

Resource 1

Transcranial Magnetic Stimulation (TMS) business case notes

Overview

- The resource aims to support the writing of a business case for TMS
- It's based on the experiences of clinical and other leads given responsibility for developing a TMS business case in the context of an NHS Mental Health Trust.
- While generally decision-makers like a concisely written business case, we have written the business case resource itself in an expansive way to cover several different dimensions that a business case might need to address. While it may not cover every area required by the specific circumstances of your Trust, there is likely to be several areas of commonality. Select the dimensions/ options that are relevant to building your business case.

Service user involvement

- Before starting the process, have you thought about the benefits of co-producing your business case with a service user representative?
- Later in these notes, we provide some information on doing this.

Key decision-makers

- Your medical directors will be key people in the decision-making process, so it is advisable to engage them early in the process, making a compelling case to them
- If it's possible to gain the Chief Executive's support this will facilitate the decision-making and implementation of your business case.

Know your audience

- Your Trust's business case template will explicitly state what evidence it wants as a minimum. Ensure this evidence is provided, closing off a reason/s for rejecting the proposal.

- Clarify who are the decision-makers. A business case is evaluated by different managers/leads with their own subject expertise lenses, focused on their areas of responsibility eg a Business Development Manager will be focused on cost and how it will be met.
 - meet with them to address their own specific issues
 - if your decision-makers put up barriers to a business change that has risk, it may be productive to arrange an informal conversation with a few of them to explore the benefits and positive impacts of the change you are proposing and how might address problems the Trust is experiencing
 - consider what issues and questions the decision-makers will be looking to be addressed and address them. Ensure your evidence is persuasive as possible
- Consider your audience's level of TMS knowledge as well as their knowledge about different dimensions of your case/ proposal. Use language they will understand, avoid jargon and minimise technical language.
 - case studies will support understanding.
 - personal stories are powerful and persuasive because they speak to personal experiences and emotional journeys.
- Avoid statements that are not supported by evidence or lack demonstration of your 'workings'
- Ensure the business case is explicitly aligned with your Trust's published strategic objectives, priorities and aims and national strategies.
- Work collaboratively with the TMS clinicians and relevant managers, regularly communicating with them and ensuring their agreement to the final business case.

Developing the business case

- The process of developing a business case is likely to surface different dimensions of the case. Their exploration will facilitate a decision on their inclusion, or not.
- This exploration is a key step in strengthening the business case because it crystallises the issues relevant to your decision-makers' perspectives and thinking. If your TMS service could be part of the solution for a Trust problem which increases its financial pressures, then focus on these. For example:
 - a Trust wants to offer specific support to staff absent with depression. The TMS service could be interwoven into the existing support structures and facilitate

staff resuming their roles in the Trust. Highlight the benefits, such as costs savings to the Trust as a result of not employing agency staff or Bank staff to cover the absent staff.

- From your meetings with the different decision-makers it is likely that you'll gain a steer about the nature of the business case that will meet their decision threshold. For example, for some decision-makers, less is more, so keep it concise.
 - If it is difficult to keep concise then consider providing an Executive Summary.

Your Trust's business case process

- If this is the first time you have written a business case, you are likely to benefit from:
 - checking the Business Change policy (or its equivalent), if there is one. It will set out the:
 - process for making a business case
 - who you should seek advice and input from
 - mandatory steps (look out for where its language switches to 'must' and 'will')
 - emphasise the different elements to the business case that they template may not reference eg Quality Impact Assessment
 - obtaining a few examples of business cases that have succeeded and failed in your Trust
 - seeking out a mentor who will be able to explain the process from their experience and what they learnt about what helped and what didn't in developing the business case

What your decision-makers might be particularly focused on

- Why their Trust needs a TMS service
- Who the service would be for
- What the level of need is and where the need is currently being met/ not
- What are the clinical benefits and impacts of the business case
- Service user and carer involvement: their voice/ views and their involvement in the service development
- How the business case aligns with national and Trust's strategic objectives

- What the financial cost will be and a detailed cost breakdown
- How this cost will be funded
- An outline of the opportunity cost associated with the current service and gaps in service provision which would be addressed by the service development
- How much the TMS service would reduce financial pressures on the Trust
- How the development would support waiting lists, productivity (eg reduction in service utilisation) and patient safety

Before submitting the business case

- Arrange for a relevant colleague (eg mentor with experience of writing a business case) to read the business case, giving them details of what you want them to check, eg it avoids technical jargon; it makes evidence-based arguments which address specific areas important to the decision-makers; and there are no obvious gaps.
- Arrange for key clinicians to read final draft and your manager to sign-off.
- At the time of submission, inform those who are waiting on the outcome that you have submitted it and the expected date of a decision.

Support

- Some potential sources of support in helping you consider the issues to be addressed in your business case:
 - Until January 2028, contact Tim Nicholls, National Implementation Lead with the NIHR Mental Health Translational Research Collaboration (MH-TRC) Mission: tim.nicholls@cntw.nhs.uk
 - Does a neighbouring Trust have a TMS service for serious mental health problems? If they do, consider contacting the key person to see if they will meet with you to discuss how they developed their service
 - Ask to attend the National Network of TMS Clinicians, which meets monthly. The person who co-ordinates the group is Cat Gullick at: catriona.gullick@somersetft.nhs.uk

Specific business case example

Overview

- The business case example is based on a scenario that draws on different real-world situations that the authors have experienced
- The scenario seeks to capture as many different areas that a business case might be required to address, without unduly overloading the example

Scenario

- The existing TMS service has been run without a specific budget for several years at a minimal level (2 service users treated each month). Its costs have been borne by the ECT service budget.

Aim of business case

- To enhance the service for a pilot period, which will put the service on a sound footing and from which to develop a long-term service and seek second stage funding. The proposal for the service is that it operates with two TMS machines.
- The duration of the pilot period will be decided by several factors and should consider time to:
 - purchase, receive and install TMS machines
 - recruit and train staff
 - produce a robust service evaluation at the conclusion of the pilot period based on an appropriate body of data
 - educate clinicians and community mental health services about TMS and encourage referrals
- If your business case is relying on generating income through private provision, then the pilot period's length should consider the length of time, amongst other things, to put in place the business infrastructure for private provision, stimulate the market and build-up private referrals to generate income.

Issues which surfaced for addressing

1. **Service user's voice:** decision-makers give weight to service users' views, however the current TMS service user questionnaire is limited and did not provide what is needed
2. **Funding the service:** the Service Group that is delivering TMS is in debt and the strong indication is that it will not increase its debt. Decision-makers want to know how the service would be funded in the initial phase of the project and the long-term
3. **Service impact:** the Trust is keen to understand the impact of its services, including:
 - a. their clinical efficacy
 - b. how it meets unmet needs
 - c. how treatment impacts on the quality of life of service users
 - d. how it addresses waiting lists
 - e. how TMS treatment reduces the service utilisation of those who have received it (so increasing productivity) and
 - f. how it will generate cost savings
4. **Problem-solving Trust issues:** investment is attracted to business cases that problem-solve issues experienced by the Trust. One issue is staff absence; another is staff retention. Can a case been made for how the TMS might support with both areas?
5. **Barriers to implementation:** be alive to possible practical barriers that might frustrate the implementation and phasing-in of the service and consider how you will address them.

The approach taken to address each of these 'surfaced' issues are considered in the appendices below.

Addressing issues which surfaced

1. Strengthening the service user voice

Issue

- Prior to the business case submission, a small cohort of service users had received treatment. None had given permission to be contacted post-treatment for their stories about how the treatment had impacted their quality of life. Information Governance advised that any approach to them would be considered 'cold calling'.

How we strengthened the service user voice

- The TMS service amended their Service User Satisfaction Questionnaire to capture views from current service users about the impact of the treatment on their quality of life (giving one example) and whether they would be willing to provide their story as part of the business case. It is important in drafting the Questionnaire not to fall into the trap of including leading questions.
- The Trust's service user organisation was approached.
 - They put out a request to their Service User Involvement Bank (SUIB). One responded to say that they would be interested in receiving TMS.
 - Through the vehicle of an 'Activity Request' to the Patient & Carer Involvement Service we were able to extend the reach of the request for views on whether they would want to have access to TMS for the treatment of depression.
- The clinician involved in delivering TMS treatment, approached service users currently receiving treatment about joining the SUIB Bank with a view to providing case studies on the impact of TMS. I was able to work with both a service user and carer in developing their linked personal stories, which, when shared with two decision-makers had a powerful impact.
- Our Trust employs a Research Involvement Co-ordinator who chairs a Research Departments Steering Group, comprising six service users. I spoke to the Group. Each of them gave feedback that they would like to receive TMS to treat their depression. One provided a full statement in support, which was incorporated into the business case as a Case study.
- We engaged with the Service User and Carer representative for the Integrated Care Board for the region. They invited me to speak to one of the Partnership Involvement Forums in the region, which led to further opportunities with other health care forums to gather views on the availability of TMS treatment provision.
- We liaised with the Trust's Service User and Carer Forum to explore delivering a presentation to the Forum on TMS

2.Funding the service/ income generation

Issue

- The Trust wants the business case to demonstrate that the cost of the service will be partially met in the pilot period with an explanation and projection of how there would be an increase in income generation in future years so that the service costs are fully met.

How we sought to evidence income generation**Income generation sources**

- A limited TMS treatment had been provided to several locality Trusts on a goodwill basis for several years
 - We approached them to explore their interest in placing these arrangements on a formal basis that would increase their access to the treatment provision at the same time as guaranteeing an income for the Trust. The income generated through these agreements would partially meet the cost of resourcing the first enhancement stage.
- The provision of treatment to private individuals/ self-funders.
 - A market analysis would support the case that the generation of income from private provision is feasible. The terms of the analysis instruction could include demand and income projections
 - It will not be possible to deliver this from day one of the enhanced service, so a proportion of the initial period will be unproductive in income terms and this could be represented in any financial planning data.
- Other ideas for potential sources of income generation:
 - private self-funding (£5-8,000 circa per course of treatment).
 - seeking an arrangement with private provider/s of TMS to provide treatment to their 'customers' where they do not have capacity to provide the treatment.
 - scope the potential for taking advantage of the 'market' in 'Mental Health Tourism', including people from other areas making the choice to be treated by your Trust

Calculating the annual profit expected to be generated from TMS private provision

- Your decision-makers will want to know the indicative income that could be generated by the TMS service in a year
- There are different approaches to making this calculation. Your Business Development Manager/ Finance team should be able to support you in doing this.
- The 4 step approach our Business Development Manager preferred was:
 - Step 1: Calculate the *income* from providing 1 x TMS session to a private patient:
 - take the fee charged to the private patient for a full course of TMS (eg £5,000)
 - divide it by the number of TMS sessions in a full course of treatment (eg 30)
 - Income: £5,000 divided by 30 = £166.67
 - Step 2: Calculate the *cost* of providing 1 x TMS session
 - The costs are likely to comprise:
 - capital costs in purchasing the machine
 - costs of adapting the physical space where the machine/s will be located
 - costs of maintaining the machine eg the cost of a warranty or a maintenance package purchased from the TMS machine supplier
 - staff costs (including admin support)
 - consumables, eg EEG caps
 - PDC interest (which is the interest on the loan for the capital cost of purchasing a TMS machine)
 - capital depreciation of the TMS machine
 - Running costs %. Your Trust may require that the TMS service costings include a percentage of the total costs calculated to reflect the cost of all the support services (eg HR, Estates, Finance) that the TMS service relies on to operate
 - We calculated the total of these costs across a year and divided this by the total expected number of TMS sessions we would deliver in a year to establish the *cost* of 1 x TMS session
 - For example: total costs per annum of running the service: £156,207 divided by total expected number of TMS sessions: 2000

- £156,207 divided by 2000 = £78
- Step 3: Calculate the *profit* from providing 1 x TMS session:
 - Income: £166.67
 - Costs: £78.00
 - Profit: £88.67
- Step 4: Multiple the profit by the expected number of privately provided TMS sessions across the year:
 - For example, your service is expected to provide TMS treatment to 24 private patients each year, a full course of treatment being 30 sessions (ie a total of 720 sessions)
 - 720 sessions x £88.67 = £63,842.40

Setting up the private provision of TMS

- **Resource 4** provides information on some of the considerations to address in establishing private provision. It is not intended to be a comprehensive guide.
- Your Trust may require any increase in private patient income by 5% is approved by the Trust's Council of Governors. Whether the income generated by the private provision of TMS breaches this threshold will depend on the level of private patient income generated by the Trust.

3. Strengthening service impact evidence (in addition to clinical effect)

Issues

1. While the service had collated evidence of its clinical effect from the service users who had received the treatment, it had not collected evidence of the social and quality of life impact of the treatment.
2. It is a working hypothesis that the clinical efficacy of TMS would lead to the reduction in service utilisation. Evidence to support this working hypothesis should be collated to provide another benefit to the Trust of funding a TMS service.

How we strengthened the evidence of service impact

1. Social and Quality of life evidence

- It was agreed that the Work and Social Adjustment Scale (WSAS) would be used to collect current service users' perspectives on the impact of the treatment on their everyday activities
- The TMS service amended their Service User Satisfaction Questionnaire to capture views from current service users about the impact of the treatment on their quality of life (giving one example) and whether they would be willing to provide their story as part of the business case.

2. Service utilisation reduction (or improvement in productivity)

- Because Information Governance had advised that we could not approach the small cohort of service users who had received treatment, we made an application to the Clinical Record Interactive Service (CRIS) to compare the pre- and post-treatment service utilisation of the service users.
- CRIS allows a Trust that has implemented CRIS to safely and securely retrieve data from their Trust's Electronic Medical Record System (Rio), de-identify it to protect service user identities and then upload it to a secure database where the data can be queried.
- The interrogated data provided valuable evidence of service utilisation reduction. The service utilisation reduction could be costed to demonstrate the cost effectiveness/ cost savings generated by the TMS service. This would be particularly valuable in relation to the high cost treatment services such as in-patient admissions and ECT
- We also asked another Trust with an established TMS service for case studies of service utilisation reduction.

Problem-solving Trust issues

Issues

1. Staff absence: one in four adults experience mental illness. Depression is a significant cause of disability. Depression and anxiety are a key cause for absence across employment settings.
2. Staff recruitment and retention: generally, Trusts experience problems with recruitment and retention.

How we evidence problem-solving Trust issues

1. Staff absent from work with anxiety and depression

- Some Trusts have services to support absent staff return to work. For example, providing a psychological support service. The Trust service may be willing to expand its offer to staff absent with depression to include TMS. Given the rates of depression, it is likely that this will be attractive to decision-makers.
- The process for achieving this development includes:
 - meeting and providing information on TMS to the support service's senior staff/ (eg its clinical efficacy and safety)
 - working out what level of referrals from the support service could be manageable, taking into account the capacity of your TMS service
 - collaborating on developing the referral process and any related documentation
 - develop a video with a clinician and staff member who has benefitted from TMS treatment which explains, for example, what TMS is, how it works and the benefits of treatment. Work with your Comms Team to develop the video. After you have treated staff members successfully, develop the video resources
 - provide information leaflets on TMS
 - jointly reviewing the referral process and implementing changes focused on improving the process
- When making this provision part of your business case, your Trust is likely to want:
 - details of the number of staff absences linked to depression, the staff roles (other than administrative staff as their absence is likely to be subsumed within the administration team), the calendar days of absence pre-treatment and post-treatment. Staff roles that mean their absence requires agency staff or bank staff to be employed
 - each Trust will have its own process for securing this data. For example, a formal request to the Workforce Planning Team.
 - The Workforce manager for the care group that the TMS service sits in should be able to help you identify the parameters for the search

- Using this data, the Business Development Manager/ equivalent responsible for your service should be able to calculate the prospective cost savings generated by a reduction in staff calendar days lost to absence.
- Embedded here is a method for making the calculation of the indicative cost-savings:



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2. Staff recruitment and retention

- Trusts providing a TMS service have reported that staff engaged with delivering the service demonstrate improved retention because they feel that they are delivering a treatment that 'works and changes lives.' In one Trust that was reviewing how to deliver its physical treatment services, staff were keen to develop knowledge and skills in the delivery of TMS.
- We have liaised with a Senior Research Lead responsible for evaluation of services to work with a staff body to develop a questionnaire to record staff views and feelings on working in the TMS service to support the second enhancement stage of the service.

Barriers to implementation

When the issue of implementation barriers was discussed at a national network meeting of TMS clinicians, 3 issues were identified: money/ budget; staffing; and physical space for the machine. The budget and workforce issues are considered in these notes and in the example of a business case (resource 2).

Issue of physical space

- Where will you site the TMS machine/s and is it a sufficient treatment space for the machine and the staff to access it safely and comfortably.
- Is there a separate staff room and a waiting area for service users
- Will the physical space identified need to be developed and are the electrical socket points in the right location and safe for carrying the machine/s electrical loading. If not, how will this be clarified and addressed.

- Ensure that the cost for any necessary adjustments to the physical location of the TMS machines are included in your costings
- Typically, TMS services are co-located with the ECT service.
 - Is it ethical to operate the two clinics at the same time of day without a physical separation between the two sets of service users to support the dignity of both?
 - If they cannot be separated, how will running the different services at different times impact on the number of TMS service users that can be seen and is this reflected in the business case.

Service user involvement

- One member of the group is co-producing a business case for another innovative mental health treatment and from this experience believes that service user involvement should at least be seriously considered before embarking on the production of a business case.

Benefits

- brings new perspectives and insights, which will add value to service planning, development and delivery
- strengthens the service user voice/ representation in the business case
- keeps the business case orientated to making a difference to people's lives and well-being through the creation of a sense of service ownership and ensuring that future services reflect the needs and wishes of those who use them
- supports credibility when engaging with service user and carer groups
- develops understanding and learning across everyone involved
- encourages reflection of the language being used in communications including documentation
- adds another weight dimension into the business case to support the achievement of the effective use of resources
- if the business case is successful, provides a platform for developing user involvement and representation in the project delivery team

Costs

- commitment to the process from everyone involved is a pre-requisite, otherwise it is likely to fall into the tokenistic trap
- needs resources of time, capacity as well as funding to pay the representative (your Trust is likely to have a service user involvement group that will renumerate the service user)
- may add time into the process
- one member of the team writing the business case should be assigned the responsibility of liaising with the service user, being their point of contact, ensuring they receive their renumeration and communicating regularly with them - even if it's to say there are no updates!

Initial tasks

- Before identifying a service user to join you in the production of a business case:
 - Clarify who you wish to be involved eg an individual service user representative or a select group of service users
 - clarify your budget for renumerating the service user
 - clarify the established renumeration rate and from which fund they will be paid and the process for ensuring payment
 - consider how you are going to involve them, for how long (eg number of meetings/ timelines of project)
 - obtain a service user agreement template, which will set out the expectations for the work and your commitments to the service user. The template should help you think through the detail of the role you would like them to undertake.
 - an example of a service user agreement is:



PPIE%20Agreement
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- the existing service user involvement lead/ team will in most cases be able to support you in both tasks. They may also have a budget for renumerating service users

Process for identifying a service user

- liaise with your Patient and Public Involvement and Engagement (PPIE) Team or Service User Involvement Bank

- a service user with lived experience of mental health problems and/ or treatments is likely to be helpful because of their existing knowledge or interest in the area and/ or motivation to develop services

Process for engaging the service user

- Your Service User Involvement Bank or PPIE Team will have a process for 'on boarding' a service user and ensuring that all governance processes are fulfilled
- Prior to any agreement being signed, provide the service user with sufficient information about the role and expectations that they can make an informed decision about whether to join you.
 - Give them space to seek any clarifications and time to think about their decision as this is more likely to result in a clear 'Yes or No'.
 - The agreement provides for the service user to withdraw from their role at any time.
- If they commit to joining you go through the service user agreement, explain the renumeration rate and how payments are processed and made.

Renumerating the service user

- It is important that you agree with the service user their preference for when payments should be made (eg after each activity they have engaged in or in one sum at the end of the piece of work) and that you ensure payment is processed promptly following receipt of their payment claim.

Checking in with the service user

- Throughout the work and at regular intervals, check-in with your service user and facilitate an honest conversation about what they are doing and their ideas for developing their role and the business case.
- Trauma-informed practice: be mindful of whether the work you ask the service user to do has the potential to trigger or re-trigger emotional distress from negative life experiences. There are 6 key principles of trauma-informed practice, which can be found at: [Working definition of trauma-informed practice - GOV.UK](https://www.gov.uk/government/publications/working-definition-of-trauma-informed-practice)