The main reason for the reduction in the capital requirement from the estimates in the OBC is the unit price of the ALS Defibrillator / Monitors. The cost used within the OBC was £[redacted] plus vat per unit. The tendered cost from the successful supplier was £[redacted] plus vat per unit, thereby generating an overall reduction of £[redacted]. There has also been a reduction in installation and aircraft certification costs to give the total reduction in capital requirements of around £1.7m.

Revenue Requirements

Option	Total Revenue Cost (Excluding Depreciation) over Contract Life £	Decrease from OBC
3 OBC Estimate	[redacted]	
3 FBC Final Cost estimate	[redacted]	[redacted]

Over the life of the contract the anticipated revenue costs have decreased by around £[redacted] from the estimates presented in the OBC. This is mainly due to revised costs for consumables.

Depreciation

The Service will incur deprecation costs of around £[redacted] per annum as a result of the capital purchase of assets for this project. This assumes a useful life of 10 years for the assets. This is an increase of around £400k per annum on the depreciation charges for the current units. The Service will be responsible for funding this from its non-core depreciation allocation.

Affordability

The OBC identified there was a revenue affordability gap at that time. The model has been re-run using actual costs and the results are as follows:

	2018/19 (£)	2019/20 (£)	2020/21 (£)	2021/22 (£)	2022/23 (£)	2023/24 (£)	2024/25 (£)	2025/26 (£)	2026/27 (£)	2027/28 (£)	2028/29 (£)	TOTAL (£)
Option 1: Do Minimum	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Option 3: Replace existing units with ALS monitor / defibrillator Unit and enhanced technology	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Funding gap	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Excluding non-recurring revenue, there remains an average annual core revenue funding gap of around £[redacted]. There are two main drivers for the core revenue funding gap:

- The quantities used for the consumable costs are based on usage incurred with the [redacted] machines. There have been issues with reliability of certain consumables for the [redacted], in particular the monitoring leads, which has driven up the usage over recent years. The [redacted] uses newer technology and it is therefore anticipated that quantities required will be lower, thereby reducing the forecast funding gap.
- The software costs associated with live streaming is around [redacted] per annum. Live Streaming provides the ability for a remote user, e.g. clinical specialist, to connect to a specific defibrillator in real-time, via a secure browser session. This facilitates remote monitoring of a patient to allow appropriate medical advice to be given to the attending crew for best patient treatment and outcome. This was not included within the costs used in OBC as this was a non–mandatory element of the tender that the clinical team have since confirmed they would like to progress.
- The [redacted] requires battery replacement at Year 6. As the model has three batteries within the unit all three batteries need to be replaced. This estimated cost is around [redacted] The battery replacement programme relating to the existing model was included as part of the support and maintenance contract and therefore no additional cost was incurred. This option is not available within the contract for the new units.

The Service has explored an in-house Medical Physics solution for support and maintenance with NHS Greater Glasgow & Clyde and NHS National Waiting Times Hospital (Golden Jubilee), however neither solution proved feasible and both options were more expensive than the cost of support and maintenance from the supplier.

Confirmed Funding Arrangements

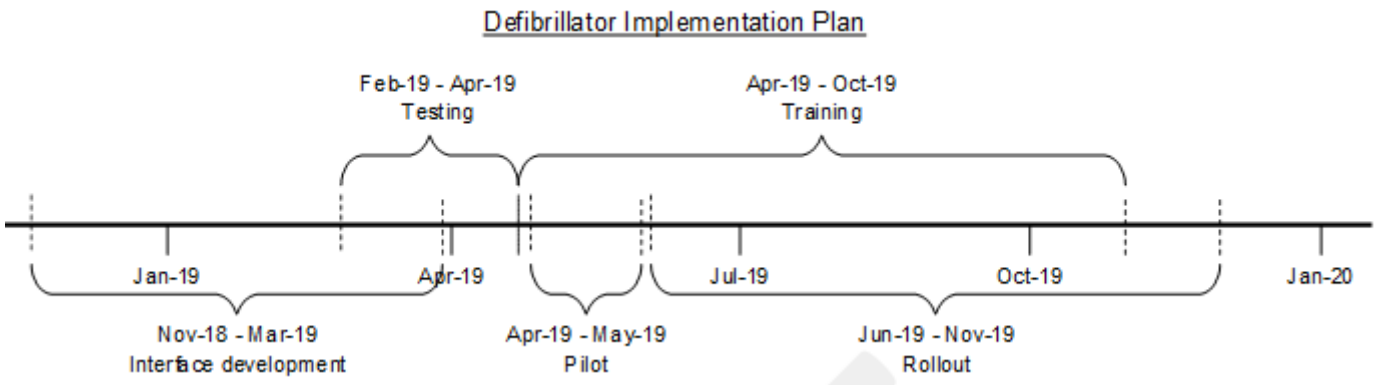
The capital costs associated with this project will be funded via an earmarked capital allocation from Scottish Government following approval of this FBC by the Capital Investment Group.

The revenue costs associated with this project will be funded by the Service's core revenue budget. The Service incorporated the revenue costs within its Financial Plan and is assuming efficiency plans will be in place to manage the additional pressure associated with the funding gap between the existing units and the replacement [redacted] from 2019/20 onwards. As the ALS monitoring / units are the Service's primary response equipment, operational staff must be provided with reliable equipment and the benefits across the NHS as a whole are significant. The Service recognises that this project must be implemented and has explored all areas of reducing the funding gap during the period between OBC and FBC. As the estimated consumables cost is based on the existing quantities associated with the [redacted], it is hoped that once implementation is complete, actual quantities required for the [redacted] will be less and therefore the consumables cost will reduce. The Service will monitor consumables usage closely to ensure costs are contained as far as possible.

1.6 Management Case

The project will report to the 2020 Steering Group via the Enabling Technology Programme Board, providing regular Highlight Reports and representation at meetings. The Enabling Technology Programme Board has been established and authorised by the Scottish Ambulance Service Board to act on behalf of the Board, monitoring, controlling, reporting on progress and providing governance on all Enabling Technology activities.

Project Plan and Key Milestones



1.7 Conclusion and Recommendation

Preferred Supplier

A procurement process has been carried out for the purchase of ALS monitors / defibrillators and this determined the following solution best meets the service requirements:

- The solution offered by [redacted]

The project will deliver the following objectives:

- To increase the early identification of critically ill and deteriorating patients and the number of patients who have return of spontaneous circulation for VF/VT by March 2020
- To improve the quality of CPR real time feedback, using new and improved technology built in to defibrillator pads by March 2020
- To provide a solution which supports access to clinical audit data to aid clinical decision making and improve training and development of staff by March 2020
- To deliver a data interface from the hardware solution to the ePR to allow automatic population of clinical data by March 2020
- To deliver hardware which supports wireless communication and data sharing by March 2020
- To reduce repair costs of the monitors /defibrillators by providing newer, more reliable units by March 2020

Recommendation

This FBC has been produced in accordance with the guidance issued by the Scottish Government Capital Investment Group and the outcome has shown that the preferred supplier is [redacted] as their solution presents value for money and is affordable.

It is recommended that the Capital Investment Group approve this FBC and the following outcome:

- Contract award to [redacted] for the purchase of [redacted] ALS monitor / defibrillators

Section 2: Introduction

2.1. Purpose

The purpose of this Full Business Case (FBC) is to confirm that the procured offer represents the best value commercial solution for delivering the project requirements within the affordability limits. It will also demonstrate that appropriate contractual, commercial and management arrangements are in place to successfully deliver the project. The FBC follows on from the Outline Business Case (OBC) which demonstrated that the preferred implementation option optimises value for money and is affordable. It also set out the supporting commercial and management arrangements to be put in place to successfully implement that option.

The FBC follows the guidance published in the Scottish Government Health and Social Care Directorate (SGHSCD) Scottish Capital Investment Manual (SCIM).

2.2 Scope

The FBC covers the procurement and vehicle installation of Advanced Life Support (ALS) monitoring/defibrillator units for operational use within the Scottish Ambulance Service (the Service) to meet the needs of patients treated by the Service.

ALS monitors/defibrillators allow clinicians to monitor the patient's heart rhythm and manually intervene if it is determined that a shock is required. In addition to the ability to deliver a shock, ALS monitors are fitted with a number of functions for patient monitoring purposes, including:

- SPO_2 monitoring to observe the oxygenation level of the patient via an external sensor
- $EtCO_2$ to monitor carbon dioxide levels
- Non-invasive blood pressure (NIBP) units to automatically measure the patient's blood pressure via a cuff
- Invasive blood pressure (IBP) used mainly with advanced transport units where patients with invasive lines can be managed during transport, either within the hospital or via ambulance or aircraft
- 12-lead electrocardiogram (ECG) which allows for rapid identification and classification of myocardial infarction. The ECG reading can be transmitted to receiving hospitals and alert cardiology teams that a patient requiring intervention is on the way. This is widely used by paramedics, with use on over 1 million patients in both emergency and urgent care settings for monitoring their condition
- CPR support to assist with the delivery of optimal circulatory support
- Performance of baseline checks such as temperature and SPO_2 levels

The ALS units are suitable for use on patients of any age, including neo-natal patients. The units can also be used on a wide range of patients with varying clinical needs and are not for sole use on patients with immediately life threatening conditions. Results can help clinicians identify the patients' clinical needs, for example a high National Early Warning Score (NEWS) indicates the early onset of sepsis. The availability and use of these monitoring functions aids clinical decision making and allows patients to be kept and treated in the home environment where clinically appropriate.

The ALS units are Resuscitation Council and UK Ambulance Service Clinical Practice Guideline (UKASCPG) compliant. The ALS units have the functionality to download data related to the quality of CPR which has been recommended by the International Liaison Committee on Resuscitation

(ILCOR). The ALS unit is also compliant with Guidelines for Post Return of Spontaneous Circulation (ROSC). These units are currently in use within the ambulance service.

The procurement and vehicle installation of ALS monitoring / defibrillator monitoring units covers the following operational areas of the Service:

• A&E Road Crews including PRU Response Cars	540 units
• Air Ambulance	6 units
• ScotSTAR	8 units
• Charity Air Ambulance	1 unit
• Education and Training Department	35 units
• SORT Teams	10 units
Total	**600 units**

This will result in an increase of 55 units from the 545 units currently owned by the Service. This is In accordance with the Service's Strategy *Towards 2020: Taking Care to the Patient* and associated workforce and financial plans which require an increase in vehicles and paramedics. The approved Clinical Response Model aims to increase the number of patients being treated at home or over the phone and reduce the number of A&E attendances where clinically appropriate. This requires an increase in the number of single responder paramedics from the number currently in operational service. Defibrillators form a part of the Service's primary response equipment and, as such, are taken to the patient in every emergency and urgent call. The planned increase in units will increase the population's access to the life saving equipment.

There is likely to be an increase in the number of Paramedics and therefore units over the next 3-5 years as the GMS contract is rolled out and the requirement to increase support by Paramedics in Primary Care. This will be dealt with on a case by case basis as operational delivery expands and changes.

In addition, the project also includes a development of an interface between the equipment and the electronic patient record (ePR) to pre-populate clinical observations, along with an interface to a central server to allow clinical audits to be carried out. This will also allow for quicker decision making and improved quality outcomes for patients along with better quality data for audit and management information uses.

<u>Interface Development</u>

The interface will allow appropriate data from the defibrillator to be automatically populated into the electronic patient record (ePR). Both [redacted] and the ePR supplier, [redacted] already provide a similar interface to some of their existing clients and have demonstrated a proof of concept to the project team. A specification has already been drafted following a workshop as well as a change request document for [redacted] in order to provisionally schedule the work. The ALS monitor/defibrillator supplier will work directly with [redacted] to develop the interface.

Actual timescales cannot be confirmed until the ALS monitor / defibrillator supplier is appointed and formal engagement has begun. However, as contingency, there is the potential to adopt a phased approach with stage 1 being the rollout of the new defibrillators and stage 2 being the implementation of the ePR interface should this be necessary.

IT network, connections, redundancy and resilience

The planned server for the project will be hosted in the SAS virtual environment and will provide a more robust and enhanced solution than the current one. It will provide appropriate resilience through the use of RAID data storage, redundant Virtual machines (VMs) and daily backups. This solution will utilise the already secure and resilient SAS local and SWAN wide area networks. Data SIMs in the defibrillators and in the existing in-vehicle communications hub will securely transmit data using 3G via existing mobile interfaces. This security and connectivity is currently used by the Telehealth / ePR solution, a tried, tested and proven, working solution. Until uploaded, data is held securely on the defibrillator on encrypted storage. Once available, it is envisaged that the Service will utilise Emergency Service Network (ESN) compatible SIMs to maximise mobile coverage for data transmission. The server will be maintained in line with the Service's security policies.

Patient receiving centres will access the data via a browser and a secure web application. Once approval has been granted, user accounts will be set up and administered by SAS ICT staff. There is no additional hardware or software required by other Health Boards.

2.3 Exclusions

The project specifically excludes the replacement of the Automated External Defibrillators (AED, otherwise known as "shock boxes") currently utilised by the Service in Patient Transport vehicles, officer and manager's vehicles and community resilience teams. There will be no detriment to service delivery as the current AEDs do not integrate with the existing ALS monitor / defibrillator device.

In addition, this project excludes the purchase of replacement mobile phones which are currently paired with the existing ALS monitors/defibrillators to transmit data directly to the Coronary Care Units (CCUs) in the geographical Health Boards. Within this project, this will be replaced with an IT interface enabling the ALS monitor/defibrillator unit to transmit the data to the CCUs. There will no longer be a requirement to provide clinical staff with these mobile phones for ECG transmission. There is no negative impact of not replacing these phones as the new defibrillator units will transmit via their own SIM or the in-vehicle communications hub.

2.4 Investment Decision Process

The Initial Agreement (IA) for this project was approved by the Scottish Ambulance Service Board on 31st May 2017. The IA was also approved by the Scottish Government's Capital Investment Group (CIG) on 25th July 2017 and authority was given to progress to an Outline Business Case.

The Outline Business Case (OBC) was approved by the Scottish Ambulance Service Board on 28 March 2018. The OBC was also approved by the CIG on 22nd May 2018 and authority was given to progress to a Full Business Case.

Post approval of the FBC, the Service will proceed to fully implement the project.

Section 3: Strategic Case

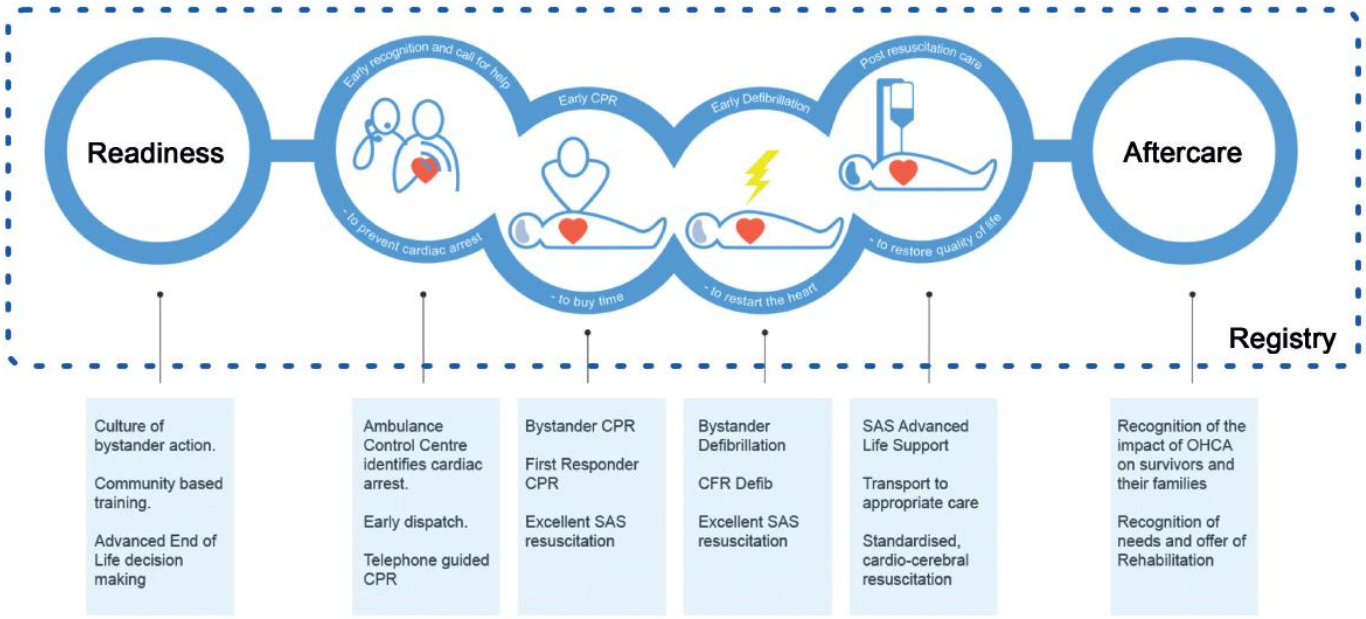
3.1 Review of Strategic Case within the Outline Business Case

Since the approval of the Initial Agreement and OBC for the ALS monitor / defibrillator unit replacement project there has been no fundamental change to the strategic context of the proposal.

The strategic case as outlined in the OBC is still in line with the Service's *Towards 2020: Taking Care to the Patient* strategic framework and the Scottish Government's Out of Hospital Cardiac Arrest (OHCA) Strategy.

<u>Out-of-Hospital Cardiac Arrest: A Strategy for Scotland</u>

In 2015, the Scottish Government launched its Out-of-Hospital Cardiac Arrest (OHCA) Strategy with the aim of increasing survival rates by 10% within 5 years, resulting in around more than 300 lives being saved each year[i]. The Strategy sets out the ambition for Scotland to be an international leader in the management of Out-of-Hospital Cardiac Arrest (OHCA). When someone suffers an OHCA their chances of survival are increased if certain things occur in a certain order, known as the 'Chain of Survival'. The key aim of the strategy is improvements in all 6 elements of the augmented chain of survival:



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The OHCA Strategy aims to improve all 6 elements in the 'Chain of Survival' and recognises the vital role the Service plays in 4 of the elements. The Strategy recognises that immediate access to reliable ALS monitors/defibrillators is vital to the patient's survival.

<u>Towards 2020: Taking Care to the Patient</u>

The Service is delivering its current strategy, "*Towards 2020: Taking Care to Patient*"[iii]. The Strategy is based on the fundamental principle that care should be appropriate to the need and where that care is delivered should be appropriate, shifting the balance of care by taking more care to the patient. The Strategy specifically sets out to improve the outcomes for cardiac patients and expand the diagnostic capability and use of technology to improve patient care. The Service aims to lead a national programme of improvement for Out of Hospital Cardiac Arrests.

One of the most common conditions presented to the Service is chest pain, with approximately 39,000 presentations per annum. A proportion of these patients are suffering from a heart attack (myocardial infarction), a sudden interruption to the blood supply to part of the heart. Unlike a cardiac arrest, the patient will remain conscious and continue breathing. A heart attack can cause permanent damage to heart and puts the patient at a high risk of experiencing cardiac arrest. There are around 26,000 hospital visits attributed to heart attacks in Scotland each year with at least 7 in 10 people surviving. In the case of a heart attack, an ALS monitor/defibrillator unit can be used to record the patient's 12-lead electrocardiogram in order to make an early diagnosis and communicate via telemetry with the nearest hospital based Coronary Care Unit to organise urgent definitive care.

Summary of current arrangements

There has been no change of material importance to the current arrangements since the approval of both the Initial Agreement and OBC. It is unlikely that the current arrangements will change during the investment process

ALS monitor / defibrillators form a part of the Service's primary response equipment and, as such, is taken to the patient in every emergency and urgent call.

The Service currently owns 545 [redacted] monitor / defibrillators deployed across the A&E response fleet to respond to patients. The units were originally purchased in 2011 alongside a 5 year support and maintenance contract from the supplier [redacted] The contract has been extended for a further 2 years to March 2018 to cover the servicing and maintenance of the units. The contract will be further extended until the replacement units are in operational use.

Summary of Drivers for Change

Driver for Change	Description
To improve patient treatment	The current CPR feedback system is not being consistently used due to the reliance on the equipment being placed in a specific position on the patient. The current machine also has a relatively long analysis time resulting in a longer than recommended hands-off chest time.
To improve staff wellbeing	Staff have raised concerns about the current equipment, namely that it is heavy and awkward to carry, the interface to input patient data is complicated, the telemetry is temperamental depending on the geographical location and the CPR real-time feedback device is very hard and uncomfortable to use.
Ageing technology and equipment	The existing equipment is now over 7 years old and uses outdated Bluetooth technology and mobile phones that are no longer commercially available to transmit patient data. An increasing number of adverse incident reports are being lodged due to equipment issues. A high proportion of these are classified as a risk to patient safety. There are ongoing concerns that product spares and consumables are no longer being developed.
Suitability of current equipment	The existing equipment has been exposed to a wide range of inclement weather conditions. This has impacted upon their resilience and has led to configuration and connectivity issues.
Warranty of current machines	The warranty of the current machines has expired and the Service is therefore incurring increasing expenditure year on year repairing faults.

Summary of Opportunities for Improvement

This project provides the opportunity to connect newly procured ALS monitor /defibrillator units to the new communication hub within emergency ambulances. This provides the opportunity to pre-populate patient records with observations and recordings from the ALS monitor / defibrillator unit. Key event data is stored and accurately recorded which is vital for service audit, research and post clinical event feedback. This may provide information on common themes enabling the development of effective training strategies. Additionally, the data can be transmitted in real time to other healthcare professionals within Health Boards, Health Centres and other clinical facilities thereby, improving clinical decision making and patient outcomes.

Summary of Investment Objectives

No	Investment Objective	Baseline Data	Relevant Stakeholders	2020 Priority Area
1	To increase the early identification of critically ill and deteriorating patients and the number of patients who have Return of spontaneous circulation for VF/VT by March 2020	Return of spontaneous circulation for VF/VT Number of patients identified as critically ill and deteriorating from NEWS (National Early Warning Score)	Patients Staff Healthcare Partners	Person Centred Safe
2	To improve the quality of CPR real time feedback, using new and improved technology built in to defibrillator pads by March 2020	% of incidents using the real time feedback device	Staff Patients	Safe
3	To provide a solution which supports access to clinical audit data and research to aid clinical decision making and improve training and development of staff by March 2020	% of clinical data accessible from data warehouse	Patients Staff Healthcare Partners	Safe Effective Quality of care
4	To deliver a data interface from the hardware solution to the ePR to allow automatic population of clinical data by March 2020	Number of ePR automatically populated with clinical data	Patients Staff Healthcare Partners	Person Centre Safe Effective Quality of Care
5	To deliver hardware which supports wireless communication and data sharing by March 2020	Number of monitors / defibrillators able to wirelessly transit data to the ePR and CCUs	Staff Healthcare Partners	Person Centred Safe Effective Quality of Care
6	To reduce repair costs of the monitors /defibrillators by providing newer, more reliable units by March 2020	Repair costs per annum	Staff	Safe Value & Sustainability

Investment Objective 6 within the OBC included the aspiration to reduce consumable costs. The evidence from the tender responses by suppliers shows that this aspiration is not achievable due to

significant increase in unit costs. The Service, will however ensure that consumables are utilised as efficiently as possible to enable cost containment where possible.

Section 4: Economic Case

4.1 Summary of Economic Case within the OBC

The Economic Case within the OBC provided a detailed analysis of the costs, benefits and risks of the three identified short-listed options to determine a preferred option which demonstrated value for money in delivering the required outcomes.

Shortlisted Option within the OBC

A short-list of implementation options was identified within the OBC:

Options	Description
Option One – Do Minimum (baseline)	Continue using the existing equipment, repairing any faults as they arise. Purchase additional units if required to meet service delivery and demand. However, this is dependent on the current model of units still being available to purchase.
Option Two – Replace existing units with Advanced Life Support (ALS) monitor/defibrillator unit and like for like technology	Existing equipment will be replaced with appropriate defibrillators but this **does not** include the provision of any interfaces to allow for connectivity of the ALS monitors to the technology already installed in the ambulances.
Option Three – Replace existing units with Advanced Life Support (ALS) monitor/defibrillator unit and enhanced technology	This will replace units with an appropriate defibrillator monitor and **enhanced technology**, allowing connection between the ALS monitors and the technology installed in the ambulances.

Outcome of Economic Analysis within the OBC

The economic appraisal considered the benefits, costs and risks of the shortlisted options to inform a value for money assessment and arrive at a rank order of the options in terms of value for money.

The outcome of the economic appraisal within the OBC is shown in the table below:

OPTIONS	BENEFITS	COSTS	COST PER BENEFIT	COST PER BENEFIT Rank Order *(lowest cost per benefit first)*	RISK
	Weighted Benefit Score	Equivalent Annual Charge	EQA £ / Points		Median risk quotient
	Points	(£)	(£s)		
Option 1: Do Minimum	183	1,135,960	6,207.43	**2**	10.00
Option 2: Like for Like Technology	497	3,829,274	7,704.78	**3**	6.00
Option 3: Enhanced Technology	786	4,011,773	5,104.04	**1**	7.00

The table shows that Option 3 was the highest ranking option based on benefits gained versus expenditure. Option 3 also carried a moderate risk profile.

Sensitivity analysis was undertaken using the 'switching values' approach. This 'what if' scenario indicates how much a variable would have to change in order to impact upon the choice of the preferred option.

- As shown in the Economic Appraisal Table above, Option 3 (enhanced technology) was been given the highest rank order in terms of cost per benefit. In order to test the sensitivity of this outcome, analysis was performed to determine the increase in costs or decrease in benefits which would be required to amend the rank order of the options.
- The cost per benefit of Option 3 (enhanced technology) would have to increase by a minimum of 75% before the rank order would change with Option 2 (like for like technology) becoming the highest ranking option. The represents a significant increase and shows that, in terms of cost, the option is not very sensitive to fluctuation.
- The benefits gained from Option 3 (enhanced technology) would have to decrease by a minimum of 18% before the rank order is changed to favour Option 2 (like for like technology). The represents a significant decrease and shows that, in terms of benefits, the option is not very sensitive to fluctuation.

Preferred Option within the OBC

The preferred implementation option was identified as **Option 3** – replace existing units with ALS monitor / defibrillator unit and enhanced technology. The economic appraisal showed that this option was the highest ranking option based on benefits versus expenditure. It also carries a low risk profile. The sensitivity analysis demonstrated that this option was not very sensitive to fluctuation in terms of cost and benefits.

4.2 Validation of the Preferred Option

Following approval of the OBC, the economic case has been reviewed to take account of new information received in the intervening period to ensure that the outcome of the economic appraisal within the OBC remains valid.

The costs used in the economic analysis were based on market prices at that time. These have been reviewed against tendered costs from the preferred supplier. This has resulted in the following change to Option 3 in the Economic Analysis:

OPTIONS	BENEFITS	COSTS	COST PER BENEFIT
	Weighted Benefit Score	Equivalent Annual Charge	EQA £ / Points
	Points	(£)	(£s)
Option 3 as per OBC	786	4,011,773	5,104.04
Option 3 – with final costs	786	3,846,097	4,893.30

The cost per benefit for Option 3 has reduced by £210.74 making it a more robust option. The driver for the reduction is that the unit price of the ALS Monitors / Defibrillators is lower than anticipated.

In addition, the risks and benefits have been reviewed regularly at project team meetings and no significant changes have taken place. Benefits and risks will continue to be monitored throughout the life of the project.

Section 5: Commercial Case

5.1 Procurement Strategy

The project will be delivered via a commercial framework (NP155/15 Defibrillators Lot 5) awarded by NHS National Services Scotland National Procurement. It has been developed fully within the European Union (EU) public sector procurement regulation framework. The framework contains a high level of detail aimed at the type of defibrillators required by the Service for responding to out-of-hospital cardiac arrests.

The framework is in place until February 2020. Additionally, any maintenance contract entered into with a termination date beyond February 2020 will be within the remit of the framework.

The following key benefits have been identified by choosing this procurement route:

- Earlier and faster delivery of projects from suppliers with prior NHS project experience
- Encourages long-term relationships between the supplier and NHS body.
- Certainty of time, cost and quantity
- Value for money

The framework provides Boards with the ability to do a mini-competition from the four suppliers on the framework. All four suppliers were invited to compete for the contract award, however only three submitted a proposal for consideration.

5.2 Selection of Preferred Supplier

The mini competition was published on PCS-Tender for the four suppliers listed within the Framework. All four suppliers were invited to submit bids. Those suppliers who submitted a bid and met the mandatory criteria were invited to provide ALS monitors / defibrillator units for use in field trials carried out by the Service's operational staff. Bids were received from three out of the four suppliers ([redacted]).

Only two suppliers met the mandatory criteria and subsequently progressed to field trials. The bid from [redacted] failed the mandatory criteria.

The ALS monitors / defibrillators units tendered by the suppliers were as follows:

[redacted]

<u>Field Trials</u>

This ALS monitor / defibrillator units provided by the two suppliers for the field trials were fitted to operational ambulances for operational use. Eight operational ambulances were dual fitted with one of the trial ALS monitor / defibrillators along with an existing [redacted] as a backup in case any issues arose. Field trials were conducted in six ambulance stations across the country (four stations had one dual fitted ambulance and two stations had two dual fitted ambulances). The units provided by the two suppliers were given to three stations each (two stations with one ambulance and one station with two ambulances). Trial sites only used one of the trial ALS monitor / defibrillators throughout the field trial period to prevent comparison of the units.

Staff at the six trial stations were trained in the relevant ALS monitor / defibrillator assigned to their station and Health and Safety and Infection Control assessments were carried out. Guidance was provided to staff along with support details and a feedback diary.

Engagement with the four Coronary Care Units (CCUs) who were receiving the trial units ECG transmissions was maintained during the period of the trials to monitor transmission functionality and to review any impact due to a change in supplier and technical solution.

The trials lasted for three months and at the end of the period, trial staff completed an evaluation survey. Results were gathered and collated.

In addition to the trials at the six ambulance stations, simulated scenarios using training equipment were developed and filmed. A number of staff across different stations from the field trials took part in this exercise. The results were reviewed and assessed by the Service's OHCA Clinical lead to provide additional feedback.

Scope of Services

The project involves the supply of ALS monitor / defibrillators for use in emergency response vehicles and the air ambulance service. This includes the development of electronic interfaces using wireless communication technology between the defibrillator units and the Service's existing ePR.

The contract also includes the provision of all related goods and services, training materials and support for Service trainers. Further inclusions are the servicing, maintenance and repairs of the devices as required, and the supply of appropriate accessories, consumables, spare parts and user manuals.

Selection Process

Several requirements were highlighted as mandatory and a supplier's failure to meet any of those essential outputs resulted in an unsuccessful bid. Non-mandatory criteria were scored in accordance with the following evaluation methodology:

Quality	Weighting	**Section Weighting**
Clinical Use	10	
Communications	20	
Installation	5	
Sustainability	3	**50**
Training	3	
Warranty, Servicing, Repairs & Business Continuity Planning	10	
Field Trials	20	**20**
Pricing	30	**30**
Total Score (100)	100	**100**

Summary of scoring process

The Quality Evaluation was carried out by assessing the bidders' responses against the evaluation criteria and specification. This was scored using the standard 0-4 Scoring methodology

0 Unacceptable	Nil or inadequate response. Fails to demonstrate an ability to meet the requirement.
1 Poor	Response is partially relevant but generally poor. The response addresses some elements of the requirement but contains insufficient/limited detail or explanation to demonstrate how the requirement will be fulfilled.
2 Acceptable	Response is relevant and acceptable. The response addresses a broad understanding of the requirement but may lack details on how the requirement will be fulfilled in certain areas.
3 Good	Response is relevant and good. The response is sufficiently detailed to demonstrate a good understanding and provides details on how the requirements will be fulfilled.
4 Excellent	Response is completely relevant and excellent overall. The response is comprehensive, unambiguous and demonstrates a thorough understanding of the requirement and provides details of how the requirement will be met in full.

Each evaluator reviewed the bids from each bidder, and scored independently. A consensus meeting was then carried out to agree a consensus score for each evaluation criterion and to generate a total quality score.

The scores for pricing and field trials were added to the quality scores to give a combined total score for each bidder. The winning bidder was the one who had the highest score.

Evaluation Panel

The evaluation panel consisted of a core team further supported by subject matter experts in the relevant areas. The core team consisted of:

- Yvonne Aitchison, Project Manager
- Paul Kelly, Clinical Governance Manager
- Jim McAspurn, Business Change Manager
- Jenna Ward, Procurement Specialist

Rejection of Offers

The bid from [redacted] Ltd did not progress to field trials, as it failed the mandatory criteria.

Final Recommendation

The outcome of the tender evaluation is as follows:

Quality	Weighting	[redacted]	[redacted]
Clinical Use	10	9.65	9.36
Communications	20	17.67	16.67
Installation	5	5.00	5.00
Sustainability	3	2.50	2.50
Training	3	2.34	1.56
Warranty, Servicing, Repairs & Business Continuity Planning	10	9.64	9.11
Field Trials	20	20	20
Pricing	30	30	26.25
Total Score (100)	100	96.80	90.45

Lowest Price	£[redacted]
Lowest Bidder	[redacted]
Score	4.00
Weighted Score (30)	30.00

Highest Price	£[redacted]
Highest Bidder	[redacted]
Score	3.50
Weighted Score (30)	26.25

Price Gap	**£**[redacted]

The winner bidder was [redacted] with their [redacted] unit.

5.3 Commercial and Contractual Arrangements

Payment Structure

The procurement involves the initial upfront purchase of the ALS monitors / defibrillator units with an ongoing repair and maintenance contract for the devices. The units will be purchased at the same time, under the same order number and charged together under one invoice which will be paid on receipt of the goods. Ongoing maintenance, service and consumables costs will be paid on an annual basis for the duration of the contract.

There are no non-standard payment structure arrangements.

Contractual arrangements

The standard National Procurement framework contractual arrangements will apply to this procurement. There is no requirement to separately compete for the interface development as this will be covered by the framework.

Contract duration

The proposed contract duration is 7 years with the option to extend for a further 3 years. The proposed warranty period for the units is 5 years. This is the standard warranty period for the units and a warranty extension would attract further costs.

Contract Management

The contract will be managed on a quarterly basis in accordance with the Service's local procurement policies which align to the Scottish Government Procurement Journey. The chosen supplier will be classified as a high risk strategic supplier and the level of contract management will be proportionate to this level of risk.

This contract will be included in the Procurement Contract Management programme with regular scheduled reviews based on the Balance Scorecard approach.

Contract management meetings will take place with Procurement, the Project Manager and the winning bidder on a regular basis during implementation, and will then decrease to quarterly for during 'in-life' management. Responsibility for contract management during the 'in-life' management phase will be passed to Procurement and Clinical staff.

Asset Ownership and Maintenance Responsibilities

The procured defibrillator units will constitute as fixed assets belonging to the Service. The contract specifies the ongoing maintenance responsibilities of the supplier for the contract's duration.

Contractual Remedies

The contract does not include any penalty causes. The nature of the contract is the procurement of medical equipment in which all machines are to be delivered at the same time. In the event of faulty equipment, the units are all subject to manufacturer's warranty which is valid for 5 years. In addition to this, all items of medical equipment sold are subject to regulations governed by the Medicines and Healthcare Products Regulatory Agency (MHRA). Any medical devices that are faulty or deemed to be unfit will be investigated by MHRA who will take any necessary action. It has been deemed that the aforesaid measures are proportionate to the level of risk associated with the project.

Compliance with Regulations and Standards

The mini-competition specification makes explicit reference to the applicable regulations and standards covering the defibrillator units which must be abided by.

Personnel Implications

On initial inspection it appears that the Transfer of Undertakings (Protection of Employment) Regulations 1981 (TUPE) are applicable. The current supplier of defibrillators to the Service

provides a member of personnel specifically employed to service and repair the units throughout the country. Where TUPE is deemed to be applicable, the new supplier will provide an opportunity for the staff member to TUPE if they wish.

5.4 Sustainability

As part of the tender process, suppliers were evaluated on their WEE compliance and their policies for improving the sustainability of the goods that will be supplied under the contract.

[redacted] have confirmed that they are responsible for WEE and battery regulations. They have confirmed they are registered in the National Packaging Waste Database (NPWD).

They have also provided copies of their environment and sustainability policies which are audited to the ISO 14001 (Environmental Management System) standard.

Section 6: Financial Case

6.1 Summary of Financial Case within the OBC

The following section summaries the estimates and assumptions that were contained in the OBC, approved in May 2018.

Funding Assumptions

The planning assumption is that funding for this project will be via an ear-marked Capital Allocation from the Scottish Government Capital Investment Group to support a capital procured solution. Any revenue costs associated with this project such as on-going support and maintenance and supply of consumables will be funded via the Service's core revenue budget in the relevant financial years funded by internal efficiency savings. The capital funding for this project will be required during financial years 2018/19 and 2019/20.

Costs of Preferred Option

The associated capital costs and revenue costs identified in the OBC for Option 3 was as follows:

Option	Capital Requirement in Year 1 £	Total Capital Requirement of Option £	Total Revenue Cost (Excluding Depreciation) over Contract Life £	Average Annual Revenue Cost £	Annual Depreciation Cost £
3	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Affordability

A funding gap of around £[redacted] per annum in revenue costs was identified in the OBC between Option 1 (baseline) and Option 3 (preferred way forward). This was been calculated by splitting the revenue funding gap across the 10 year project life, excluding non-recurring project costs (which total £[redacted] over the first 3 years of the project).

The funding gap was primarily due to the estimated increase in the consumable costs. The increase is driven by an increase in unit price rather than the volume of consumables anticipated. As the technology within the new ALS monitor / defibrillators has developed since the existing units were purchased, the consumables have adapted to be compatible and this has resulted in a significant increase in unit costs. Within the OBC a number of options to reduce the gap were identified:

- Options were explored with National Procurement regarding the purchase of non-peripheral consumables to ascertain whether this could reduce the funding gap.
- Options considering an in-house Medical Physics solution (with the Golden Jubilee) to reduce the commercial service contract.
- Options explored with Scottish Government regarding the non-recurring revenue project costs.
- Further negotiations on the consumable costs as the contract appointment progresses.

The additional revenue funding to be supported by the Service over the project life is:

Financial Year	Recurring Revenue (£)	Non-Recurring Revenue (£)	Total (£)
2018/19	[redacted]	[redacted]	[redacted]
2019/20	[redacted]	[redacted]	[redacted]
2020/21	[redacted]	[redacted]	[redacted]
2021/22	[redacted]	[redacted]	[redacted]
2022/23	[redacted]	[redacted]	[redacted]
2023/24	[redacted]	[redacted]	[redacted]
2024/25	[redacted]	[redacted]	[redacted]
2025/26	[redacted]	[redacted]	[redacted]
2026/27	[redacted]	[redacted]	[redacted]
2027/28	[redacted]	[redacted]	[redacted]
2028/29	[redacted]	[redacted]	[redacted]

When interpreting the above table, it is important to note the following:

- There will be no real saving in year 1 (2018/19) as the Service will still be responsible for purchasing consumables for the existing units before the new ALS monitors/defibrillators become operational.

- Whilst not financially measurable, it is expected that staff time will be saved once the units are fully operational. There will be fewer requirements for staff to input data and this will free up their time, allowing them to focus on clinical outcomes.

6.2 Confirmation of affordability

The financial case has been revised using the preferred supplier's tendered costs and this has resulted in the following changes from the estimates in the OBC as shown in the above section:

Revised Capital Requirements

Option	Total Capital Requirement of Option £	Capital Requirement in Year 1	Capital Requirement in Year 2
3 OBC Estimate	[redacted]	[redacted]	[redacted]
3 FBC Final Costs	[redacted]	[redacted]	[redacted]

The main reason for the reduction in the capital requirement from the estimates in the OBC is the unit price of the ALS Defibrillator / Monitors. The cost used within the OBC was £[redacted] plus vat per unit. The tendered cost from the successful supplier was £[redacted] plus vat per unit, thereby generating an overall reduction of £[redacted]. There has also been a reduction in installation and aircraft certification costs to give the total reduction in capital requirements of around £1.7m. The capital costs are broken down as follows:

Description	Total £	2018-19 £	2019-20 £
ALS Monitor / Defibrillators	[redacted]		[redacted]
Installation	[redacted]	[redacted]	[redacted]
Interface Development Costs	[redacted]	[redacted]	
Total Capital Costs	[redacted]	[redacted]	[redacted]

Revised Revenue Requirements

Option	Total Revenue Cost (Excluding Depreciation) over Contract Life £	Decrease from OBC
3 OBC Estimate	[redacted]	
3 FBC Final Cost estimate	[redacted]	[redacted]

Over the life of the contract the anticipated revenue costs have decreased by around £1.8m from the estimates presented in the OBC. This is mainly due to revised costs for consumables. The following table shows the revenue costs per annum over the 10 year contract:

	Total	2018/19	2019/20	2020/21	2021/22	2022/23	2023/24	2024/25	2025/26	2026/27	2027/28	2028/29
Ongoing Support, Maintenance & Repairs	[redacted]											
Consumables	[redacted]											
Implementation, Training and Project Support costs	[redacted]											
Disposal Costs	[redacted]											
Software Licence & IT Costs	[redacted]											
Mobile Data Charges	[redacted]											
Total Revenue Costs	[redacted]											

It should be noted that consumable quantities are based on the usage of the current [redacted] machines. This unit has had particular issues with the reliability of monitoring leads which has resulted in substantial quantities being consumed. It is anticipated that the [redacted] will not encounter these issues and therefore consumable costs will not be as high as forecast.

The Service will build a proposal to submit to SG to try and secure non recurring revenue support for the implementation and disposal costs in 2019/20.

Depreciation

The Service will incur deprecation costs of around £[redacted] per annum as a result of the capital purchase of assets for this project. This assumes a useful life of 10 years for the assets. This is an increase of around £[redacted] per annum from the charges for the current unit. The Service will be responsible for funding this from its non-core depreciation allocation.

Affordability

The OBC identified there was a revenue affordability gap at that time. The model has been re-run using actual costs and the results are as follows:

	2018/19 (£)	2019/20 (£)	2020/21 (£)	2021/22 (£)	2022/23 (£)	2023/24 (£)	2024/25 (£)	2025/26 (£)	2026/27 (£)	2027/28 (£)	2028/29 (£)	TOTAL (£)
Option 1: Do Minimum	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Option 3: Replace existing units with ALS monitor / defibrillator Unit and enhanced technology	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Funding gap	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Excluding non-recurring revenue, there remains an average annual core revenue funding gap of around £[redacted]. There are two main drivers for the funding gap:

- The quantities used for the consumable costs are based on usage incurred with the [redacted] machines. There have been issues with reliability of certain consumables for the MRX, in particular the monitoring leads, which has driven up the usage over recent years. The [redacted] uses newer technology and it is therefore anticipated that quantities required will be lower, thereby reducing the funding gap.
- The software costs associated with live streaming is around £[redacted] per annum. Live Streaming provides the ability for a remote user, e.g. clinical specialist, to connect to a specific defibrillator in real-time, via a secure browser session. This facilitates remote monitoring of a patient to allow appropriate medical advice to be given to the attending crew for best patient treatment and outcome. This was a non – mandatory element of the tender that the clinical team have since confirmed they would like to progress.
- The [redacted] model requires battery replacement at Year 6. As the model has three batteries within the unit all three batteries need to be replaced. This estimated cost is around £[redacted]. The battery replacement programme relating to the existing model was included as part of the support and maintenance contract and therefore no additional cost was incurred. This option is not available within the contract for the new units.

The Service has explored an in-house Medical Physics solution for support and maintenance with NHS Greater Glasgow & Clyde and NHS National Waiting Times Hospital (Golden Jubilee), however neither solution proved feasible and both options were more expensive than the cost of support and maintenance from the supplier.

Confirmed Funding Arrangements

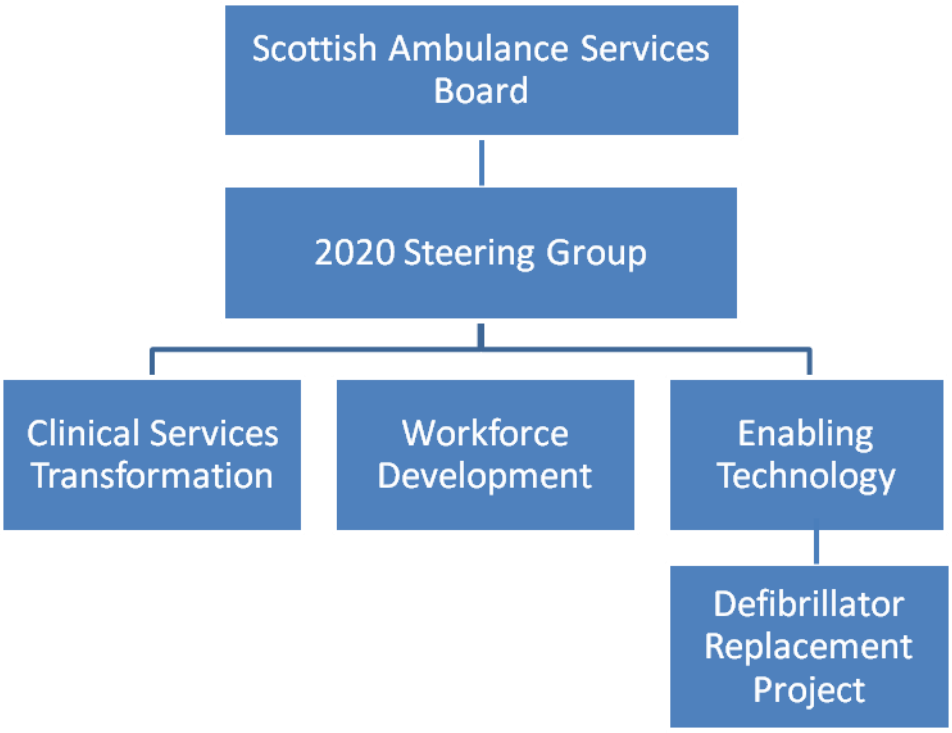
The capital costs associated with this project will be funded via an earmarked capital allocation from Scottish Government following approval of this FBC by the Capital Investment Group.

The revenue costs associated with this project will be funded by the Service's core revenue budget. The Service incorporated the revenue costs within its Financial Plan and has prepared plans to manage the cost pressure associated with the funding gap between the existing units and the replacement [redacted]. As the ALS monitoring / units are the Service's primary response equipment, operational staff must be provided with reliable equipment. The Service recognises that this project must be implemented and has explored all areas of reducing the funding gap during the period between OBC and FBC. As the estimated consumables cost is based on the existing quantities associated with the [redacted], it is hoped that once implementation is complete, actual quantities required for the [redacted] will be less and therefore the consumables cost will reduce. The Service will monitor consumables usage closely to ensure costs are contained as far as possible.

Section 7: Management Case

7.1 Reporting Structure and Governance Arrangements

A high level governance structure has been established by the Service to monitor all programmes of work and to provide governance in line with the published Strategic Framework. This is summarised below.



The project will report to the 2020 Steering Group via the Enabling Technology Programme Board, providing regular Highlight Reports and representation at meetings. The Enabling Technology Programme Board has been established and authorised by the Scottish Ambulance Service Board to act on behalf of the Board, monitoring, controlling, reporting on progress and providing governance on all Enabling Technology activities.

The project structure will include a Project Team and a Project Board. The Project Team will meet regularly and report to the Project Board.

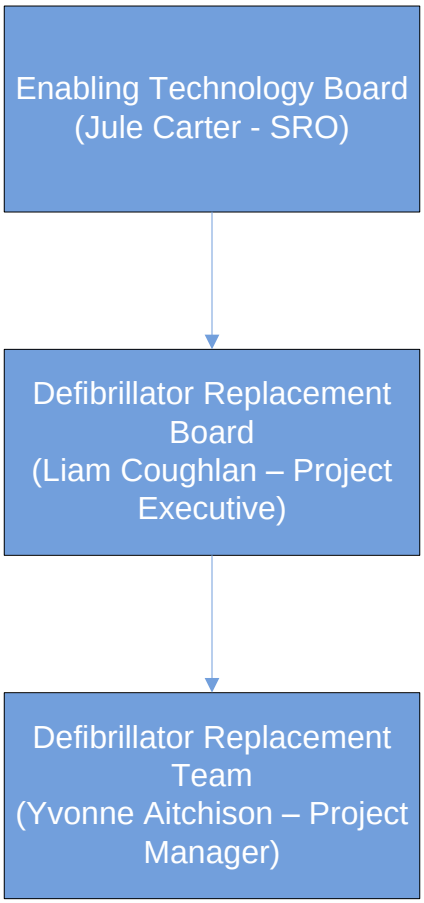
<u>Enabling Technology Programme Board</u>

The Enabling Technology Programme Board is responsible for the following:

- To provide strategic direction and guidance
- To ensure the programme remains aligned to the Service's Strategy
- To ensure the Business Case remains valid
- To monitor the programme progress at key intervals through regular highlight reports
- To review risks and issues and to provide guidance where necessary on resolution
- To report progress to the Service's 2020 Steering Group

Key Roles and Responsibilities

The following figure and tables detail the project organisation structure.



Enabling Technology Programme Board Members		
Project Roles & Main Responsibilities	**Named Person**	**Experience of Similar Project Roles**
Senior Responsible Owner (SRO) - Senior finance representative – representing the organisation's business and financial interests	**Julie Carter**	Scottish Ambulance Service Director of Finance and Logistics Project involvement
Programme Manager – responsible for overall Enabling Technology Programme delivery	**Liam Coughlan**	Experienced Programme Manager
Programme Director	**John Baker**	Head of the Scottish Ambulance Service ICT Project experience – Police Scotland & Scottish Ambulance Service Participates in Gateway Reviews
Business Change Manager	**Jim McAspurn**	Experienced Paramedic Involvement in similar clinical and ICT projects
Procurement specialist	**Jenny Neville**	Head of the Scottish Ambulance Service Procurement Wide experience in delivering projects
Stakeholder representative – representing stakeholders' interests	**Steven Gilroy**	Experienced paramedic Staff & Union representative

Patient representative – to represent patient interests on the Board	**Martin Hunter**	Patient Representative on the ET board since inception, overseeing numerous projects
Clinical representative – representing Clinical Service Transformation on the Board	**Paul Gowens**	Service Lead Consultant Paramedic. Programme Director for Clinical Service Transformation Programme. Involvement in previous defibrillator procurements.
Operations Representative – representing stakeholders' interests	**Graham MacLeod**	Experienced operational manager. Airwave Senior User.

Defibrillator Replacement Project Board Members		
Project Roles & Main Responsibilities	**Named Person**	**Experience of Similar Project Roles**
Project Executive	**Liam Coughlan**	Senior Finance Manager Experienced Project Accountant Similar Project involvement
Project Manager	**Yvonne Aitchison**	Experienced Project Manager
Operational Senior User	**Julie Shields**	Represented Operations on previous Service-wide implementation projects
Clinical Senior User	**Paul Gowens**	Service Lead Consultant Paramedic. Programme Director for Clinical Service Transformation Programme. Involvement in previous defibrillator procurements.
Health and Safety Representative	**Tony Wigram**	Has provided Health and Safety advice on numerous Service projects
Project Assurance	**Rebecca Board**	Experienced Project Manager. Programme Manager for Enhancing Capability Programme

Defibrillator Replacement Project Team Members		
Project Roles & Main Responsibilities	**Named Person**	**Experience of Similar Project Roles**
Senior finance representative – representing the organisation's business and financial interests	**Melanie Barnes**	Senior Finance Manager Experienced Project Accountant Similar Project involvement
Senior service representative – representing the technical aspects of the project	**Steven Short**	Specialist in OHCA Involvement in similar projects Vested interest in the Scottish Ambulance Service success
Senior technical (information, communications and technology) representative – representing the technical aspects of the project	**John Burns**	Experienced ICT Team Leader Involvement in Telehealth and previous OHCA solutions
Procurement representative	**Jenna Ward**	Senior procurement specialist at SAS Wide experience in procurement and contract management to support project and BAU requirements

Stakeholder representative – representing stakeholders' interests	**Paul Kelly**	Seasoned paramedic with lots of front line experience Involved in previous defibrillator rollout User of current and future devices
Project Manager	**Yvonne Aitchison**	Experienced Project Manager
ICT Training Lead	**Colin Gough**	Experienced ICT Trainer
Networks and Security advisor	**Robert Kay**	Network & Security Manager
Education Lead	**Vicky Burnham**	Experienced Education Lead
Health and Safety advisor	**Graham Forman**	Experienced Ergonomist
Operational input	TBC	TBC –role to be filled by experienced operational staff

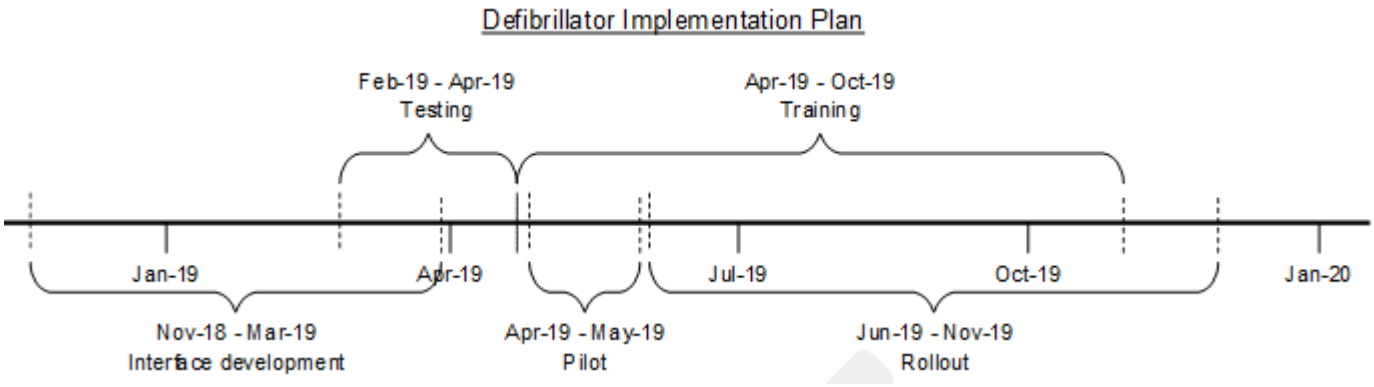
The project will be managed in line with established PRINCE2 methodology, utilising the following tools where appropriate:

- Project Initiation Document
- Project Plan
- Highlight Reports
- Exception Reports
- Risk Registers
- Issue Registers
- Lessons Learned Reports
- Quality Plan
- Request for Change
- Work Package
- End of Project Report

<u>Project Recruitment Needs</u>

The project will be fully delivered by the Service and does not intend to utilise shared support from other NHS Boards or the wider public sector. There may be some requirement for the Service to recruit for specialist roles on a fixed term appointment basis.

7.2 Project Plan and Key Milestones



A more detailed project timeline is included in Appendix A – Project Timeline

7.3 Operational and Service Change Plan

There will be no major operational or service change as a result of this project because it simply involves the replacement of existing medical equipment.

New processes will be implemented in terms of data transfer and live streaming. To achieve successful change management outcomes for these areas, key staff will continue to be involved in a process of developing detailed operational policies and service commissioning plans. Staff will be provided with appropriate training and support prior to implementation of these processes.

7.4 Project Changes and Exceptions

Change control is the process to ensure that all requests for change to the original project specification are controlled. Requests for change will initially be logged as project issues and then recorded in the change register. The project will follow an agreed change control process, with all project changes out with agreed tolerances going to the SRO and/or Programme Board for approval. Appendix B shows the outline of the project change control process.

Exceptions will be managed firstly via a report to the Project Executive and this will be escalated as appropriate to the Project Board and Senior Responsible Owner.

The monitoring and control strategy will be reviewed as part of the audit process to assess its effectiveness. Any lessons learned will be recorded in the project lessons learned log for use in this and future projects.

7.5 Workforce Training and Development Plan

A variety of training formats (train the trainer, classroom training and online modules) and materials (paper, electronic) will be developed and delivered to ensure staff are well prepared, confident and supported throughout the rollout of the new defibrillator devices into operational use, as well as any additional functionality, i.e. ePR updates, receiving centre alerting, etc.

Standard processes will also be updated to ensure new staff and progressing staff are trained and familiarised with the latest equipment and procedures. These will be aligned to Service polices in terms of Health and Safety and improving patient care.

7.6 Benefits Realisation

Delivering benefits is a key focus of the Service's Enabling Technology Programme as they are a fundamental determinant of the success or otherwise of the Programme. As a project under the Enabling Technology Programme, the Defibrillator Replacement Project will follow the same approach to realising benefits.

The benefits of the programmes and projects run as part of the Enabling Technology Programme are realised through the following mechanisms:

- Benefits workshops will be held to identify, define and prioritise the benefits and disbenefits and these will be recorded in dedicated benefits registers. All benefits will be describable; observable; attributable; and, measurable (DOAM Test).
- A benefits realisation plan will be created to track the realisation of benefits across the programme and set review controls.
- Benefits will be base-lined prior to the introduction of any changes that the programme delivers and measured again after the changes have become embedded into the business.
- The Enabling Technology Business Change Manager will have the core responsibility of realising the benefits of the project by ensuring that the outcomes delivered by the programme are embedded into the business.

Updated Benefits Register

A benefits and risks workshop was held on 23rd August 2017 which was attended by a range of staff across the Service including clinical and operational, information and communications technology and finance staff. A further benefits workshop was carried out on 4th June 2018 and the benefits register was updated. The latest benefits register, including their measurement methodology, has been agreed and is included in Appendix C – Benefits Register & Realisation Plan. The benefits criteria are all desirable outcomes for the preferred option.

Full Benefits Realisation Plan

The benefits identified will be monitored in line with the Benefits Realisation Plan (Appendix C).

Benefits will be reviewed regularly at project team, project board and programme board meetings and there will be a formal benefits review at the end of each project and /or at appropriate points during a project, e.g. end of a phase/stage. Any lessons learned will be recorded for use in this and future projects.

The post project review will have a particular focus on benefits realisation.

7.7 Risk Management

A risk can be defined as an uncertain event or set of events that, should it occur, will have an effect on the achievement of objectives. Risks will initially be identified through workshops for each of the constituent programmes and projects. The risks will be assessed using the Scottish Ambulance Service risk analysis tools as detailed in Appendix D – Risk Assessment Matrix. All risks will be captured in the relevant project Risk Register. All risks will be given an owner who will be ultimately responsible for managing the risk.

Risks that are scored ‘High’ or ‘Very High’ will be added to the Enabling Technology Programme Risk Log as will any other risk that may have a direct effect on the wider Enabling Technology Programme.

Risk registers will be circulated and reviewed at every project team, project board and programme board meeting. Dedicated workshops will be held twice a year to review and update risk logs. New or changed risks will be included in the highlight report that goes to the Enabling Technology Programme Board for review.

As one would expect, the Service has a long track record of procuring replacement equipment effectively and efficiently. Nevertheless, the risks of the project and means of managing these risks are outlined in the Risk Register (Appendix E) which was reviewed at the benefits and risks workshop held on 23rd August 2017 and again more recently on the 4th June 2018.

Preventative actions and contingency plans have been agreed and a risk owner has been identified. The risk register will be actively managed by the Project Manager and reviewed on a monthly basis. A proactive approach to risk management will be taken, allowing the Project Manager to track and manage any risks as they arise.

7.8 Transition into Service/Business As Usual

The following details outline the transition into service plan:

- Reporting structure is aligned to the main project governance structure
    - This will be managed by the Project Manager and key Operational leads reporting to the Project Team and Project Board

- Key stages
    - Communications Plan
    - Equipment purchased
    - Interfaces developed and tested
    - Receiving Centres/CCUs trained and ready for Go-Live
    - Staff Training confirmed
    - Devices installed, configured, tested and signed off
    - Legacy equipment de-installed and disposed of
    - Service Desk scripts and procedures developed, tested and signed off
    - Contract and support and maintenance agreements in place
    - Transition period from project to BAU completed and signed off
    - Review and update processes, where necessary
    - Accepted into daily service operations

- Resource requirements
    - Divisional/Station Leads/ICT/Supplier/Training/Fleet

7.9 Post Project Evaluation

The project will also be formally evaluated 6 months after full implementation with a view to improving future project appraisal, design, management and implementation. The process will essentially consider the extent to which the desired outcomes and benefits of the project have

been realised and to what extend the actual project inputs varied from what was planned. Ongoing assessment of benefits will be monitored, recorded and reported on.

Post Project Evaluation Process

The full evaluation is a three stage process as summarised below:

	Stage	Description
Stage One	Project Appraisal	Plan and cost the scope of the post project evaluation exercise. This is carried out at the outline business case/full business case stage
Stage Two	Evaluate Project Outputs	Monitor the progress and evaluate outputs (tangible assets) on completion of implementation.
Stage Three	Review the Outcomes	The service aspects of the project shall be reviewed once it is operational. The desired outcomes shall be compared against the actual project outcomes. The actual project inputs (capital and revenue costs, time, and project management resources) will be compared to the estimated inputs detailed in the full business case stage. Completion of this stage is expected to take between one to three months.

Evaluation Team

The Evaluation Team will comprise of in-house resources. Their role is to assess the extent to which the project had been implemented as planned and to propose any lessons that might be usefully incorporated into the next project. The project will also undergo the Scottish Gateway Review Process.

Quality in Projects

All projects will be managed in line with PRINCE2. Projects will detail their acceptance criteria against which the quality will be reviewed to ensure that the products delivered are fit for purpose. Where applicable, products will be delivered in line with any regulations, standards and guidelines. All test cycles will have detailed test plans with appropriate sign-off of competed test scripts.

Assurance

The project will be subject to internal audit. The Service uses Scott Moncrieff to conduct internal audits on programmes and projects within the Service. Where appropriate, projects will use the Scottish Government Risk Potential Assessment Use form to assess the suitability or otherwise for the project to undergo the Scottish Government Gateway Review process.

All projects will be required to produce and complete a project assurance plan and will have a Project Assurance Lead on the Project Board. In addition to this, all projects will go through 'go-live' gateways, where a final decision on the progress or otherwise of each project will be decided.

Review

The quality and assurance strategy will go to both the Project Team and Programme Board for approval. The strategy will be reviewed and updated regularly and particularly at any Business Case reviews.

The strategy will also be reviewed as part of the audit process to assess its effectiveness. Any lessons learned will be recorded in the project lessons learned log for use in this and future

projects. The post project review will reference this strategy to assess how well it was implemented by the Project.

Post Project Review

Following a bedding-in period, a post project review will be undertaken to assess the following points;

- Have the project outcomes been delivered?
- Have all relevant tasks been carried out to deliver the project requirements/objectives?
- Has the solution been successfully transitioned over to BAU?
- What lessons have been learned – positive and negative – to inform future projects?
- Benefits Realisation on track and review and assessment plan in place to monitor and report on progress?
- Have all risk and issues been addressed, removed or mitigated?

Section 8: Conclusion and Recommendation

8.1 Preferred Supplier Statement

This FBC has revisited the outcomes of the OBC. The preferred option for investment is **Option 3** (Replace existing units with Advanced Life Support (ALS) monitor/defibrillator unit and enhanced technology) maximising benefits to patients, staff and healthcare partners alike whilst carrying minimal business risk. This option compliments the aims of the Scottish Government's OHCA Strategy and eHealth Strategy. Additionally, this option meets the aims of the Service's 2020 Strategy by enabling more people to be cared for at home or in a homely setting.

Risks, benefits and operational requirements workshops have been held with key stakeholders to ensure that any changes to information have been identified and considered fully in this FBC.

A procurement process has been carried out for the purchase of ALS monitors / defibrillators and this determined the following solution best meets the service requirements:

- The solution offered by [redacted]

The project will deliver the following objectives:

- To increase the early identification of critically ill and deteriorating patients and the number of patients who have return of spontaneous circulation for VF/VT by March 2020
- To improve the quality of CPR real time feedback, using new and improved technology built in to defibrillator pads by March 2020
- To provide a solution which supports access to clinical audit data to aid clinical decision making and improve training and development of staff by March 2020
- To deliver a data interface from the hardware solution to the ePR to allow automatic population of clinical data by March 2020
- To deliver hardware which supports wireless communication and data sharing by March 2020
- To reduce repair costs of the monitors/defibrillators by providing newer, more reliable units by March 2020

8.2 Recommendation

This FBC has been produced in accordance with the guidance issued by the Scottish Government Capital Investment Group and the outcome has shown that the preferred supplier is [redacted] as their solution presents value for money and is affordable.

It is recommended that the Capital Investment Group approve this FBC and the following outcome:

- Contract award to [redacted] for the purchase of [redacted] ALS monitor / defibrillators

Appendix A – Project Plan Milestones

Milestones	Outcomes	Outline of work to be undertaken	Timescale
Project Initiation	• FBC approval • Finalised project organisational structure • Project Board/Project Team terms of reference reviewed • PID • Project Plan • Communications Strategy and Plan • Change Management Strategy • Benefits Register • Risk Register • Reporting Format	Plan Project Initiation; develop core project documentation, final governance structure, regular reports, meetings & communications	Oct-Dec 18
Procurement	• Contract • Purchase Orders • Invoices • Contract Performance	Contract awarded and purchase order raised, SLAs/Support & maintenance agreed; ongoing accessories and consumable needs. Quarterly meeting with supplier to review performance.	Nov 18 then POs as required from contract award.
Interface Development	• Requirements specification • Interface Design • Interface development • Prototype	Interface: confirm specification of requirements, supplier development to develop an interface for testing and implementation.	Nov 18 – Apr 19
Testing	• Test Scripts • Issues Tracker	Testing: develop test scripts, establish resource and dates/times required for each testing area/phase; track	Feb 19 – Apr 19

Milestones	Outcomes	Outline of work to be undertaken	Timescale

	• Testers & Testing Schedule
	  ○ Interface UAT
	  ○ H/W Acceptance
	  ○ Vehicle Fitting Acceptance
	  ○ Connectivity UAT
	• PVIDs
	• Service Readiness
		and resolve issues/changes, develop appropriate vehicle installation documentation (PVIDs); ensure relevant detail is captured for transition into BAU	Mar/Apr 19
			May – Nov 19

Pilot/Trial	• Trial Script • Trial Schedule • Tracker • Evaluation • Signoff	Pilot; establish trial criteria, timescale, resource, feedback & assessment to address any outstanding actions before accepted & signed off	Mar 19 – May 19

Training	• Training Needs Analysis
	• Further requirements
	• Training materials
	  ○ Train the Trainer
	  ○ Classroom Training
	  ○ Online module(s)
	• Trainee & Training Schedules
	• Staff Training Signoff
	• Policy, Process and Procedure Updates
		Training: Service requirements identified, courses & materials developed to meet needs; establish trainer /trainee requirements; trainees & training schedules; confirmation of training delivered; ensure all relevant Policies, Processes, Procedures updated and in place for BAU.	Dec 18 – Feb 19
			
			Apr 19 – Oct 19

Rollout (phased implementation	• Requirements • Rollout Schedule	Rollout: establish all activities involved in rollout; resource, timings, locations, vehicles, de-install of old	May 19 – Nov 19

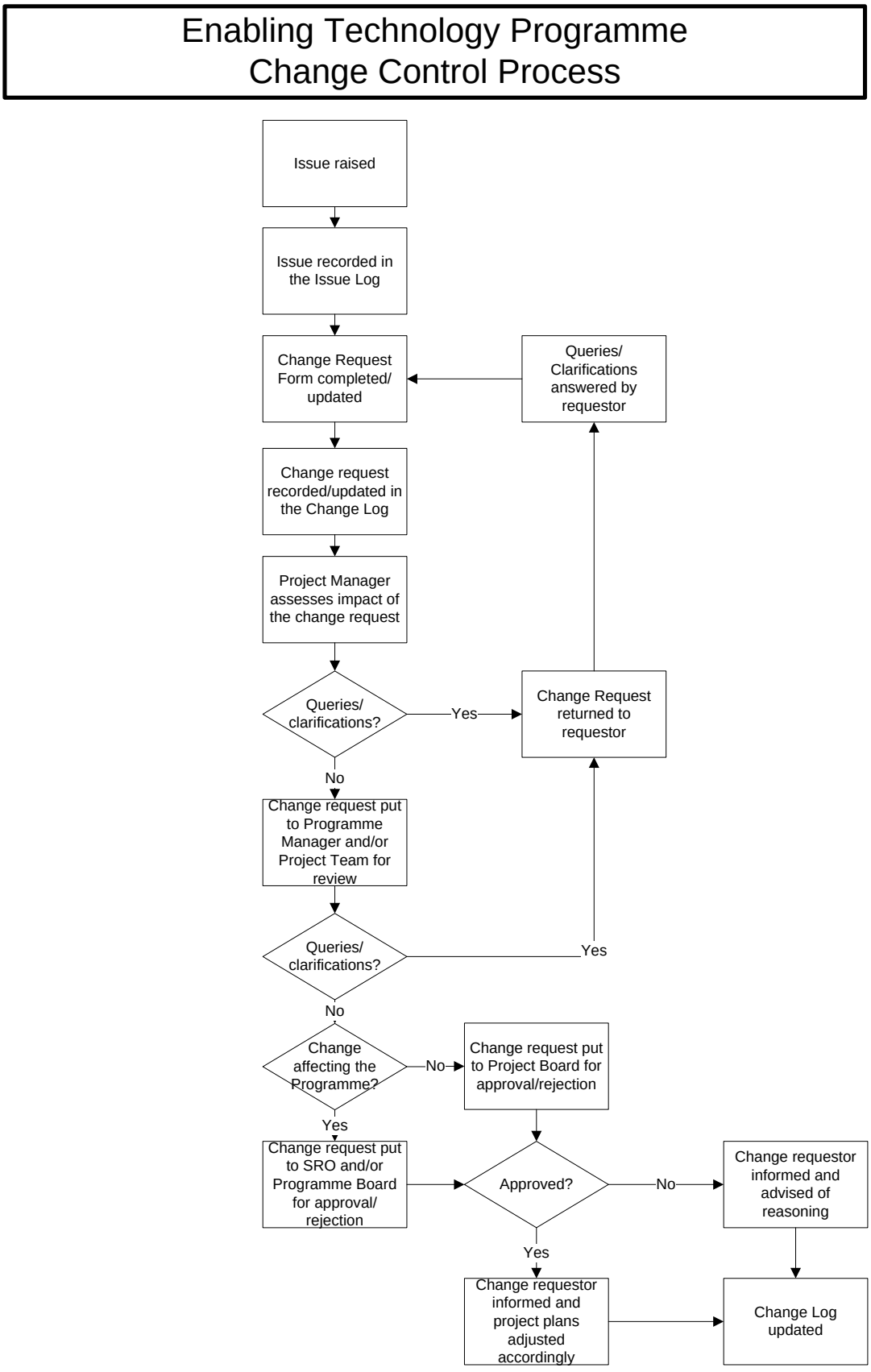
Milestones	Outcomes	Outline of work to be undertaken	Timescale

across regions; North, West and East.)	• Check List
	  ○ Vehicle fitting
	  ○ Device install
	  ○ Connectivity
	  ○ Consumables
	  ○ Asset Management
	• Commissioned in to Service
		and installation of new devices and brackets; configure and test device & connectivity; accessories/consumable supplies; asset tagged and added to the Service's assets; approved for Service use and passed in to operation service.	May 19 – Nov 19

Disposal	• Decommissioning Check List • Disposal Process and Signoff	Disposal: ensure all old hardware is identified, cleared of any data /identification & stored appropriately until disposed of by the method agreed by the project; remove from the Service's assets.	Jun 19 – Dec 19
Service Transition (Phased in line with Rollout)	• Service Desk Scripts • Service Desk procedures • Transition period • Handover to BAU	Transition: Establish the process for staff to report any issues with new devices, interface & connectivity; support procedures & SLAs dependent on the issue, provide project support during transition period until support fully handed over to BAU	May 19 – Nov 19
Business Continuity (BC)	• The Service Business Continuity Plan • Supplier BC arrangements	Business Continuity (BC): Update & cascade BCP actions; confirm, record and agree supplier BC arrangements in supporting the Service	By Nov 19
Project Closure	• Post Project Evaluation • End of Project Report • Share Lessons Learned • Benefits Realisation	Closure: assess whether the project delivered the objectives and outcomes. Have risks been closed or mitigated? What lessons have been learned to aid future projects? Who will be responsible for	Dec 19 – Mar 20 Ongoing assessment

Milestones	Outcomes	Outline of work to be undertaken	Timescale
		outstanding/ongoing task?	of benefits.

Appendix B – Project Change Control Process



Appendix C - Benefits Register and Realisation Plan

Benefit ID	Benefit Category	Benefit Description	Who Benefits	Measurement Criteria	Actions	Baseline Observation	Dependencies	Post Implementation Observation	Owner	Benefits Status
ET-DRP-001	Operations / Finance	The provision of new equipment will reduce the number of power / battery faults / failures reported for the first 2 years post-implementation	Patients – more effiicient and safer healthcare provided as a result of reduced equipment failure Ambulance Crews – reliable hardware which is fit for purpose Operational Performance – improved patient outcomes as a result of reduced equipment failure Supplier – few maintenance visits to equipment	Number of confirmed hardware/software faults reported during the year pre and post implementation	Obtain reports via Datix / supplier	208 helpdesk reported issues 24 May 2015 - 23 May 2016 148 helpdesk reported issues from 24 May 2016 - 24 May 2017 Total 356 over 2 years Breakdown of figures on attached sheet.			BCM	
ET-DRP-002	Operations / Finance	The provision of new equipment will reduce the number of Cable / Consumable faults / failures reported for the first 2 years post-implementation	Patients – more effiicient and safer healthcare provided as a result of reduced equipment failure Ambulance Crews – reliable hardware which is fit for purpose Operational Performance – improved patient outcomes as a result of reduced equipment failure Supplier – few maintenance visits to equipment	Number of confirmed Cable or consumable faults reported during the	Obtain reports via Datix / supplier				BCM	

				year pre and post implementation						
ET-DRP-003	Operations / Finance	The provision of new equipment will reduce the number of Telemetry faults / failures reported for the first 2 years post-implementation resulting in more reliable diagnosis and treatment	Patients – more effiicient and safer healthcare provided as a result of reduced equipment failure Ambulance Crews – reliable hardware which is fit for purpose Operational Performance – improved patient outcomes as a result of reduced equipment failure Supplier – few maintenance visits to equipment	Number of confirmed Telemetry faults / failures reported during the year pre and post implementation	Obtain reports via Datix / supplier				BCM	
ET-DRP-004	Operations / service	It will be less time consuming to input information on the device providing an enhanced user experience	Ambulance Crews – less time spent inputting data thereby allowing more efficient healthcare	Number of keystrokes / button presses to insert basic required patient data on Defib / Monitor	Run simulation of data entry using same patient details on both old and new devices and compare number of actions required.		Device not yet agreed - may not be realised		BCM	
ET-DRP-005	Operations / Patients	The equipment will support treatment compliance	Patients – optimising treatment Ambulance Crews – reduction in mistakes during diagnosis/treatment Service – reduced risk of litigation from errors	Compare treatment compliance rates pre and post implementation Review CPR feedback			Device not yet agreed - may not be realised		BCM	

ET-DRP-006	Finance	The provision of new equipment will reduce the number of maintenance faults reported	Finance – reduced expenditure on fault resolution	Expenditure on fault resolution across monitor / defibrillator asset base pre and post implementation	Seek financial report / prediction from current supplier	2016/17 costs: Defibrillator = £92105.55 Accessories = £30206.31 Total = £122221.86			BCM	
ET-DRP-007	Operations	The new equipment will be smaller and lighter than the current equipment	Ambulance Crews – reduction in injuries related to equipment weight	Compare the size and weight of the existing equipment and new equipment Datix reports of injury due to handling for set period	Physical dimensions from supplier and assessment Obtain Datix report		Device not yet agreed - may not be realised		BCM	
ET-DRP-008	Operations	The new equipment will provide a technology interface to the Ambulance Telehealth Equipment for data population and transmission	Ambulance Crews - enables automatic population of clinical data to ePR	Confirmation that monitor / defibrillator units are supported by the comms hub and tablets as part of the testing	Scripted test for connectivity and evidence from suppliers	The current defib interface relies on outdated Bluetooth technology and no connection is possible to	Device not yet agreed - may not be realised		BCM	

				process		either our interim ePR or the future ePR without significant expenditure				
ET-DRP-009	Operations	Improved design and location of device securing bracket in vehicle improves ergonomic properties and reduces injury risk	Ambulance Crews – design of bracket provides single handed operation improving ergonomics	Compare how and where the monitor / defibrillator unit is accessed pre and post implementation. Staff feedback. Assessment from Ergonomics lead.	Practical assessment		Device not yet agreed - may not be realised		BCM	
ET-DRP-010	Operations	The provision of a new device will improve print quality due to improved resolution of print out	Ambulance Crews – print out will be clear and legible Receiving Centre – print out will be clear and legible	Staff survey pre and post implementation to measure printout legibility and staff perception	Comparison view of various ecg rhythms available for assessment on both version printouts.		Device not yet agreed - may not be realised - May be disbenefit re position of printer on chos		BCM	

							en devi ce			
ET - DR P- 01 2	Op erat ion s / Pati ent s	The equipment will have the ability to transfer ECG data via the in-vehicle communications hub to the receiving treatment centre reducung the risk of failed transmission and providing a clearer diagnostic tool	Patients – reliable transfer of clinical data to receiving centre results in more accurate treatment Patient / Operations– reduced number of secondary transfers as patients taken to the receiving centre most able to provide treatment Receiving Centre – timely access to clinical data improves clinical decision making	Staff and Health care partne r surve y of curre nt arran geme nts	Scripted end to end test of data transfer and ECG delivery / recognition at receiving centre	The curre nt defib trans mits data to recei ving centr es via outda ted Blue ooth techn ology . It has prove n diffic ult to sourc e the mobil e phon e versi ons requi red to carry out this transf er when repla ceme nts are requi red and has repor ted trans missi on failur es.	Devi ce not yet agre ed - may not be reali sed		B C M	
ET - DR P- 01 3	Op erat ion s	The equipment software will be able to apply software remotely and will eliminate the need to take the defib / monitor out of use to perform updates	Patients – quicker ambulance response times as a result of less vehicle downtime Operations – less vehicle downtime as a result of software updates Supplier – complex logistical rollout eliminated	Confir m softw are updat es can					B C M	

				be performed remotely and compare vehicle downtime pre and post implementation						
ET-DRP-014	Operations / Service	Automatic population of clinical data from the monitor / defibrillator unit will result in an improved accurate completion of key data fields in the ePR as a result of less key strokes/ manual entry errors	Service – ePR data will be more complete and accurate. Clinical governance and audit data will be more reliable	Report number of preagreed incidents where it is expected to have observations from the monitor / defib and data is missing from ePR over a set time period.	Ask MI team to provide report				BCM	
ET-DRP=016	Operations / Patients	Increased functionality will allow increased options of treatments for patients e.g. Pacing / cardio-version	Patients - increased number of treatment options for various conditions Staff - Increased opportunity for skill improvement and development of new skills	Compare functionality available and used on current Defib with that on			Staff skill levels / training		BCM	

				new defib						
ET-DRP=017	Operations / Patients	The ability to provide instant feedback via the vehicle tablet device for post incident analysis	Ambulance Crews - Ability to review CPR performance as soon as practical after an event to allow learning / understanding.	Compare current feedback options / process			Vehicle tablet needs to facilitate access to web site - Access rights to web site.		BCM	
ET-DRP=018	Service	More efficient access to audit information	Service - New web based data portal with wider access for managers - accessible at station level	Compare current process for accessing audit information			Supplier not yet agreed - traign requirements and timescales.		BCM	
ET-DRP-D01	Finance	Use of third party consumables will negate some warranty conditions on the new equipment	Service - Risk of equipment failures / faults will not be covered under warranty creating unexpected costs.	Warranty agreement / supplier recommendations		Currently use third party shock and monitoring pads and printer paper.	Warranty terms and contract agreement		BCM	
ET-DRP-D02	Operations / Service / Financ	Removal of the requirement to provide a mobile phone for ECG transmission reduces the crews access to a telephone for operational communications when other means are unavailable.	Operations - no communications resiliance if radio / data fails and crews may have to use their own personal devices for voice communications	Number of times the in vehicle phone is used	Ask telecoms for report on number of telephone calls made from vehicle devices over a 6 month period to gauge the operationa limpact and refer to Operations for decision.	The new defib will have an inbuilt SIM (or			BCM	

	e			to make telephone calls rather than data transmission		similar) but ideally connect direct to the vehicle communications hub directly as default. This project does not include the replacement / update or maintenance of a mobile phone. Operations will need to consider the requirement and securing funding if they want to replace the mobile phone.				

Appendix D: Risk Assessment Matrix

Table 1 – Impact/Consequence Definitions

Descriptor	Negligible	Minor	Moderate	Major	Extreme
Patient Experience	Reduced quality of patient experience/clinical outcome not directly related to delivery of clinical care.	Unsatisfactory patient experience/ clinical outcome directly related to care provision – readily resolvable.	Unsatisfactory patient experience/ clinical outcome; short term effects – expect recovery <1wk.	Unsatisfactory patient experience/ clinical outcome; long term effects – expect recovery >1wk.	Unsatisfactory patient experience/ clinical outcome; continued ongoing long term effects
Objectives / Project	Barely noticeable reduction in scope, quality or schedule.	Minor reduction in scope, quality or schedule.	Reduction in scope or quality of project; project objectives or schedule.	Significant project over-run.	Inability to meet project objectives; reputation of the organisation seriously damaged.
Injury (physical and psychological) to patient/visitor/staff	Adverse event leading to minor injury not requiring first aid.	Minor injury or illness, first aid treatment required.	Agency reportable, e.g. Police (violent and aggressive acts). Significant injury requiring medical treatment and/or counselling.	Major injuries/long term incapacity or disability (loss of limb) requiring medical treatment and/or counselling.	Incident leading to death or major permanent incapacity.
Complaints / Claims	Locally resolved verbal complaint.	Justified written complaint peripheral to clinical care.	Below excess claim. Justified complaint involving lack of appropriate care.	Claim above excess level. Multiple justified complaints.	Multiple claims or single major claim Complex justified complaint
Service / Business Interruption	Interruption in a service which does not impact on the delivery of patient care or the ability to continue to provide service.	Short term disruption to service with minor impact on patient care.	Some disruption in service with unacceptable impact on patient care. Temporary loss of ability to provide service.	Sustained loss of service which has serious impact on delivery of patient care resulting in major contingency plans being invoked.	Permanent loss of core service or facility Disruption to facility leading to significant “knock on” effect.
Staffing and Competence	Short term low staffing level temporarily reduces service quality (< 1 day). Short term low staffing level (>1 day), where there is no disruption to patient care.	Ongoing low staffing level reduces service quality. Minor error due to ineffective training/implementation of training.	Late delivery of key objective / service due to lack of staff. Moderate error due to ineffective training/implementation of training. Ongoing problems with staffing levels.	Uncertain delivery of key objective/ service due to lack of staff. Major error due to ineffective training/ implementation of training.	Non-delivery of key objective/service due to lack of staff. Loss of key staff. Critical error due to ineffective training/ implementation of training.
Financial (including damage / loss / fraud)	Negligible organisational/ personal financial loss. (£<1k). (NB. Please adjust for context)	Minor organisational/personal financial loss (£1-10k).	Significant organisational/personal financial loss (£10-100k).	Major organisational/personal financial loss (£100k-1m).	Severe organisational/personal financial loss (£>1m).
Inspection / Audit	Small number of recommendations which focus on minor quality improvement issues.	Recommendations made which can be addressed by low level of management action.	Challenging recommendations that can be addressed with appropriate action plan.	Enforcement action. Low rating. Critical report.	Prosecution. Zero rating. Severely critical report.

Adverse Publicity / Reputation	Rumours, no media coverage. Little effect on staff morale.	Local media coverage – short term. Some public embarrassment. Minor effect on staff morale/public attitudes.	Local media – long-term adverse publicity. Significant effect on staff morale and public perception of the organisation.	National media/adverse publicity, less than 3 days. Public confidence in the organisation undermined. Use of services affected.	.National/international media/adverse publicity, more than 3 days. MSP/MP concern (Questions in Parliament). Court Enforcement. Public Inquiry/ FAI.

Table 2 – Likelihood Definitions

Descriptor	**Rare**	**Unlikely**	**Possible**	**Likely**	**Almost Certain**
Probability	Can't believe this event would happen – will only happen in exceptional circumstances.	Not expected to happen, but definite potential exists – unlikely to occur.	May occur occasionally, has happened before on occasions – Reasonable chance of occurring.	Strong possibility that this could occur – Likely to occur.	This is expected to occur frequently / in most circumstances – more likely to occur than not.

Table 3 - Risk Matrix

Likelihood	**Impact/Consequences**				
	Negligible	**Minor**	**Moderate**	**Major**	**Extreme**
Almost Certain	**Medium**	**High**	**High**	**V High**	**V High**
Likely	**Medium**	**Medium**	**High**	**High**	**V High**
Possible	**Low**	**Medium**	**Medium**	**High**	**High**
Unlikely	**Low**	**Medium**	**Medium**	**Medium**	**High**
Rare	**Low**	**Low**	**Low**	**Medium**	**Medium**

Appendix E – Project Risk Register

Defibrillator Replacement Project

Function	**Defibrillator**
Title	**Replacement Project**
Risk Log Owner	**Yvonne Aitchison**
Checked By	**Loraine Jackson**
Date	**Aug-18**

Risk ID	Risk Type	Risk Subtype	Description	Controls in place	Likelihood (current)	Consequence (current)	Risk level (current)	Action Planning (Future Controls)	Likelihood (Target)	Consequence (Target)	Risk level (Target)	Assurance sources	Risk Owner	Risk Owner Title
3939	Project Risk	Financial	There is a risk there will be a substantial increase in current revenue cost during the next 2 financial years because of the existing units being out of warranty and increased risk of component failure resulting in increased revenue costs.	Consider interim measures to redistribute consumables and spare units where possible, lease units form supplier, and use AED's where able in order to keep revenue costs to a minimum. Renew in a timely manner.	Possible = May occur occasionally, has happened before on occasions - reasonable chance of occurring	Moderate = Significant impact to Org or RIDDOR or Significant Injury requiring medical treatment and/or counselling	Medium	Escalate to SMT for interim funding.	Possible = May occur occasionally, has happened before on occasions - reasonable chance of occurring	Moderate = Significant impact to Org or RIDDOR or Significant Injury requiring medical treatment and/or counselling	Medium	Project Team	Barnes, Melanie	Head of Costing & Capital Accounting
3940	Project Risk	Operational	There is a risk the Business Case process will not be completed within the set timescale because of workforce pressures resulting in funds not being released during 2018/19 financial year, causing delays to implementation.	Monitor and manage Business Case process timescales to keep on track and attempt to avoid unsatisfactory patient experience.	Unlikely = Not expected to happen but definite potential exists - unlikely to occur	Major = Major impact to Org or major injuries / long term incapacity or disability	Medium	Request additional resource to help process. OBC has been approved.	Unlikely = Not expected to happen but definite potential exists - unlikely to occur	Major = Major impact to Org or major injuries / long term incapacity or disability	Medium	Project Team	Aitchison, Yvonne	Project Manager
3941	Project Risk	Strategic	There is a risk that the successful supplier cannot deliver the full remit of the contract within the required timescales because of a limited understanding of the delivery timescales resulting in a suboptimal product or delayed delivery.	Carry out robust tender process to select reliable and experienced supplier and control/motivate via clear delivery targets with payment milestones.	Unlikely = Not expected to happen but definite potential exists - unlikely to occur	Moderate = Significant impact to Org or RIDDOR or Significant Injury requiring medical treatment and/or counselling	Medium	Escalate to supplier to assess how any overruns minimised or eliminated	Unlikely = Not expected to happen but definite potential exists - unlikely to occur	Moderate = Significant impact to Org or RIDDOR or Significant Injury requiring medical treatment and/or counselling	Medium	Project Team	Aitchison, Yvonne	Project Manager

3943	Project Risk	Operational	There is a risk that the procurement process takes longer than anticipated because of pressures in resources and planning resulting in implementation timescales not matching the funding timescales which may result in a funding pressure.	Carry out clear, robust procurement process with realistic timescales, closely monitored.	Unlikely = Not expected to happen but definite potential exists - unlikely to occur	Major = Major impact to Org or major injuries / long term incapacity or disability	Medium	Assess and identify the key delays. Escalate if/where necessary to address if possible	Unlikely = Not expected to happen but definite potential exists - unlikely to occur	Major = Major impact to Org or major injuries / long term incapacity or disability	Medium	Project Team	Ward, Jenna	Procurement Specialist
3944	Project Risk	HR	There is a risk that insufficient resourcing is assigned to the Programme because of conflicting demands on key staff resulting in a delay to the implementation process	Clear scoping and monitoring of resource requirements and roles and responsibilities in relation to the approach and necessary activities involved at every stage.	Possible = May occur occasionally, has happened before on occasions - reasonable chance of occurring	Moderate = Significant impact to Org or RIDDOR or Significant Injury requiring medical treatment and/or counselling	Medium	Request additional resources, as required, to meet timescales.	Possible = May occur occasionally, has happened before on occasions - reasonable chance of occurring	Moderate = Significant impact to Org or RIDDOR or Significant Injury requiring medical treatment and/or counselling	Medium	Project Team	Carter, Julie	Director of Finance and Logistics
3946	Project Risk	Strategic	There is a risk that substantial organisational change/ priorities within the Service may change because of political or operational pressures resulting in an impact on delivery costs and / or programme timescales.	Finances and requirements known at SG & Service level. Defibrillators are essential to service delivery in treating CA patients.	Unlikely = Not expected to happen but definite potential exists - unlikely to occur	Major = Major impact to Org or major injuries / long term incapacity or disability	Medium	Replan project as necessary.	Unlikely = Not expected to happen but definite potential exists - unlikely to occur	Major = Major impact to Org or major injuries / long term incapacity or disability	Medium	Project Team	Aitchison , Yvonne	Project Manager
4311	Business Risk to the Organisation	Financial	There is a risk that the Service may require an extension to the current defibrillator contract because of a change in timescales for delivery resulting in a need to extend the contract and potentially increased costs.	Procurement is being appraised of current position. Supplier will be notified as soon as risk becomes an issue.	Possible = May occur occasionally, has happened before on occasions - reasonable chance of occurring	Moderate = Significant impact to Org or RIDDOR or Significant Injury requiring medical treatment and/or counselling	Medium	Extension to current contract agreed with supplier.	Possible = May occur occasionally, has happened before on occasions - reasonable chance of occurring	Moderate = Significant impact to Org or RIDDOR or Significant Injury requiring medical treatment and/or counselling	Medium	Project Team	Aitchison , Yvonne	Project Manager

4344	Project Risk	Strategic	There is a risk that insufficient revenue funding will be available to deliver to the desired defibrillator specification because of the need for funding to be phased resulting in a suboptimal product being delivered.	Understand financial envelope and ensure specification meets Service needs within the envelope. Ensure appropriate representation, experience and consultation to make every effort to identify all probable costs involved.	Rare = Cannot believe this event would happen - will only happen in exceptional circumstances	Major = Major impact to Org or major injuries / long term incapacity or disability	Medium	Reassess the number of defibrillators and focus on the essential requirements. High confidence from Finance that capital funding will be available, therefore, monitor as required. Initial agreement of OBC approved - ensure FBC is submitted within appropriate timescales.	Rare = Cannot believe this event would happen - will only happen in exceptional circumstances	Moderate = Significant impact to Org or RIDDOR or Significant Injury requiring medical treatment and/or counselling	Low	Project Team	Carter, Julie	Director of Finance and Logistics
4345	Business Risk to the Organisation	Financial	There is a risk that the Service may require an extension to the current defibrillator contract because of a change in timescales for delivery resulting in a need to extend the current contract and potentially increased costs.	Procurement is being appraised of current position. Supplier will be notified as soon as risk becomes an issue.	Possible = May occur occasionally, has happened before on occasions - reasonable chance of occurring	Moderate = Significant impact to Org or RIDDOR or Significant Injury requiring medical treatment and/or counselling	Medium	Extension to current contract will require to be agreed with supplier. Negotiate minimum possible terms.	Possible = May occur occasionally, has happened before on occasions - reasonable chance of occurring	Moderate = Significant impact to Org or RIDDOR or Significant Injury requiring medical treatment and/or counselling	Medium	Project Team	Ward, Jenna	Procurement Specialist
4346	Project Risk	Financial	There is a risk that the overall procurement may be subject to a procurement challenge because of the size of the contract resulting in a delay to delivery timescales.	Solid procurement process with detailed supporting documentation for unsuccessful supplier	Likely = Strong possibility that this could occur - likely to occur	Major = Major impact to Org or major injuries / long term incapacity or disability	High	Ensure dates are scheduled for follow up meetings to mitigate impact on overall timescales of delivery.	Possible = May occur occasionally, has happened before on occasions - reasonable chance of occurring	Major = Major impact to Org or major injuries / long term incapacity or disability	High	Project Team	Ward, Jenna	Procurement Specialist
4347	Project Risk	Operational	There is a risk that the installation and verification of the defibrillator cannot be undertaken at the right time because of logistical pressures for delivery resulting in an increased timeline.	Solid implementation plan. Early engagement with Fleet, Operations and lessons learned from similar projects.	Possible = May occur occasionally, has happened before on occasions - reasonable chance of occurring	Moderate = Significant impact to Org or RIDDOR or Significant Injury requiring medical treatment and/or counselling	Medium	Regular monitoring and oversight of implementation plan to ensure this is updated as required.	Unlikely = Not expected to happen but definite potential exists - unlikely to occur	Moderate = Significant impact to Org or RIDDOR or Significant Injury requiring medical treatment and/or counselling	Medium	Project Team	Aitchison, Yvonne	Project Manager
4348	Project Risk	Education & Training	There is a risk that funding relating to training may be inconsistently applied because of variances in divisional application resulting in training not been undertaken.	Early engagement with Regions on how funding will be applied and best utilised.	Possible = May occur occasionally, has happened before on occasions - reasonable	Moderate = Significant impact to Org or RIDDOR or Significant Injury requiring medical treatment and/or counselling	Medium	Ongoing monitoring of funding utilisation by Programme Support. Continuous	Unlikely = Not expected to happen but definite potential exists - unlikely to occur	Moderate = Significant impact to Org or RIDDOR or Significant Injury requiring medical	Medium	Project Team	Aitchison, Yvonne	Project Manager

					chance of occurring			liaison with Regions.		treatment and/or counselling				

Appendix F – Footnotes

[i] Scottish Government, (March 2015) *Out-of-Hospital Cardiac Arrest: A Strategy for Scotland,* available at: http://www.gov.scot/Resource/0047/00474154.pdf (last accessed: 14/12/17)

[iii] Scottish Ambulance Service (2015) *Towards 2020: Taking Care to the Patient* available at: http://www.scottishambulance.com/UserFiles/file/TheService/Publications/Strategic%20Plan_Online%20pdf.pdf (last accessed: 14/12/17)