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Emergency planning and business continuity: why blood services must plan for both. How the EBA working group (WG) is assisting blood services

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Background In 2016, the Executive of the European Blood Alliance (EBA) decided to explore whether there was sufficient interest amongst member countries on whether they saw value in the re-establishment of a Working Group on contingency planning. A survey of members was carried out and as there was sufficient interest a Working Group (WG) was established. The question then was how could the work of the WG add value to member countries in their contingency planning process? We set out to establish this.

Method Members of the WG decided that there were three areas where the WG should concentrate on and these were as follows: (1) share lessons learnt during past contingencies and response to major disasters, (2) exchange contingency plans and (3) test run of contingency plans. As a first step, it was decided that we would share our existing contingency plans and when these were shared the WG undertook to carry out a gap analysis. It became evident that the state of contingency planning varied across countries. It is vitally important that each BTS ensures that their critical functions of manufacturing, testing and supply management have contingency arrangements in place whether that is within the country or with an international partner. However, having them in place is not enough they must be tested on a regular basis to ensure that they work. It was important that the WG formulated formal terms of reference to inform its work and also to set out clear deliverables. Draft Terms of Reference (ToR) were drawn up and sent to the Board of the EBA for approval in line with the normal procedure for WGs. These have been approved by the Board and are as follows:

(1) To share and leverage the knowledge of EBA members so all can move towards best practice (e.g. ISO 22301)
(2) To share experience, documentation, risk and other relevant materials and identify common training needs and opportunities.
(3) To identify opportunities for mutual aid in business continuity and emergency planning processes, consumables and the provision of services and products and develop these into agreed heads of agreement in bilateral or multilateral mutual aid arrangements.
(4) To create routes and mechanisms of communication on business continuity and emergency planning issues between EBA members, and to maintain a forum for discussion on these matters (e.g. EBA newsletter, EBAse).
(5) To engage in and lead the conversation on business continuity and emergency planning with the Commission and Competent Authorities to ensure a workable and consistent approach across EBA member states.

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Outcome The work of the group will deliver a better understanding of contingency planning with tangible examples and case studies which demonstrate how these plans have been activated and the lessons learnt from the events that required their activation. Some of the lessons learnt to date are that (1) there can never be too much communication on the contingency arrangements and there must be deputies in place for the main functional leads in the plan because inevitably the event occurs at a weekend where the nominated people are not always available, (2) the carrying out of a desktop exercise can be very useful and can expose any shortcomings in the contingency plan in a safe environment and (3) communication between the BTS and their contingency partner must ensure that any changes by either party are communicated so that any impact is worked through. The work of the WG is continuing.

Key words: business continuity planning and emergency preparedness, contingency planning, emergency planning

Introduction

Emergency planning is familiar to healthcare systems: a range of preplanned responses to a variety of events including major accidents, natural disasters, warfare and terrorism [1]. It is the mechanism by which healthcare organizations provide emergency health care to those directly affected by an event. An example of this approach is the dedicated prehospital urgent care systems provided by ambulance services in the United Kingdom, although the mechanism of delivery varies in other countries. These services exist mainly or solely to provide this type of care: a preplanned response to accidents and incidents.

Business continuity emerged during the 1970s as a mechanism by which businesses assess and improve their ability to continue should they face a disruptive challenge [2]. This discipline began with the resilience of computer mainframes, but by the 1980s had spread to other aspects of business and, as a response to terrorist attacks, such as the World Trade Centre attacks (9/11/2001) and natural disasters, such as the massive hurricanes in the USA in 2003-4. Business continuity had, by the early 2000s, become a consideration across the full range of business disciplines in the early 2000s [3].

While the two disciplines are allied and have common features, they are distinct. Emergency planning is an outward facing activity delivering assistance to those affected by an event, whereas business continuity faces internally, dealing with the impact of an event on the business itself.

Discussion

Blood services have had a response role in emergencies since their inception, delivering product to hospitals outside scheduled delivery times, often using preplanned dedicated protocols and, in many countries, using vehicles with lights that indicate that the vehicle is engaged on emergency business. In recent years, blood services have used their emergency provision to cover many high-profile incidents. These have included events in Paris (November 2015), Brussels Airport (March 2016), Nice (July 2016) and Orlando (June 2106).

Just this year, in the United Kingdom there has been a terrorist attack on Westminster Bridge (22 March 2017), a suicide bomb in the Manchester Arena (22 May 2017), an attack on people enjoying an evening near London Bridge (3 June 2017), a fire in a tower block in Kensington, London (14 June 2017), and an attack on worshippers at a mosque in Finsbury Park (18 June 2017). The clinical challenges presented by these different incidents and the amount of product ordered varied enormously.

The common factor is that all blood services need to plan to ensure a number of considerations are made and that the materials needed to respond are in place before the events occur. Stock, staff to issue products, vehicles, drivers and specialist clinical transfusion advice all are required to respond to these situations. All these events were unavoidable and other than having well-prepared emergency plans could not have been foreseen. However, we know other events such as natural disasters or failure in complex systems occur and blood services should work with Municipal/Civil Authorities in ensuring that they can respond effectively. The past number of years have seen a series of major disasters afflicting a wide range of complex systems: nuclear power plants, chemical installations, 'roll-on/roll-off' ferries, off-shore platforms and railway networks. While many investigations of these events focus on the front-line failure in more recent

cases, the accident investigations have focused on systemic failures [4,5]. Both the Zeebrugge and King's Cross inquiries concluded that 'rather than being the main instigators of these disasters, those at the human – machine interface were the inheritors of system defects created by poor design, conflicting goals, defective organisation and bad management decisions. Their part, in effect, was simply that of creating the conditions under which these latent failures could reveal themselves' [6].

There is little doubt that human error contributes to the majority of incidents and accidents that occur within complex systems. A study was undertaken in 2007 to understand the human factors that contributed to railway accidents and incidents in Australia. The results of this study were published by Melissa T. Baysari *et al.* [7]. They used a theoretical framework the Human factors Analysis and Classification System (HFACS) and reviewed forty rail safety investigation reports in their study. They accept that in arriving at their findings, a greater number of reports would need to be examined to validate their results. However, notwithstanding this caveat their review revealed that over half the cases of accidents and incidents were associated with equipment failures, mostly due to '*inadequate monitoring and checking of equipment*'. In incidents which resulted from the actions of front-line staff, the majority were slips in attention (i.e. skill-based errors) and these were associated with a reduction in alertness and physical fatigue. They also found that *'nearly all incidents were associated with at least one organisational influence, suggesting that problems with resource management, organisational climate and organisational processes need to be addressed in order for error reduction in the Australian railway system to occur'* Even allowing for their caveat about the size of the study, these findings are in line with the findings of Reason [6] and highlighted in the major disasters referred to in the previous paragraph.

There is also an onus on blood services to continuously review their processes in the light of incidents that occur. One way of doing this is to automate as many of the processes as possible so that the amount of human intervention is minimized and consequently the possibility of human failures and error.

These failures can have consequences for the blood service and that is why it is essential that there is good co-ordination with the relevant State Agencies, Civil Authorities and Rescue Services so that each knows what is expected from them. Only then can the event be managed effectively.

There are many methods and models that can be used to develop emergency plans and one of them is the 'Four Stages of Emergency Planning' [8].

These are:

(1) Mitigation – any activity that can reduce the impact of an unavoidable event, for example sufficient blood, developed plan and communication strategy
(2) Preparedness – plans that have been developed and tested so that the blood service can respond successfully to the emergency, for example holding disaster drills
(3) Response – putting your plans into action, for example being able to respond to the event as it unfolds and having the structures and plans in place to do this
(4) Recovery – getting operations back to normal and reviewing the response so that the lessons can be taken on board and plan improved.

Management of the emergency

Initial briefing crucial

Should cover:

(1) Where exactly incident occurred
(2) Type of incident, bombing, shooting, major crash, earthquake, etc.
(3) Disruption to transport, access, utilities, travel, etc.
(4) Potential number of casualties and type of injuries
(5) Destination of casualties.

Public response

This type of incident brings with it another response requirement for blood services – the well-documented desire of the public to donate blood. This has been a predictable public response to disaster since the instigation of blood services [9]. The reaction of the public after the Manchester Arena incident was enormous and had to be managed in a compassionate way. NHSBT has processes to manage the donor response, and a significant part of this response was that communications were

issued calling for donors to register to give blood routinely rather than just attending a donor session in an ad hoc manner [10]. While this was an unusual step, the piece was attempting to set out how the blood supply chain works and how donors can best support it. This was like 9/11, Paris and Orlando shooting. It is the natural human response because members of the public want to do something to help and one way is to give blood.

This latter process is not an emergency response; it is a continuity plan aimed at mitigating or preventing the consequences experienced by the New York Blood Centre following the terrorist attack on the World Trade Centre. A large-scale collection of blood in response to the public desire to do something to help led to blood being discarded for a variety of reasons and, therefore, donor numbers fell [11]. What we know from these events is that the requirement for blood in the immediate aftermath of the incident is not very much more than normal.

Therefore, it is vital that blood services have detailed communication strategy in place with pre-prepared messaging that can be distributed over many platforms such as website, Facebook, Twitter, call centre and broadcast media. One example of such a strategy is the one drawn up by the Scottish Blood Transfusion Service which details a set of responses. The key elements are set out below:

Example of strategy – SNBTS

(1) Message 1 – Situation Assessment and Holding Statement
(2) Message 2 – Normal Demand for Blood Donors
(3) Message 3 – High Demand for Blood Donors
(4) Message 4 – Low Response to message 2
(5) Message 5 – Exceptional Demand for Blood Donors
(6) Message 6 – Low Spontaneous Response with high demand
(7) Message 7 – Catastrophic Failure in Supply.

For many years, the blood services perpetuated the idea that people should respond to disasters by donating blood. The blood services now need to educate the public on the supply chain process and why it is vital that there is a consistent blood supply so that there is sufficient blood available when the event occurs and that is the best way they can help.

Lessons learnt from recent events

(1) Usage and demand of blood components on the day and days following a terrorist attack or major accident is not much higher than normal
(2) Examples of where there was sufficient blood in the immediate area of the disaster – Madrid train explosions, Boston Marathon bombing and massive explosion at a fertilizer plant in West Texas, bombing in Manchester, UK,
(3) Communication regarding status of blood supply is important – contact between blood centres is essential to ensure that sufficient blood is available and unnecessary distribution does not occur – the human response is to give blood and to control this is difficult
(4) Logistics: transportation of blood and staff could be hampered. It is crucial to set this out in a plan
(5) An integrated approach to planning between Blood Establishment, Head of Sector and Government Agency in charge of disaster is essential so all know what their roles are in the case of a disaster.
(6) It is important to continually update and test emergency plans.

Business continuity planning

While much of the media focus and profile, understandably, is given to the events outlined above, arguably what is much more important from the blood service perspective is to have appropriate and well-tested business continuity plans in place so that they can return to normal operations as soon as possible after the disruption. This disruption can be because of flooding (Filton, NHSBT, 24 September 2012) or failure of IT system at the National Blood Management System Australian Red Cross Blood Service (4 July 2012) or failure of a device or product which disrupts normal operations.

Blood services should have well-developed business continuity plans that will return the organization to normal operations as soon as possible after a disruption event occurs. While many blood services have done a lot of work in this area, the difficulty is maintaining an awareness throughout the organization of the need to continue to update the plan and test it. There are many methodologies for BCP, but what has been found [12] is that there are three problems with the methodologies. These are the lack of implementation methods, the lack of dynamic plan maintenance and the lack of continuous education and involvement for employees. Consequently, it is imperative the blood services make BCP a part of their business operation.

The Working Group carried out a survey of members to ascertain whether they had a BCP or what was the status of their preparedness. The responses received are set out below on an anonymous basis:

Contingency Planning ~ Working Group: Definition: The ability of the Blood Service to supply in different scenarios.

Country	Contingency Plan in Place?	Contingency Arrangement Internal/External	Activities where contingency in place	How often is contingency arrangement tested	Where do you see a gap in your contingency arrangements
1.	Yes	Internal	Whole blood collection	1 × Annually	
		Internal	Blood component manufacture	4 × Annually	
		Internal	Blood component testing	4 × Annually	Bacterial testing single facility
		External	Blood component distribution road	1 × monthly	
		External	Blood component distribution air	1 × Annually	
		External	Blood component supply	2 × Annually	
		Internal/External	Mass casualty blood component demand	1 × Annually	
		Internal	IT applications	1 × Annually	
		Internal/External	IT and telecoms infrastructure	2 × Annually	
		Internal/External	Tissues and cells clean room		
		Internal/External	Adverse Weather	1 × Annually	
		Internal/External	Records Management	1 × Annually	
		Internal/External	Procurement	1 × Annually	
		Internal/External	Pandemic Influenza	Bi Annually	
2.	In part: Draft (National) + internal	External	Testing	Planned (- 1 × annually)	IT compatibility
		Internal	Manufacture (evacuation place)	1 × annually	Equipment sufficiency/readiness
		External	Distribution/logistics	Constantly (alternative suppliers in use)	Delay
		Internal/External	Prioritization of component use in shortage	Draft (agreed with hospitals)	Chain of command/execution speed
		Internal	Collection	Constantly (decentralized operations in use)	Logistics
		Internal/External	Catastrophe/exception blood component demand	1 × annually	Logistics/delay
		Internal/External	IT applications	1 × annually (double servers, connections)	
		Internal	Procurement (reserve stock: reagents, bags, solutions etc.)		Sufficiency/logistics
3.	No	Since 2009, the activities of the blood system are monitored through the National Blood Information System. The data collection covers a complex data set fulfilling the information on the general management of all blood establishments and blood collection units. Moreover, the data recorded are used to guarantee the delivery of basis healthcare levels in the area of transfusion activities and the management/co-ordination of intra- and inter-regional compensation flows.			
4	Partly	Internal and external	Central Test Laboratory: Pandemic Emergency	1/year	A project was set up in order to have a fully implemented BCP by mid-2017
5.	Yes	External	Blood component supply	Annually	Testing
		Internal	Donation Session	Annually	
		External	IT	Annually	
6.	Partly	Internal	West Nile Virus		Overall contingency plan (currently planned to develop)
7.	Yes	Internal/External	BCP in place. Desktop exercise planned 2016	TBC	It is intended that GAPs will be identified during the desktop exercise, these will then be

(Continued)

Country	Contingency Plan in Place?	Contingency Arrangement Internal/External	Activities where contingency in place	How often is contingency arrangement tested	Where do you see a gap in your contingency arrangements
					addressed and a plan developed for a more in-depth exercise.
		Internal	Blood component production	1 × Annually (minimum)	
		External	Blood component importation	1 × Annually (minimum)	
		External	Blood component testing	4 x Annually	
		External	IT Disaster Recovery	Planned 2016	
		External	Distribution	TBC	
		External	NHIRL	TBC	SLAs currently being developed with contingency partners
		External	Tissue Bank	TBC	SLAs currently being developed with contingency partners

Blood services like most organizations are heavily reliant on IT systems to carry out their business. Therefore, it is imperative that they have a well developed and tested disaster recovery site so that they can continue to operate if there is a system failure. Where they host all their applications in house, there are three approaches to disaster recovery that need to be evaluated, namely:

(1) Cold site – where there are some critical applications in a remote site but the servers are not turned on
(2) Warm site – there are a number of the critical applications in a remote site and connectivity has been established
(3) Hot site – where there is full replication of all the applications in a remote site.

Where the blood service has a managed services contract with an external provider, they must ensure that the provider has appropriate contingency arrangements in place.

As can be seen from the following example, business continuity for blood services, however, is not limited to responding to the non-clinical consequences of large-scale incidents. For example, the English National Health Service (NHS) found itself a victim of the worldwide release of the ransomware "WannaCry." So severe was the effect on the UK NHS that early reports in the British media suggested that this was an NHS specific attack. NHSBT IT systems were unaffected, but many hospitals could not order blood using the standard online blood ordering system, either as a direct result of WannaCry, or because local IT services had been switched off to prevent immediate spread or to allow patches to be applied. The standard contingency for such computer failures (either wide scale or individual hospitals) is to revert to ordering by fax. Largely, this was effective, but at a recommendation from the UK Department of Health some hospitals had removed fax machines entirely and others were using 'Voice Over Internet Protocol' (VOIP) telephone systems which are managed by servers, which had been affected. In these circumstances, orders were made using mobile phones or email. Although this incident did not affect NHSBT directly, there were adequate plans in place within NHSBT to ensure that the supply of blood continued to meet the needs of patients while maintaining compliance with regulation.

NHSBT has also experienced some recent disruption in the inbound supply chain of consumables. One impacted on the blood donation function, potentially preventing NHSBT taking donated blood in compliance with regulation and its own procedures. The other was a test kit and so had the potential to prevent a mandatory test being completed, meaning that manufactured product could not be validated and issued. In both circumstances, the failure of the inbound supply chain had the potential to prevent NHSBT supplying blood components to hospitals. Continuity plans enabled these supply issues to be resolved, and hospitals were unaware of any potential supply difficultly.

Demand for red cells is declining across the world as blood is used more effectively [13],) and consequently, blood stock has declined similarly [14]. This means that there is less capacity in the supply chain to enable blood services to meet the demands of both external mass casualty events and internal disruptive challenges. The better use of blood in hospitals means that there is less flexibility within the hospitals to postpone or cancel transfusion

exacerbated by the greater demand for efficiency within the healthcare system.

How to test the plans

There are several methods for testing plans ranging from a walk-through to fully live exercises where real assets are deployed. A walk-through simply steps through the plan without a scenario, to test how a plan functions in the hands of front-line staff; this lacks any context or reality and is best used when a plan is very new to check for gross errors and omissions. Other mechanisms of testing call for much more detailed preparation. A desktop exercise uses a scenario, but deploys no real assets and may often make jumps in time: while this type of exercise is necessary and beneficial, it is difficult to create the sense of urgency that exists in a real situation. Many health systems use a methodology called Emergo Train System which tries to mimic how a disaster would unfold, and this builds in a greater degree of realism. This system is in use in many countries across the world, and blood services should examine it to see whether it would be applicable. A live exercise tests a response plan in real time either in full or in part, deploying real assets (like staff and vehicles) but often stops short of using real product; this type of exercise can create risks for the organization and so should be used with care. In desktop and live exercises, there is usually an observer who assesses how the team responded and what lessons can be learned from the exercise.

The Irish Blood Transfusion Service (IBTS) carried out a desktop test of its BCP in June 2016. The exercise was to address the three phases of disruption, that is emergency, crisis and business or Service Recovery. The BCP Management Team (BCPMT) responded to the situation. A scenario was painted that the main Centre was flooded over a weekend, and there was also flooding in the immediate vicinity with restricted vehicular access. It was expected to last three days, but the flooding in the adjacent areas would not be finally cleared for upwards of a week. There were three further injections to this scenario. First was after one hour when there was a power cut and not sure when it would be restored. One hour later, the BCPMT was informed that there was some damage to wireless and landline communications, and finally, they were informed that the generator supplying backup power had only two hours of fuel supply remaining. This was a very worthwhile exercise and showed a number of gaps in the current plan. The main learning points were that members of the BCPMT must be familiar with the operation of the plan, deputies must be nominated and equally familiar with the plan, there needed to be better cross-referencing in the Plan, there were gaps in communications with external bodies and importantly mitigation steps against flooding for what is now effectively a single-site operation had not been taken. The outcome has also put greater focus on how we manage our ICT assets. The lessons learnt have been taken on board and BCP revised. It is planned to carry out a further test in 2017.

Like many blood services, NHSBT has consolidated some functions into fewer locations with resulting changes to the configuration of infrastructure. Recently, NHSBT tested the proposed change in the configuration of cold rooms resulting from the consolidation of manufacturing services – this was tested in a series of exercises called "Calefaction" (from the Latin "to make warm"). This was a desktop exercise and challenged the existing plans for cold room failure. Players, front-line staff in Hospital Services, were exposed to a scenario in which one blood centre in their region had a significant failure of a cold room. Players were provided with stock figures, demand from hospitals, vehicles to transport product, staff availability and availability of transport containers. They were asked to work together using the existing plan with the aim of discovering gaps in that plans – there were a number that included the fact that frozen product was not included in any failure plan, the customer services function had no out of hours provision and so NHSBT dealt with customers in an ad hoc way, IT access was not at the appropriate level for staff to manage the incident, irradiated products became an immediate problem and, for some cold rooms and freezers, it was not clear how long they held temperature. Work was done to rectify these gaps, and the plan was significantly updated.

Real events should not be discounted as tests of a plan – they are a type of unplanned live exercise. As has been referred to, there have been a number of events in UK over recent months that, while tragic, also give the opportunity to review plans and a number of lessons were learned from these events that were put in place quickly and the lesson learned about communicating with donors in Manchester was implemented and had effect for the incident on London Bridge. There are also unexpected lessons that can be learned, NHSBT is still reviewing blood usage data from the Manchester Arena event to learn more about blood usage in a much younger demographic than is normally affected by mass casualty incidents.

Any test of the emergency plan is best carried out in conjunction with the Civil Authorities; blood services should make contact with their relevant authorities to ensure that they understand what is expected from them.

Conclusion

With large media-sensitive incidents occurring with regularity, as well as the normal emergencies that require transfusion support, blood services need to be aware that

they are required to ensure that they are ready to respond to mass casualty events as they have always done. Given the constraints on the system, however, this preparation needs to be more rigorous than ever before, especially considering the falling demand for blood and related reduction in stock levels.

Blood services should also be aware that they operate either as single source suppliers to hospitals or at least a supplier with very few alternatives. The products supplied are essential in the successful treatment of many patients and, for most purposes, there is no alternative product. The ability of a blood service to ensure supply, therefore, is critical to the provision of healthcare services.

This means that blood services no longer have the luxury of being able use their stock as a buffer against disruptive incidents. Active emergency and business continuity planning need to be a central plank of the business planning that blood services undertake on a day-to-day basis.

In order for blood services to be prepared for both sets of eventualities the following should act as a prompt to enable preparedness:

(1) Have a clear and unambiguous plan that is familiar to key people
(2) Share the Plan with the Municipal/Civil Authorities, Rescue Services and Hospitals
(3) Have a very clearly defined communication strategy that can be actioned across different platforms,
(4) Test the plans to ensure that it will work and the underlying assumptions are valid, and
(5) Do not become complacent about emergency preparedness and business continuity planning.

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