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Improving Ischemic Stroke Care in the US and UK

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Executive Summary

The paper studies the system implications of deploying ultrasound technology in the stroke care pathway. The paper compares the current system of stroke diagnosis utilizing CT Scan technology with a new system for stroke diagnosis that utilizes ultrasound technology. Our team examined both the processes and incentives associated with the system of care to envision the future state. To further model the system of care surrounding stroke treatment, we have also included a system dynamics model to evaluate the impact of deploying the new stroke care pathway that utilizes ultrasound technology.

1. What is a Stroke?

Stroke is a disease that affects the arteries leading to and within the brain. A stroke occurs when a blood vessel that carries oxygen and nutrients to the brain is either blocked by a clot or bursts. When that happens, part of the brain cannot get the blood (and oxygen) it needs, so it starts to die.

There are two types of stroke: Ischemic (85% prevalence) and Hemorrhagic (15% prevalence). Ischemic stroke (Figure 1) results from an obstruction in the blood vessel supplying blood to the brain. This type of stroke can occur when a blood vessel is blocked by fatty deposits called plaque. Blood cells can build up around the plaque and form a clot, stopping the flow of blood to the brain. It is more common of the two types of strokes.

Figure of ischemic stroke removed due to copyright restrictions.
A blood clot in a brain artery stops the flow of blood to an area of the brain, resulting in brain damage due to lack of oxygen supplied to brain tissue downstream of the blood clot.

Hemorrhagic stroke (Figure 2) results when a weakened blood vessel ruptures. The leaked blood kills certain cells and depriving other cells from receiving blood they need to keep them alive.

Figure of hemorrhagic stroke removed due to copyright restrictions.
In a hemorrhagic stroke, a weakened or diseased blood vessel in the brain ruptures, and blood leaks into the surrounding brain tissue.

According to the American Heart Association, the causes of stroke include high cholesterol or build-up of plaque in the arteries, high blood pressure, and diseases that cause blood to clot more easily than usual. Some symptoms of stroke include sudden numbness or weakness of the face, arm or leg (especially on one side of the body), sudden confusion, trouble speaking or understanding speech, sudden trouble seeing in one or both eyes, sudden trouble walking, dizziness, loss of balance or coordination, and sudden severe headache with no known cause. In addition, once these symptoms start occurring, it is critical to treat stroke in a timely manner. Typically, 1.9 million neurons are lost for each minute a stroke goes untreated.

Stroke is mainly treated through surgery, medications, hospital care, and rehabilitation. In particular, tissue plasminogen activator (tPA) is a clot-dissolving drug used to treat ischemic stroke. Because tPA dissolves the clot and restores the flow of blood to the brain, this can potentially lead to excessive bleeding. Therefore, tPA should not be administered in cases of hemorrhagic stroke. It is critical to determine the type of stroke very early in the process because tPA can only be safely administered within 3 hours of stroke onset.

2. How is Stroke Diagnosed?

In order to diagnose a stroke to distinguish between ischemic vs. hemorrhagic stroke, a Computed Tomography (CT) scan is used. A CT scan can show areas of abnormalities in the brain and can help differentiate between areas of the brain receiving insufficient blood (ischemic stroke) vs. a ruptured blood vessel (hemorrhagic). A CT scan uses X-rays to create images of cross-sections of the brain. Some advantages of CT scans include its ability to show the inside of the head (including bones, brains, blood vessels, and soft tissue) and the size and locations of brain abnormalities.

In contrast, CT scans have several disadvantages. First, CT scans are expensive, thereby limiting their availability. Having a cheaper device would potentially equip multiple facilities with the ability to diagnose strokes. Although the availability of CT scanners is not an issue in metropolitan areas such as Boston and London, it is an issue for more rural areas in the US and the UK. Also CT scanner availability in the UK is much lower than that in the US. Second, CT scans are not portable and cannot be used while transferring the patient to the treatment center. Having a portable diagnosis would increase the speed of diagnosis and increasing the chances of a successful treatment. Finally, CT Scans require technical expertise to operate. An easy-to-use device could help diagnose stroke sooner because more members of the medical community could assist in diagnosis.

3. What other methods could be used to diagnosis Stroke?

Along with CT scanners, ultrasound devices are another type of technology used to diagnose stroke to differentiate between ischemic vs. hemorrhagic stroke. A comparison of both CT scanners and ultrasound technology is shown below in Table 1.

Table 1: Comparison of CT Scans and Ultrasound Devices

	CT Scan	Ultrasound
Technology	Series of X-Rays	Real-time images of major blood vessels
Pros	Great images	Portable, less expensive
Cons	Very expensive, not portable, requires technical expertise , radiation risk	Not capable of penetrating bones, poor image quality, and user-to-user variability

Ideally, a device for diagnosing stroke would be cheap, portable, and easy to use in the field. These are further described below:

- *Cheap*: It is affordable enough that it could be deployed in ambulances or community hospitals.
- *Portable*: It could fit inside an ambulance.
- *Easy to use in the field*: EMTs, paramedic staff, and nurses could use it in the field and in community hospitals such that the results are not too operator-dependent

3.1 Ultrasound

Even though the image quality of ultrasound is poorer than that of a CT scan, the team wanted to determine if the ultrasound images were “good enough”. The team first looked at studies to judge the effectiveness of ultrasound for stroke diagnosis. Data from a study completed by Cocho et al is shown below in Table 2, which compares the sensitivity and specificity of ultrasound technology compared to CT angiography.

Table 2: Comparison of Sensitivity and Specificity of Ultrasound Compared to CT angiography
(Source: Cocho et al)

	Sensitivity	Specificity
Anterior Cerebral Artery	100%	94.5%
Middle Cerebral Artery	95.6	96.2
Posterior Cerebral Artery	57.1%	100%
Any Artery	81.8%	94%

Thus, ultrasound is valid compared with CT angiography for the diagnosis of arterial occlusions in patients with acute ischemic stroke, especially in middle cerebral artery obstructions.

3.1.1 Developments in Ultrasound Technology

There is active research in the field with the aim of overcoming the limitations of ultrasound compared to other imaging technologies. Here is an excerpt from a recent article entitled “3D Ultrasound Could Improve Stroke Diagnosis and Care” posted in the *Hospital and Healthcare Management Journal*:

“Research says, 3D ultrasound can compensate for the thickness of the skull and image the brain’s arteries in real time. Experts believe that these advances will ultimately improve the treatment of stroke patients, giving emergency medical technicians (EMTs) the ability to quickly scan the skulls of stroke victims while inside the ambulance. Senior study author Stephen Smith said that “This is an important step forward for scanning the vessels of the brain through the skull, and we believe that there are now no major technological barriers to ultimately using 3D ultrasound to quickly diagnose stroke patients...Speed is important because the only approved medical treatment for stroke must be given within three hours of the first symptoms”...The team injected 17 people with contrast dye to enhance the images then aimed ultrasound “wands” into the brain. The researchers found that 3D ultrasound sensors could compensate for the skulls thickness and for the first time provide real-time clear ultrasound images of the brain arteries. Stephen Smith added: “It’s safe to say that within five to 10 years, the technology will be miniaturized to the point where EMTs in an ambulance can scan the brain of a stroke patient and transmit the results ahead to the hospital.” “

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3.1.2 Ultrasound Deployment Trends

Odessa, Texas was the pioneer in introducing ultrasound for use by Emergency Medical Services to help better diagnose stroke in a shorter time frame to differentiate between ischemic vs. hemorrhagic stroke. Since then, the use of ultrasound has been adopted by a number of cities/towns, most notably in Europe. Having such a precedent is encouraging as it provides a proof-of-concept and also lays the foundation for extending the use of the deployed equipment for other purposes.

4 Current State of the System Surrounding Stroke Care

In the next section, we will look at the current state of the system of stroke care treatment. Specifically, we will examine the current state in the context of the US vs. UK.

4.1 US

The statistics below highlight some of the statistics surrounding stroke in the United States according to the American Heart Association. We will examine the US System of Stroke Care in terms of cost, access to care, and treatment.

- 6.4M (2.9%); Males – 2.5M; Females – 3.9M
- White: Males - 2.3%; Females - 3.1%
- Black: Males - 3.8%; Females - 4.3%
- Mexican Americans: Males – 2.8%; Females – 3.1%
- Hispanics: 2.6%
- Asians: 1.8%

- American Indians: 3.9%
- Every year 795,000 people experience new or recurrent stroke.
- Stroke mortality for 2006 was 137,119 (54,524 males; 82,595 females). One death every 4 minutes
- Death Rate = $137,119/795,000 = 17.25\%$
- Brain Stroke is the third leading cause of death in US (behind heart disease and cancer)
- On average every 40 seconds someone in the US has a stroke
- Of all strokes 87% are Ischemic; 13% are Hemorrhagic (10% intra-cerebral and 3% subarachnoid)
- About 15% of the strokes are preceded by Transient Ischemic Attack (TIA)
- About half of the patients who experience TIA fail to report to their healthcare providers
- The leading cause of disability in US.

4.1.1. Cost (Source: Medivance Reimbursement)

The estimated direct and indirect cost of stroke for 2010 is \$73.7 billion. The mean life time cost of ischemic stroke is \$140,048. This includes inpatient care, rehabilitation and follow-up care necessary for lasting deficits (all numbers converted to 1999 dollars using the medical component of CPI). In addition, the Medicare reimbursement payment for tPA is \$15,933.18.

4.1.2 Access to Care

Access to care in rural and urban communities is very different. The table below from Kleindorfer et al depicts this:

Table showing disparities in access to designated stroke centers in urban and rural areas has been removed due to copyright restrictions.

Despite this disparity in treatment in rural vs. urban areas, according to a new study in the journal *Radiology*, the number of CT scans in U.S. emergency rooms has jumped from 2.7 million in 1995 to 16.2 million in 2007.

4.1.3. Treatment

In 2004 study by Persse et al, between 10,800 and 12,600 patients received tPA for stroke in the US. It was used to treat ischemic stroke patients 1.8% to 2.1% of the time. In Section 4.3, we will further describe the current gold standard of stroke treatment processes: stroke centers.

4.2 UK

The statistics below highlight some of the details surrounding stroke care in the UK according to the NAO Stroke Care Report and Stroke Association in the UK. We will also examine the UK system of stroke care in terms of cost, access to care, and treatment.

4.2.1 Prevalence (from NAO Stroke Care Report and the Stroke Association in the UK)

- 150,000 people have a stroke each year in the UK.
- 67,000 people die each year as a result of stroke in the UK.
- The death rate from stroke varies from study to study. One study found a death rate of $67,000/150,000 = 44.67\%$ however the National Audit Office (NAO) claims the death rate is 25%. In either case, this is a much higher death rate than the 17.25% rate for the US.
- Most common cause of disability. More than 300,000 people are living with moderate to severe disabilities as a result of stroke.
- Stroke patients occupy around 20 percent of all acute hospital beds and 25 percent of long term beds.
- 25% of the strokes occur in people under the age of 65.
- 50% of stroke victims are left dependent on other people.

4.2.2 Costs (from NAO Stroke Care Report and the Stroke Association in the UK)

The direct cost to NHS is £2.8 billion (over £3 billion as per NAO). The cost to wider economy is £8 billion. In addition, NHS spends approximately 4% of its budget on stroke care. Acute stroke services are currently funded via the “Payment by Results” tariff of around £4,000 per patient episode. Figure 3 & 4 below further highlights some of the costs associated stroke care.

Elements of Best Practice Tariff AA22z

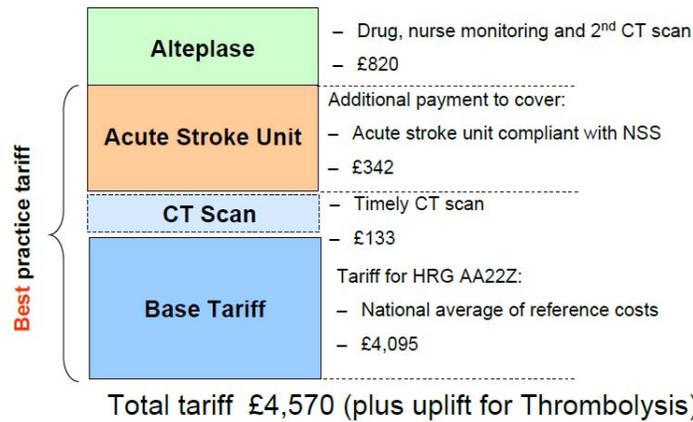


Figure 3: UK Costs (Source: NAO Stroke Care Report)

CT 1 Area	£359
CT 2 Areas	£440
CT 3 Areas	£509
CT Contrast	£89
3D Reconstruction	£444
MR 1 Area (exc. Cardiac MR)	£451
MR 2 Areas (exc. Cardiac MR)	£670
MR 3 Areas (exc. Cardiac MR)	£899
MR Contrast	£115
Image Guided Laser Therapy - Initial Assessment	£532
Image Guided Laser Therapy Treatment	£4,936
Ultrasound	£112
Doppler Ultrasound	£112

Image by MIT OpenCourseWare. Source: University College London Hospitals.

Figure 4: Cost of CT Scan and Ultrasound (Source: University College London Hospitals)

4.2.3 Access to Care (from OECD Health Data)

In the UK, only 12% of hospitals have protocols in place with ambulance services for the rapid referral of those with suspected stroke and less than 50 % of hospitals with acute stroke units have access to brain scanning within three hours of admission to hospital. In addition, less than 1% of patients with ischemic stroke received thrombolysis (treatment with clot-busting drugs) in 2006. Although two-thirds of stroke patients are managed in stroke units at some time during their hospital stay, only about 10 % of patients are likely to be admitted directly to a stroke unit. In more recent times, all hospitals provided access to scans, with 59% of applicable patients in England given a brain scan within 24 hours, an increase from 42 % in 2006. Finally, general wards have 14% to 25% higher mortality rate than stroke units.

4.3 Stroke Care Treatment Protocol

Currently, stroke centers are the gold standard of care in both the US and UK. Stroke centers are specialized units within hospitals that have the staff and resources to diagnose and treat stroke. A stroke center would typically have a stroke team consisting of neurologist, neuro-radiologist along with a physician and a nurse well versed in treating stroke patients. Persse et al describes that the expertise and co-ordination stroke centers provide has resulted in more favorable patient outcomes.

4.3.1. US Stroke Care Treatment Protocol

Ideally, patients are treated in a stroke center within a 3 hour window of stroke onset. In the list below, we have identified the key steps involved within stroke centers in the US:

1. EMT evaluates the patient with stroke like symptoms
2. Medical control center directs the EMT to a hospital (preferably a stroke center)
3. ER nurse is assigned to the patient
4. Patient's condition is evaluated by the doctor. (There is a protocol to decide on the severity of the stroke)
5. CT scan device immediately cleared
6. Neuro-Radiologists read the CT Scan. Physicians can assume this role.
7. Neurologists synthesize the CT scan information with patient's medical history and decide whether to prescribe tPA or not. Physician can assume this role as well.

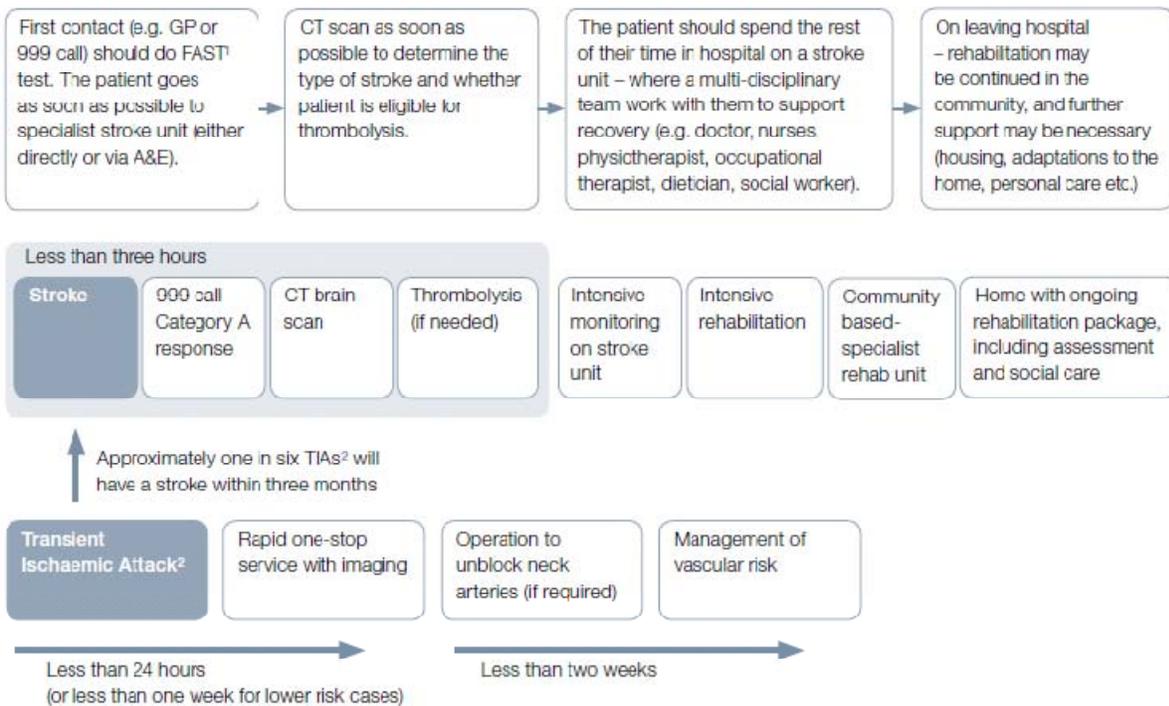
4.3.2 UK Stroke Care Treatment Protocol

The acute phase of care often begins in a hyper-acute stroke unit (HASU) in the UK (shown in Figure 5 below). HASUs are 24 hour centers providing high-quality expertise in diagnosing, treating and managing stroke patients. Patients with a suspected stroke will be taken by the London Ambulance Service to the HASU that involves the shortest journey time and this will be located no more than 30 minutes travel time away.

FAST is the face, arms, speech test which is currently used by the London Ambulance Service to identify possible stroke patients. On arrival, a patient will be assessed by a specialist, have access to a CT scan and receive clot-busting drugs if appropriate, all within 30 minutes. Patients will then be admitted to a HASU bed where they will receive hyper-acute care for up to the first 72 hours following admission.

Following a patient's hyper-acute stabilization, patients will be transferred to a stroke unit. Stroke units will provide multi-therapy rehabilitation and ongoing medical supervision. The length of the stay will vary and will last until the patient is well enough to be discharged from acute to inpatient setting. Which stroke unit a patient should be taken to is determined by a catchment table which assigns all London postcodes to a stroke unit. The intention of the catchment table is to ensure patients are transferred to a stroke unit close to their home; this may be the stroke unit in the same hospital as the HASU. Following their stay in the stroke unit, patients will be discharged home with access to appropriate community rehabilitation services or discharged to a specialist inpatient facility.

Stroke care pathway – ‘time lost is brain lost’



Source: Department of Health adapted by National Audit Office

NOTES

- 1 FAST test is used for identifying strokes.
- 2 Transient Ischaemic Attack (TIA) – like a stroke, but the symptoms resolve within 24 hours.

Morse, Amyas. *Report by the Comptroller and Auditor General: Progress in improving stroke care*. National Audit Office, HC 291 Session 2009 - 2010. The Stationary Office, 2010.

Figure 5: UK Stroke Care Pathway (Source: NAO 2010 report)

4.4 Stakeholders and Incentives

In the following section, we have outlined the key stakeholder groups in the system of stroke care in both the US and UK.

4.4.1 US Stakeholders and Incentives

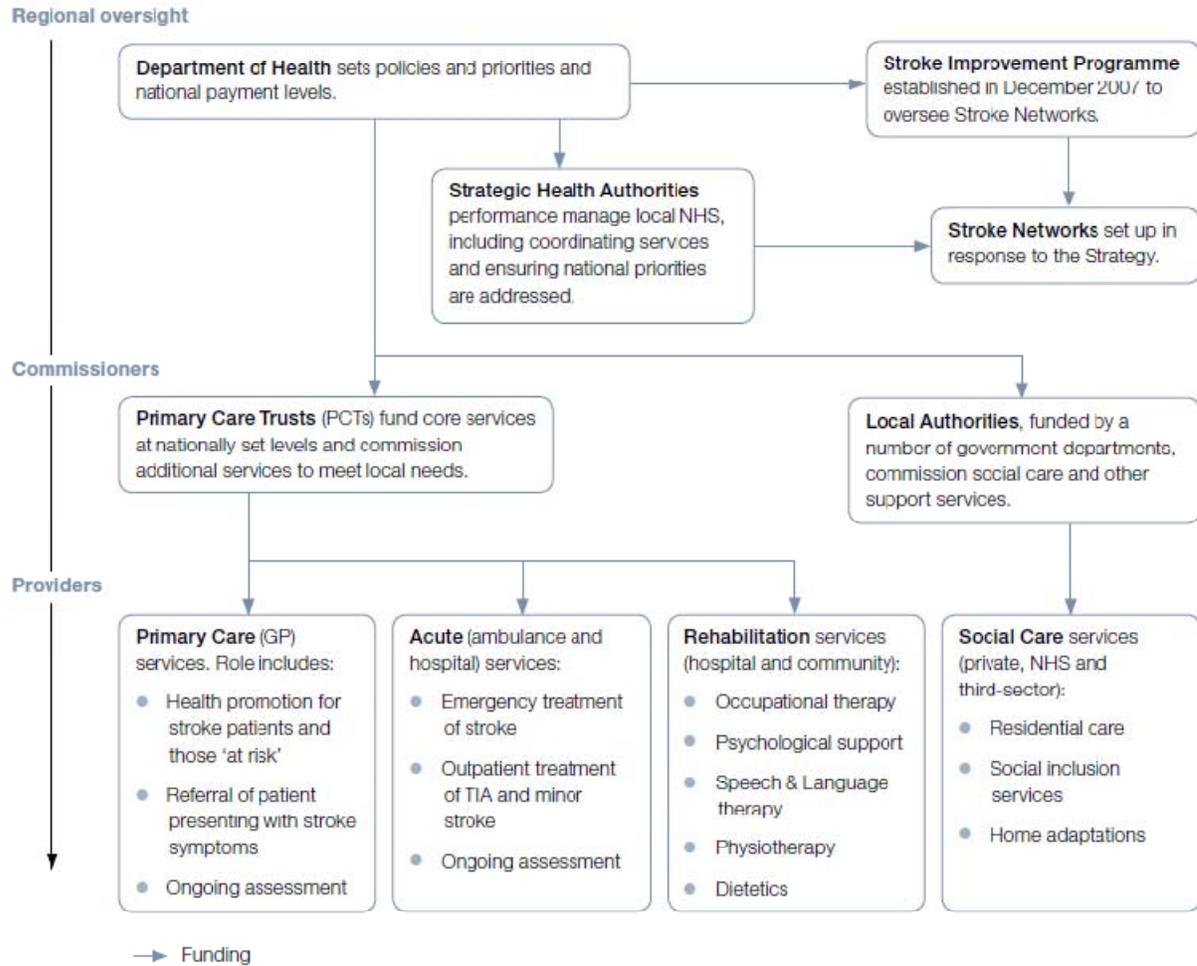
Table 4 highlights the incentives and challenges surrounding each of the key stakeholder groups of the US stroke care pathway.

Table 4: Incentives for US Stakeholder Groups

STAKEHOLDER	INCENTIVES	CHALLENGES
Patient	Optimum Treatment	Lack of knowledge about stroke symptoms
Emergency Medical Service	Public pressure to meet certain standards like fast response time and accurate triaging of patients	Increased professional demands
Emergency Physician	Additional payment if part of a "stroke center" at the hospital	<ol style="list-style-type: none"> 1. Overworked 2. Generally lacks stroke specific expertise 3. Lack of support from neurologist and radiologist
Emergency Nurse	Salary Incentives	<ol style="list-style-type: none"> 1. Overworked 2. Generally lacks stroke specific expertise
Hospital	Reduced Liability	<ol style="list-style-type: none"> 3. Re-imbursements are not sufficient to cover the cost of running a stroke center 4. Payment denials
Neurologist	Reimbursement payments	<ol style="list-style-type: none"> 1. Stroke care is less lucrative than the outpatient care that neurologists typically provide 2. Inconvenient as an emergency can arise at off hours
Radiologist	Reimbursement payments	<ol style="list-style-type: none"> 1. Inconvenient as an emergency can arise at off hours
NIH – NINDS	Reduce long-term costs by establishing appropriate protocols, policies services for effective treatment	<ol style="list-style-type: none"> 1. Modifying the health care system to promote system optimization rather than local optimization.
Non-profits (ex: Northeast Cerebrovascular Consortium, American Stroke Association)	Purpose of the Organization (philanthropic)	Coordinating amongst different stakeholders
Nursing and Re-Habilitation Center	Increased revenue if quality standards are maintained	Improving the quality of care
Payers (Insurance Company, CMS, Individual)	Reduce treatment cost	<ol style="list-style-type: none"> 1. Recognize the value added by stroke centers 2. Remove payment restrictions on concurrent services
Primary Care Physician	Reimbursement payments	Lack of financial incentive for preventive care

4.4.1 UK Stakeholders and Incentives

The NAO report outlines several of the key stakeholder groups within the UK. We have highlighted the relationships between the UK stakeholder groups below, which include the patient, Department of Health, Stroke Improvement Programs, Strategic Health Authorities, Primary Care Trusts, Primary Care Providers, Acute (ambulance) services, rehabilitation services, and social care services.



Source: National Audit Office

Morse, Amyas. *Report by the Comptroller and Auditor General: Progress in improving stroke care*. National Audit Office, HC 291 Session 2009 - 2010. The Stationary Office, 2010.

Figure 6: Organization of Various Stakeholders Groups within the UK for Providing Care (Source: NAO 2010 Report)

5 Future State of Stroke Care System

In addition to the problems of resources, stroke care protocols, and incentive structures, the key limiting variables associated with improving the stroke care pathway are temporal and geo-spatial in nature. The three-hour window that frames the administration of tPA for Ischemic stroke patients limits access to care. Furthermore, a patient's location during an onset of stroke, as in, the patients geographical distance from a stroke care center is the second most vital limitation of the current system of care.

A study done by the University of Pennsylvania¹⁶ claims that fewer than 1 in 4 Americans (22 percent) have access to a primary stroke center within 30 minutes. Just over half (55 percent) can reach one within an hour when ambulances are not permitted to cross state lines. Patients are most able to get to a primary stroke center by ground within 60 minutes if they live in the Northeast (64 percent), followed by the Midwest (61 percent). In the South and West portions of the country, just over half (52 percent and 51 percent) of patients can reach those advanced facilities within an hour. Five states had no in-state ground access to primary stroke centers within 60 minutes, and only in the District of Columbia could all residents reach such a facility in an hour. The National Institute for Neurological Disorders and Stroke authors noted that, "we focused on minimizing the time to treatment. ... Such a benefit from early treatment is consistent with our understanding of the process of infarction and the narrow window of opportunity for effective intervention."

The introduction of new technologies such as portable ultrasound technology and a revision of protocols will modify the current state. In order to evaluate and explain the future state, three different scenarios have been constructed. Each scenario plays out the "future" state in a different geographical locations in both the US and the UK. Through the evaluation of the changes in the stroke pathway, an attempt to quantify the changes in tPA administration, qualitatively assess changes in stroke care pathway, resources, and incentives have been proposed.

Before delving into the three scenarios, the overall effect of the introduction of portable ultrasound has been outlined:

1. Pre-hospital triage using ultrasound speeds up stroke diagnosis and treatment limiting the damage done by stroke and also making more people eligible for tPA
2. More efficient use of resources:
 - (1) Hospitals that cannot afford CT Scan would become eligible for treating Stroke
 - (2) Ultrasound could be a cheaper way for diagnosing strokes even in hospitals with CT Scan
 - (3) Ultrasound could be used for follow-on stroke care
 - (4) More efficient triaging using ultrasound should reduce the costs associated with providing care to false positive cases. UK assumes 15% of the patients suspected to be stroke victims are false positives.
3. Changes the incentive dynamics by shifting some of the responsibilities to EMT
4. Portable ultrasound could also be used to diagnose and treat patients in the field.

Thus, looking at the changes that could be brought about through the implementation of ultrasound technology, situations where ultrasound could be used are as follows:

1. Field diagnosis and administration of tPA
2. Hospitals where CT scan is not cost-effective

To further describe the implementation of the ultrasound technology, we have described three scenarios, which are first outlined in Table 5 below. Within each scenario, we describe the problem, provide a vignette that provides some context and describes the enabling processes, and finally outline the geo-spatial timeline associated with each scenario.

Table 5: Scenarios for Ultrasound Technology Utilization

<i>Scenario</i>	<i>Situation Context</i>	<i>Future state major change</i>
1	Patient located in a rural region with access to a stroke center >3 hours	Emergency Medical Services diagnosis using Ultrasound and tPA administered in the field
2	Patient location is a semi-urban/semi-rural region with access to a small hospital within <3 hours	Ultrasound used in Community Hospital in place of a CT scanner
3	Patient location is a semi-urban/semi-rural region with access to a large hospital (that is not a stroke center) within <3 hours	Creation of Chief Engineer to ensure stroke care coordination

5.1 Scenario 1 – Rural US/UK - Emergency Medical Services diagnosis and tPA administered in the field

The Problem

Currently, 135.7 million Americans are without 60-minute access to a Primary Stroke Center. Even if you have access to air ambulances, this increases access of Americans to a Stroke Center from 22.3% to 26.0% for 30 minute access, 43.2% to 65.5% for 45 minute access, and finally 55.4% to 79.3% for 60 minute access. Therefore, approximately 20% of the country is greater than 60 minutes away from stroke center even by air. This is further highlighted by Figure 7 from Albright et al.

Figure showing access to in-state primary stroke centers in the United States has been removed due to copyright restrictions.

Figure 7: Access to in-state primary stroke centers at 30-, 45-, and 60-minute ground (A) and ground or air (B) ambulance travel times (Source: Albright et al)

In this scenario, our goal is to implement the ultrasound technology in the large “white areas” depicted in the above Figure because it is difficult for this population to reach a stroke center (or often times even a hospital) within the 3hr time window.

Deployment Scenario 1: Ultrasound Technology Utilization In the Field

Betty McKenzie, 88 (Fictional)

- Does not call until 60 minutes post onset
- >1 hours away via air to stroke center
- EMS arrives at home 90 minutes post onset

National Situation

- EMS performs check-list
- At Betty's home, paramedics utilize ultrasound
- Send images to "on-call" neurologists
- Receive clearance to administer tPA
- Transport to closest hospital

Enabling Processes

- Portable, easy to use ultrasound device
- Trained, knowledgeable paramedics
- "Telemedicine" services
- Access to 24/7 neurologists through telemedicine services



Vignette for Scenario 1: Betty McKenzie

- (1) To further highlight this, we will describe a vignette that provides some context for implementing the ultrasound technology in the field. Betty McKenzie is an 88-year old female living in a remote area of North Dakota, who experiences a stroke. Because she is unsure of the symptoms and is not really aware that she is having a stroke, Betty waits approximately 60 minutes to call 911 and emergency services do not arrive until 30 minutes later. Unfortunately, this places Betty 90 minutes into the 3 hr. tPA administration window. As shown in the map below on the right of Figure 8, Betty is quite far from to neurological services. This information was obtained from the Center for Disease Control and Prevention and outlines the access of Americans to stroke care and treatment facilities. In fact, North Dakota does not contain a single stroke center.

Figure 8: Vignette Describing Scenario 1, Ultrasound Technology Utilization in the Field

Once Emergency Services arrives on-site, they perform a check-list to determine if Betty is eligible for tPA administration. Once this information is obtained and verified, paramedics utilize the ultrasound technology to take images of Betty's brain to differentiate between ischemic vs. hemorrhagic stroke. These images are sent to "on-call" neurologists that are located remotely. These neurologists then review the images and give the paramedics clearance to administer tPA. From here, Betty is transported to the closest hospital for follow-up care.

As described above, the main enabling processes associated with this scenario, include the use of a portable, easy to use ultrasound device in the field, trained paramedics, and access to 24/7 “on-call” neurologists via telemedicine services.

Timeline

In order to evaluate the timeline associated with utilizing this technology in the field within the field, we have broken down each of the steps into two areas: variable vs. standardized. The top half of Figure XX highlights the two variables times associated with this scenario: x equals the time for the patient to call EMS and z equals the time for EMS to arrive on-scene. The bottom half of the Figure shows the standardized or fixed processes associated with this scenario. Each of these steps occurs in a very predictable, measurable way. Therefore, EMS requires 60 minutes for the standardized processes, so x+z need to occur in less than 2 hours, so that tPA can be administered within the 3 hour window.

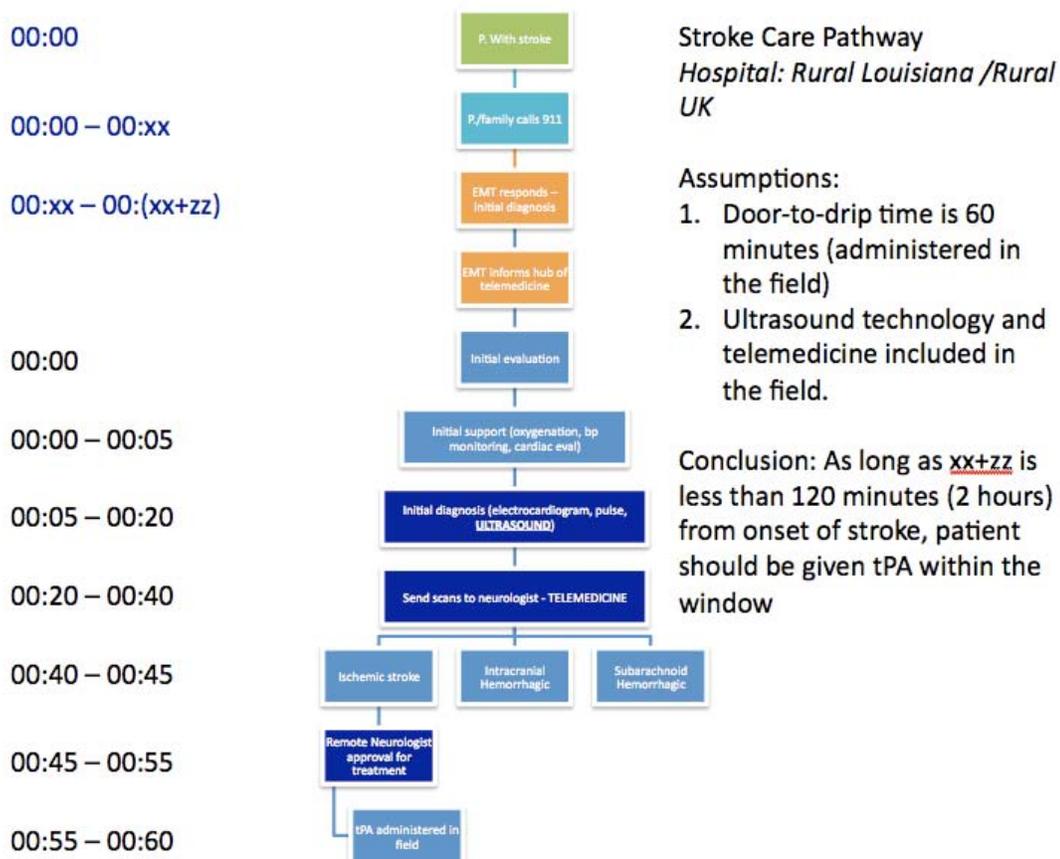


Figure 9: Timeline associated with Stroke Care provided in Scenario 1.

5.2 Scenario 2 – Semi Rural/Semi Urban: Ultrasound used in Community Hospital

The Problem

In the United States, CT scanners are widely available. Approximately 10% of all hospitals in the US do not have access to a CT scanner. These 10% of hospitals in the US are currently small-scale hospitals mostly located in semi-urban, semi-rural areas of the US. For the purposes of this scenario, we are calling such hospitals “community” hospitals. While 10% of all US hospitals may seem like an insignificant number of hospitals, the lack of CT scanners, due to resource limitation, incentive structure amongst other things, is a lot more evident in hospitals in the UK. Hospitals that currently do not have access to CT scanners are therefore, unable to treat stroke.

Scenario 2 thus is applied in the semi-urban/semi-rural US regions such as in the state of Montana where there are only a select few hospitals have access to neurology services. Thus, scenario 2 is applied to the areas with lighter shades of purple in Figure 10 below. Similarly, scenario 2 can be applied to the UK in the white space in the map below (Figure 11), where the density of red dots is low.

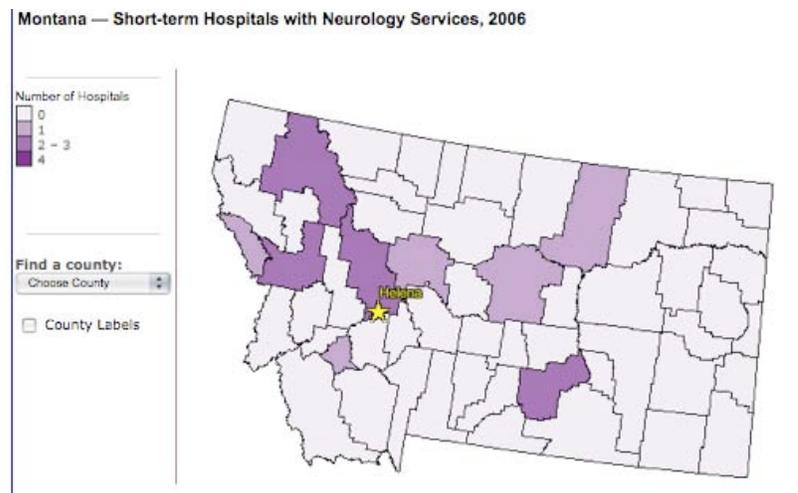


Figure 10: Short term hospitals with neurology services in Montana (US) (CDC data).

Map of the UK from Google Maps showing locations of all hospitals has been removed due to copyright restrictions.

Figure 11: All hospitals in the UK (red dots) (Image from Google maps)

In this scenario, our goal is to implement the ultrasound technology in such community hospitals and by doing so enable them to administer stroke care.

Vignette for Scenario 2: Sean Missoula

(2) To further highlight this, we will describe a vignette that provides some context for implementing the ultrasound technology in community-based hospitals. Sean Missoula is an 80-year old male living in a semi-remote area of Montana or the UK, who experiences a stroke. Because he is unsure of the symptoms and is not really aware that he is having a stroke, Sean waits approximately 60 minutes to call 911 and emergency services do not arrive until 10 minutes later. Unfortunately, this places Betty 70 minutes into the 3 hr. tPA administration window. As shown in the map below on the right of Figure 12, Sean is quite far from neurological services. This information was obtained from the Center for Disease Control and Prevention and outlines the access of Americans to stroke care and treatment facilities.

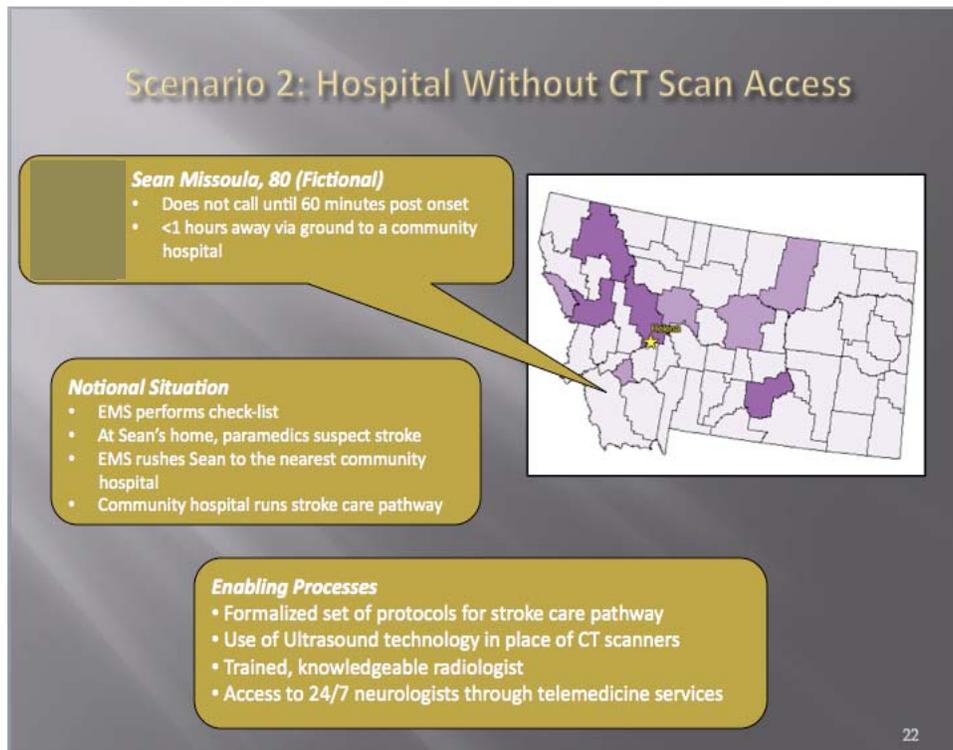


Figure 12: Vignette Describing Scenario 2, Ultrasound Technology Utilization in community hospitals

Once Emergency Services arrives on-site, they perform a check-list to determine if Sean is eligible for tPA administration. Once this information is obtained and verified, paramedics rush Sean to the closest community hospitals. These community hospitals that do not currently have CT scanners are – in the future state are able to utilize the ultrasound technology to take images of Sean's brain to differentiate between ischemic vs. hemorrhagic stroke. These community hospitals that do not currently have neurologists on their staff are able to send these images to round-the-clock "on-call" neurologists

that are located remotely. These remote neurologists then review the images and give the community hospital physician in charge, clearance to administer tPA.

As described above, the main enabling processes associated with this scenario, include the use of an easy to use ultrasound device in community hospitals in situations where CT scanner technology is presently unavailable due to budgetary/incentive structure of the system. In addition to implementation of the ultrasound technology, trained radiologists as well as access to 24/7 “on-call” neurologists via telemedicine services need to be enabled to make this a working pathway.

Timeline

In order to evaluate the timeline associated with utilizing this technology in the field within community, we have broken down each of the steps into two areas: variable vs. standardized. The top half of Figure 13 highlights the two variables times associated with this scenario: x equals the time for the patient to call EMS and y equals the time for EMS to transport the patient from his location to the community hospital. The bottom half of the Figure shows the standardized processes associated with this scenario, based on a number of research papers. Each of these steps occurs in a very predictable, measurable way. Therefore, as long as x+y is less than 1 hour 50 minutes, eligible ischemic stroke patients can be administered tPA.

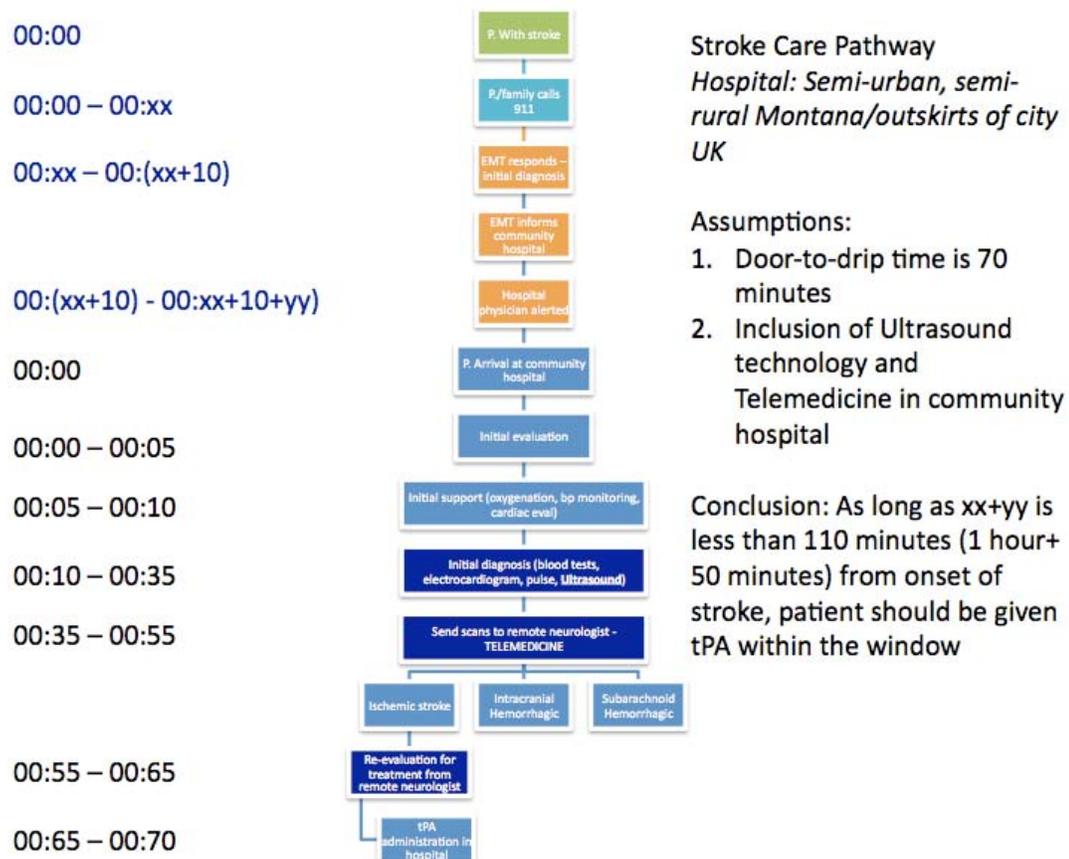


Figure 13: Timeline associated with Stroke Care provided in Scenario 2.

5.3 Scenario 3 –Semi-rural/ Semi-urban hospital - Creation of Chief Engineer to ensure stroke care coordination

The Problem

This is a special scenario where we explore the current system in which the implementation of new technology will not bring about a significant difference. In this scenario we explore the remaining 90% that are not stroke centers US, and a lot of hospitals in the UK. A number of studies done in the US revealed that only 29% of hospitals have the ability to perform and read CT images in-house around the clock. Of 82 hospitals in the US that were studied only 21% of the hospitals reported to have a stroke team and only 1 percent of reporting hospitals have a neurologist on staff round-the-clock.¹⁷

In these much larger hospitals – the limitation is no longer technology. These hospitals have a CT scanner, if not multiple scanners and trained radiologists. Most also have a neurologist on call for at least some part of the day. Consequently these hospitals have the individual components of the stroke care pathway and yet tPA is not being administered to a lot of ischemic stroke patients.

Moreover, when a stroke patient is reached to such a hospital, 76% of the time, the patient is transferred to a stroke center before tPA is administered¹⁷. Through the following analysis we hope to explore the areas in which the current system can be improved without the introduction of new and additional technology.

This scenario is applicable to semi-urban, semi-rural regions such as Montana. In figure 14 (below) one can see that there are some hospitals in almost every county. However, tPA administration rates are still minimal. Figure 15, however, shows the number of neurologists present in Montana. Only 2 counties in the entire state have an adequate number of neurologists present. The scenario is applicable to semi-urban, semi-rural hospitals in the UK as well.

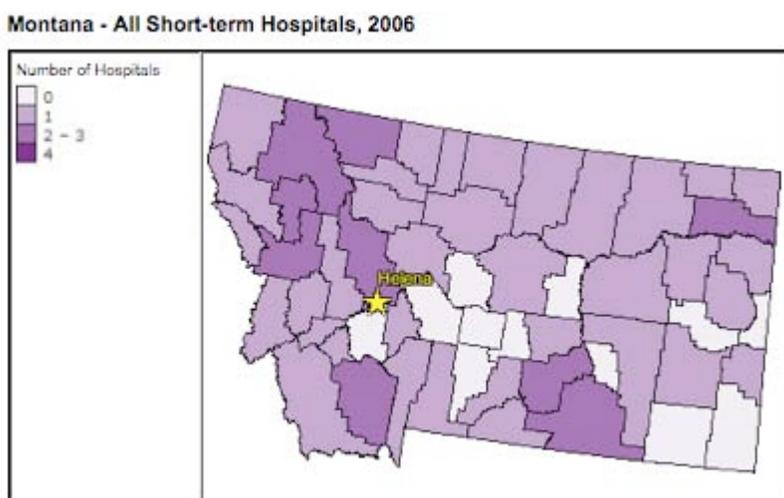


Figure 14: All Short term hospitals in Montana (Source: CDC data).

Montana - Neurologist, 2006

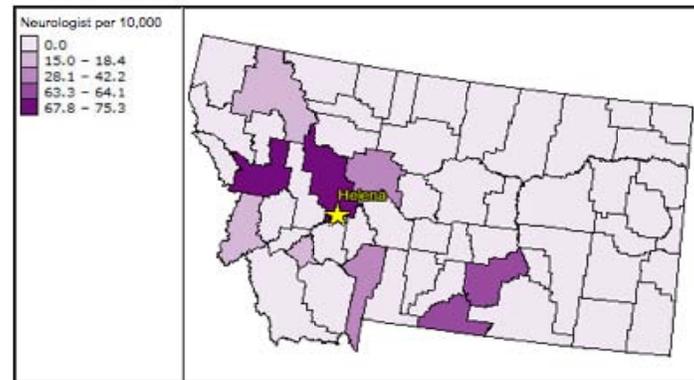


Figure 15: Number of neurologists present in the state of Montana (Source: CDC data).

In this scenario, our goal is to implement the ultrasound technology in the large “white areas” depicted in the above Figure because it is difficult for this population to reach a stroke center (or often times even a hospital) within the 3hr time window.

Vignette for Scenario 1: Betty McKenzie

(3) To further highlight this, we will describe a vignette that provides some context for changing the current care pathway. Bob Montana is an 86-year old male living in a semi-rural area of Montana, who experiences a stroke. Because he is unsure of the symptoms and is not really aware that he is having a stroke, Bob waits approximately 60 minutes to call 911 and emergency services do not arrive until 10 minutes later. The EMTs take a certain amount of time to get Bob to the hospital, giving Bob a little less than 90 minutes into the 3 hr. tPA administration window. As shown in the map below on the right of Figure 8, Bob is near from to neurological services. This information was obtained from the Center for Disease Control and Prevention and outlines the access of Americans to stroke care and treatment facilities.

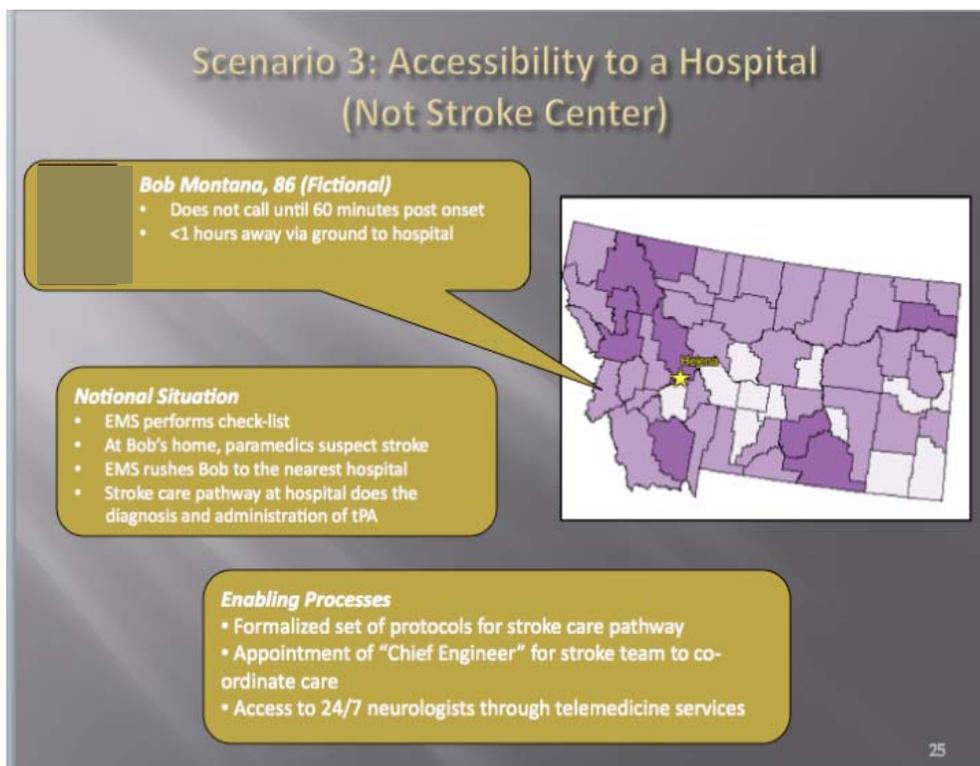


Figure 16: Vignette Describing Scenario 3

Once Emergency Services arrives on-site, they perform a check-list to determine if Bob is eligible for tPA administration. Once this information is obtained and verified, paramedics rush Bob to the nearest hospital. Now the hospital has been enabled to actually administer tPA. The hospital has appointed a "chief engineer", a point person who would co-ordinate care, ensuring that a stroke code is called. In addition, they would ensure that the neurologist on-call is on time to administer care, the CT scanner is available to be used, and the care pathway runs efficiently. When a neurologist is not on call within the hospitals, then the CT scans are sent to "on-call" neurologists that are located remotely through the process of Telemedicine. These neurologists then review the images and give the paramedics clearance to administer tPA. F

As described above, the main enabling processes associated with this scenario, includes the appointment of a “chief engineer” as well as access to 24/7 “on-call” neurologists via telemedicine services.

Timeline

In order to evaluate the timeline associated with utilizing this technology in the field within the field, we have broken down each of the steps into two areas: variable vs. standardized. The top half of Figure XX highlights the two variables times associated with this scenario: x equals the time for the patient to call EMS and y equals the time for EMS to transfer the patient from his home to a hospital. The bottom half of the Figure shows the standardized or fixed processes associated with this scenario. Each of these steps occurs in a very predictable, measurable way. Therefore, as long as x+y need to occur in less than 2 hours, so that tPA can be administered within the 3 hour window.

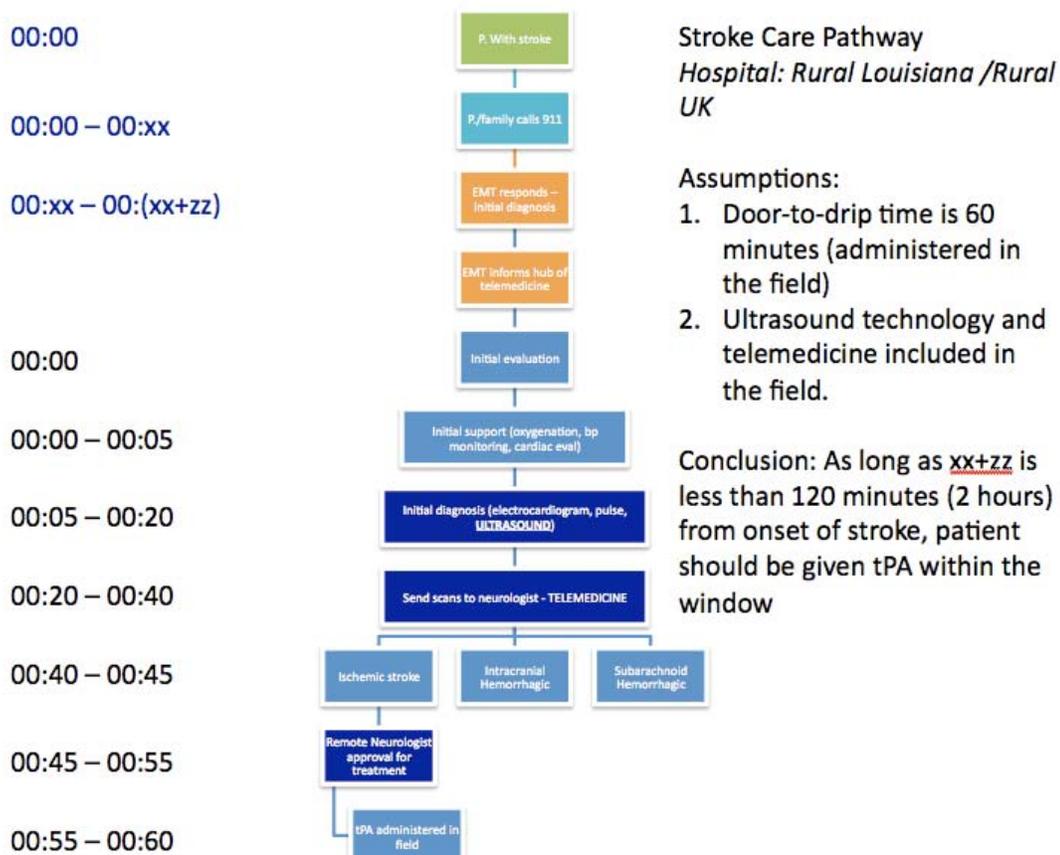


Figure 17: Timeline associated with stroke care provided in Scenario 3

5.4 System effects of implementing Scenarios 1, 2 and/or 3

The three scenarios are compared to the current state-of-the art care available in certain regions of the world, including at stroke centers in the metropolitan Boston and London area. At such centers, the

door-to-needle time for the administration of tPA is about 25 minutes, allowing the remaining 155 minutes of the 180 minutes of the window for the patient to call 911 and arrive at the hospital.

Table 6: Summary of future state scenarios in comparison with a state-of-the-art care pathway

	<i>Geographical location</i>	<i>Resources Present</i>	<i>Proximity to adequate care (in minutes)</i>	<i>Average approximate "door-to-needle" time</i>	<i>Intervention</i>
Scenario 0	Metropolitan Boston (MA) / Metropolitan London (UK)	Stroke Center, state of the art care pathway.	Average transport time: 25 minutes	Average time: 25 minutes	Nothing
Scenario 1	Rural regions (LI)/ Rural UK	No hospital in the near vicinity	Exceeding 180 minutes (>3 hours)	Door to drip time is irrelevant	Usage of ultrasound technology for diagnosis, telemedicine for decision-making and tPA administration in the field.
Scenario 2	Semi-urban-rural regions (MO)/UK	Community Hospital, No CT scanner, no neurologist present	Average transport time (0 to 120 minutes)	Average time is 60 minutes	Increasing resources through the addition of Ultrasound technology in the hospital with the ability to perform telemedicine
Scenario (a,b)	Semi-urban-rural regions (MO)/UK	Hospital CT scanner, neurologist present	Average transport time (0 to 120 minutes)	Average time is 45 minutes a.	Establishing a chief engineer to co-ordinate effective care

Changes to the healthcare pathway are required in order to successfully implement the scenarios discussed. The table below discusses some of these changes in detail.

Table 7: Comparison of System Effects of Implementing Scenarios 1, 2, and 3.

	Scenario 1	Scenario 2	Scenario 3
Description of Scenario	There is no hospital nearby. Ultrasound and tPA administration by emergency medical technicians	Nearby hospital does not have a CT scanner however they do have ultrasound equipment and tPA	Implementation of a Chief Engineer to coordinate stroke care
Insurers/Medical - US Only	Payment must be defined	New DRGs may be required	N/A
NHS Trusts - UK only	Trust budget shifts required: Ambulance service trusts must receive more funding while hospital trusts receive slightly less money	N/A	N/A
Policy Makers	Each EMS region will need to approve new protocols	New country wide protocols required	N/A
Hospital	Increase in complications from the administration of tPA.	-Increase stroke volume at non-stroke center hospitals -New IT infrastructure such that scans can be read off-site by the appropriate medical professional.	Chief engineer to coordinate the care must be hired
EMS (Emergency Medical Services)	-Training for all EMS providers required. -Change to certification curriculum likely required. -Ultrasound equipment must be purchased. -infrastructure for having the appropriate medical professional offsite read the scan must be created.	EMS personnel will need to know how to balance the tradeoff of distance verses hospital capabilities	N/A
Med Schools/Nursing Schools	Need to further educate Emergency Department workers of impact of tPA and what they may see when tPA was delivered in the field	Need to educate future Emergency Department workers on use of ultrasound as a diagnostic tool for stroke	N/A

6 System Dynamics Model

In addition to incentives, and changes in the stroke care pathway, the introduction of new technology such as the portable ultrasound in the field or in a hospital will have cost implications for the system. In order to evaluate the cost implications and to quantify the value associated with the changes, we have

generated a systems dynamic model. Our model stimulates the care pathway of two of the three scenarios outlined above. The scenarios modeled are where Ultrasound technology is implemented in the field and when ultrasound technology is implemented in a community hospital. For each scenario, a closer look at the costs associated with this proposed system of care, through the system dynamics model has been done.

6.1 Model Description

With the system dynamics model we have simulated a system where the **inputs** are as following:

- Number of Stroke patients
- Recommended new polices:
 - Scenario 1: Policies to use ultrasound equipment for ischemic stroke diagnosis in the field by Emergency Medical Services.
 - Scenario 2: Policies to use ultrasound equipment for ischemic stroke diagnosis in the Rural Hospitals by doctors
 - Scenario 3: Policies to create chief engineering to coordinate stroke care in hospitals that are currently not stroke centers but have CT scanners

The system **outputs** will be the different levels of “stocks” representing:

- Hospital Costs
- Death Costs
- Disability Costs

6.1.1 Types of Patients

The base case in the model simulates the processes and flow of stroke patients across the system.

We have divided the patients into four main groups, and have simulated two chains of procedures accordingly.

Table 8: Types of Patients in System Dynamics Model

Group	Description
1	Ischemic Patients arrive to hospital > 3 hours. After stroke onset, patients cannot receive tPA, which is only effective within a small time window after the first onset symptoms.
2	Ischemic Patients arrive to hospital < 3 hours, but tPA cannot be provided because of other complications such as age or diabetes. The solution for this group lays in new tPA treatment innovations and it is not in the scope of this work.
3	Ischemic Patients arrived to hospital < 3 hours not provided tPA. This group represents patients who arrive on time to hospital, but who do not receive tPA due to avoidable reasons, such as lack of consensus between doctors, delay in diagnosis due to the lack of incentive, etc.
4	Ischemic Patients arrived to hospital < 3 hours and are provided tPA.

6.1.2 Variables Used

The variables we have used in order to simulate the processes cost have been extracted from several sources (Cocho et al, UK Stroke Statistics) and are represented in the following table:

Table 9: Variables Used to Model Stroke Care Pathway in Systems Dynamics Model

Model Parameter	Base-Case Value	Description
Ischemic Rate	87%	% of patients with Ischemic Stroke arriving to the hospital
Hemorrhagic Rate	13%	% of patients with Hemorrhagic Stroke arriving to the hospital
Stroke Pathway probabilities		
% Patients arrived >3h to hospital	55%	% of patients arriving to the hospital after 3 hours onset.
% Patients arrived on time non eligible for tPA	75%	% of patients that cannot be provided tPA due to natural reasons like age, diabetes
% Patients provided tPA	3%	% of patients that receive tPA treatment in the hospital.
Probabilities functional outcome		
Stroke non tPA Death	33%	% of patients who die after a stroke even if they have received tPA
Stroke tPA Death	24%	% of patients who die after a stroke without receiving tPA
Stroke non tPA Dependence	33%	% of patients who remain with disabilities due to stroke and who have not received tPA treatment.
Stroke tPA Dependence	21%	% Patients who received tPA but remained with disabilities
Length of stay because of stroke		
ICU tPA	4 days	Average number of days a patient who has received tPA stays in Intensive Care Unit
ICU non-tPA	10 days	Average number of days a patient who has not received tPA stays in Intensive Care Unit

Hospital-rehab center non tPA	33 days	Average number of days a patient who has not been provided tPA will spend in an in-patient ward or rehab center.
Hospital-rehab center tPA	10 days	Average number of days a patient who has been provided tPA will spend in an in-patient ward or rehab center.
Costs		
ICU Cost per Day	\$200	Average Cost per Day per patient in ICU
Hospital-Rehab Cost per Day	\$100	Average Cost per Day per patient in Hospital
Impairment Daily Cost	\$40	Average Costs an impaired patient cost to the system due to daycare needs, familiar not working.
Death Costs	\$1,000	Cost of hospital
tPA Costs	\$15,933	Total cost associated to tPA provision(tPA, technicians, specialists)

6.2 The System Dynamics Model



Stroke_Sys_Model.mdl

Figure 18: System Dynamics Vensim Executable

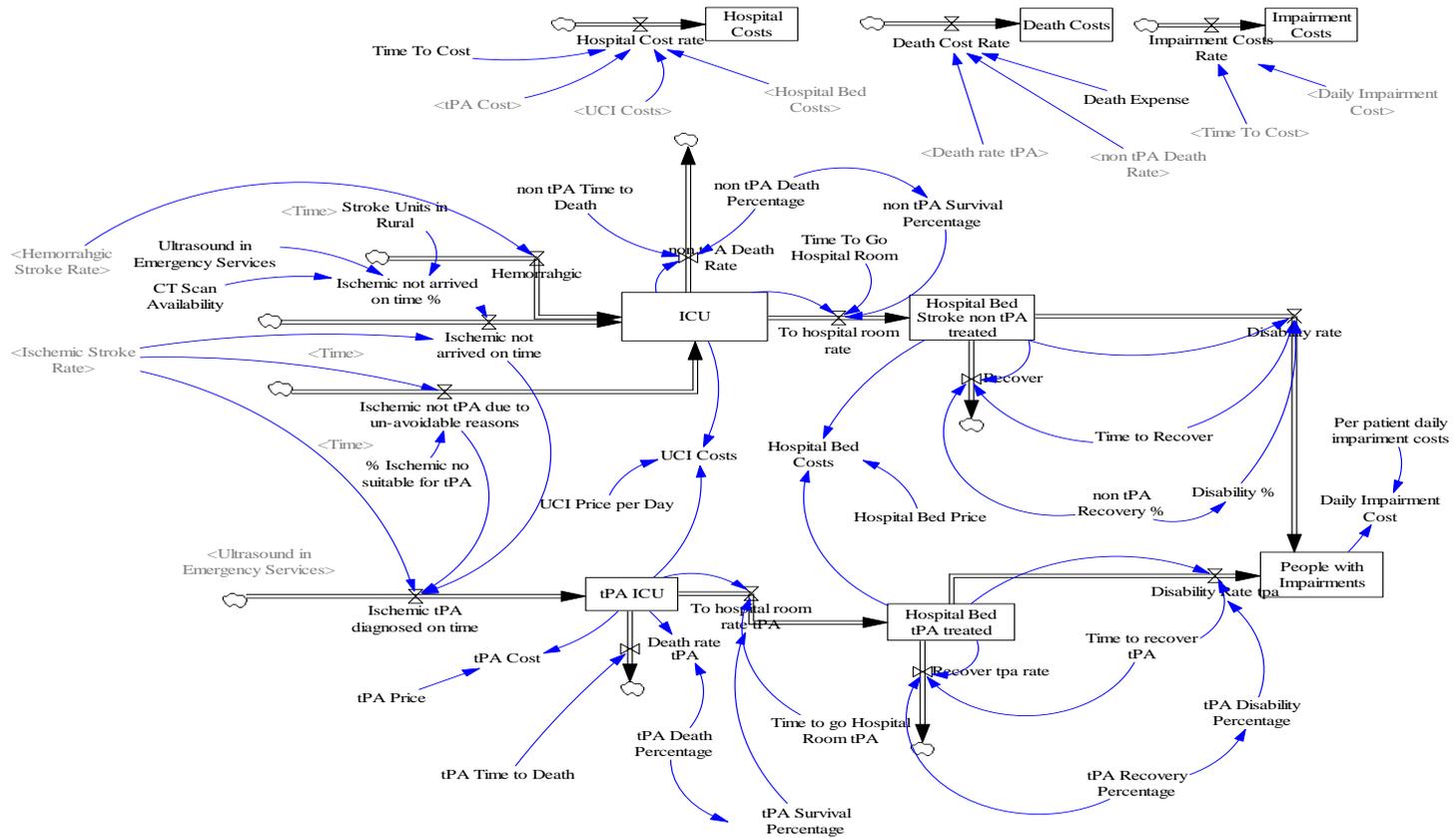


Figure 19: System Dynamics Model

6.3 Model Results

6.3.1. US Results

In this section we present the research results obtained from the application of the two scenarios presented in this paper in the US:

- Scenario 1 (Rural): EMT, Ultrasound and delivery of t-PA to the rural areas, which increases the number of patients that will receive tPA by 15%.
- Scenario 2 (Less Rural): Community hospitals, ultrasound, and delivery of t-PA, which increases the t-PA administration rate by 10%.

The assumptions are shown below and the costs outputs are taken from the System Dynamics model. Although the hospital costs will increase linearly at the beginning, the savings in impairment costs will decrease exponentially. Therefore, the scenario application in the US could reduce healthcare costs.

Assumptions:

- Ischemic Stroke: 1824 patients/ day
- Hemorrhagic: 357 /day
- Scenario 1(Rural): EMTs, Ultrasound, deliver t-PA
 - tPA provided increased rate by: 15%
- Scenario 2 (Less Rural): community hospitals, ultrasound, deliver t-PA
 - tPA provided increased rate by: 10%

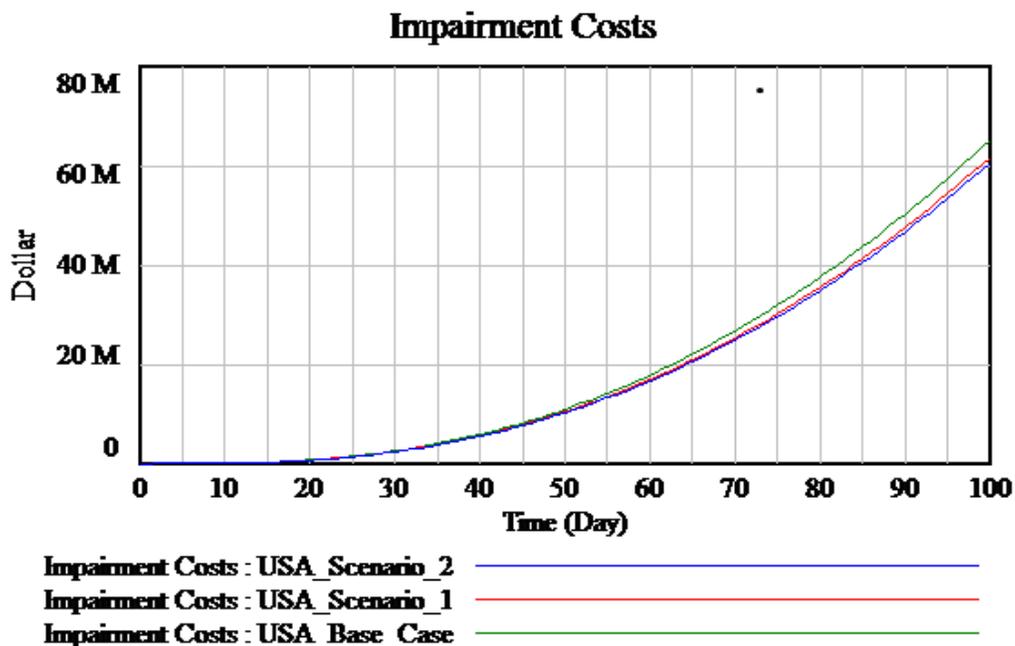


Figure 21: Impairment Costs Graph from System Dynamics Model (US)

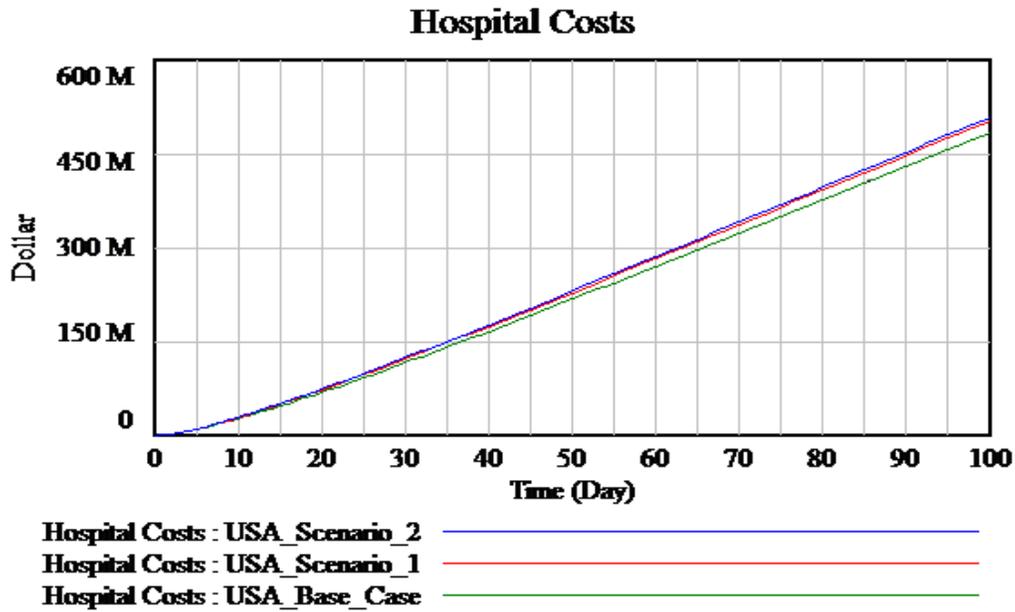


Figure 22: Hospitals Costs Graph from System Dynamics Model (US)

6.3.2 UK Results

In this section, we present the research results obtained from the application of the two scenarios presented in this paper in the UK:

- Scenarios 1 (Rural): EMT, Ultrasound and delivery of t-PA in rural areas, which increases the number patients receiving tPA by 5%.
- Scenario 2 (Less rural): Community hospitals, ultrasound, and delivery of tPA will increase the t-PA administration rate by 2.7%. See assumptions below and costs outputs taken from the System Dynamics model.

As we can see, although the hospital costs will increase linearly at the beginning, the saving in impairment costs will decrease exponentially. Therefore, the scenario application in the UK could reduce healthcare costs. However, due to the smaller population and fewer rural areas, the improvement in the healthcare costs due to the presented scenarios is less significant in the UK compared to the US.

Assumptions:

- Ischemic Stroke: 283 patients/day
- Hemorrhagic : 54 /day
- Scenario 1 (Rural): EMTs, Ultrasound, deliver t-PA
 - tPA provided increased rate by 5%
- Scenario 2 (Less Rural): community hospitals, ultrasound, deliver t-PA
 - tPA provided increased rate by 2.7%

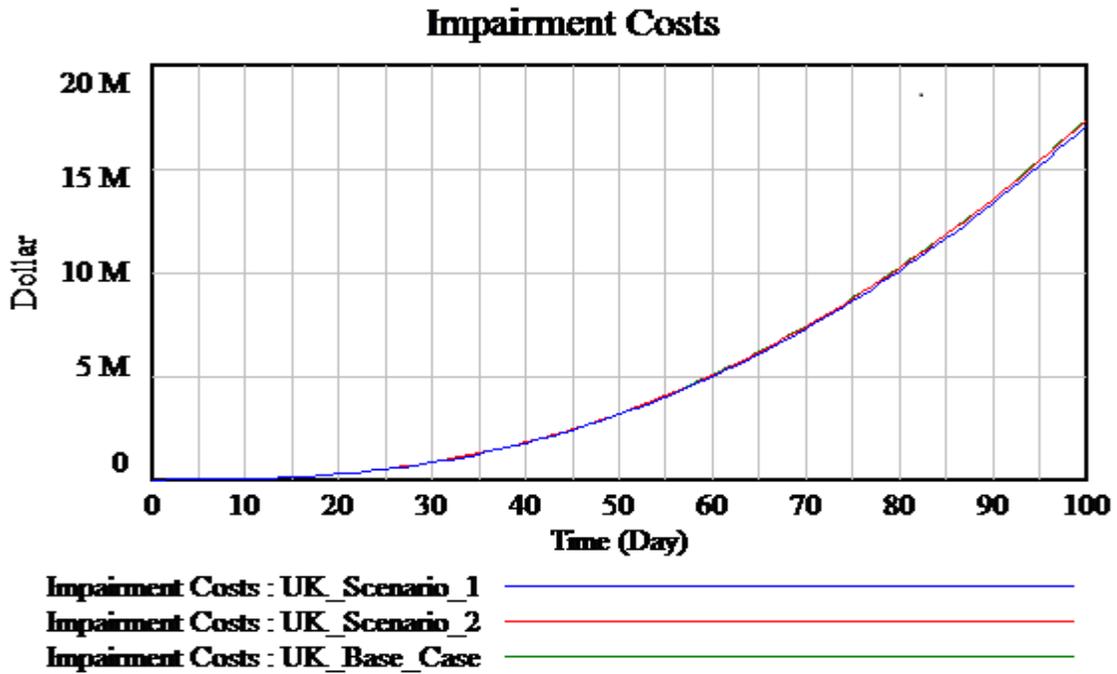


Figure 23: Impairment Costs Graph from System Dynamics Model (UK)

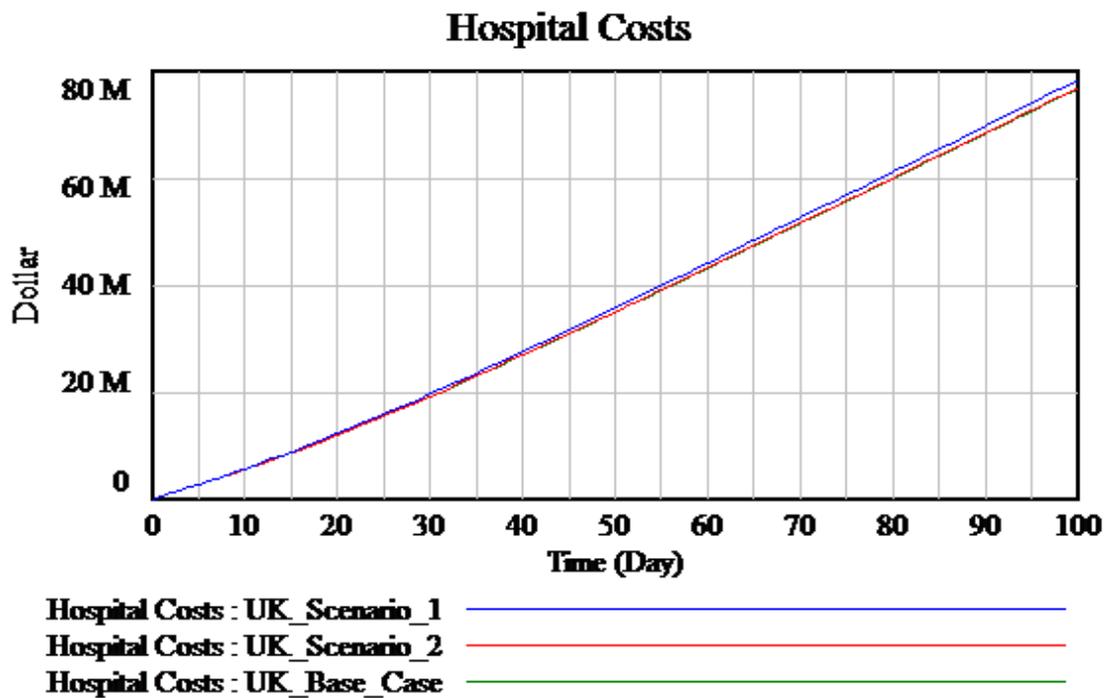


Figure 24: Hospital Costs Graph from System Dynamics Model (UK)

7 Conclusion

Thus, the paper studies the system implications of deploying ultrasound technology in stroke care pathway. We have compared the current system of stroke diagnosis utilizing CT Scan technology with a new system for stroke diagnosis that utilizes ultrasound technology in different scenarios that can play out both in the US and the UK. Through an analysis of the processes and incentives associated with the system of care, as well as the geospatial and temporal dimensions of stroke care pathway, a future state system of care has been created. To further model the system of care surrounding stroke treatment, we have also included a system dynamics model to evaluate the impact of deploying the new stroke care pathway that utilizes ultrasound technology, through a cost based analysis.

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