Evaluating Inputs of Failure Modes and Effects Analysis in Identifying Patient Safety Risks

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Structured Abstract

Purpose: There is a growing awareness on the use of systems approaches to improve patient safety and quality. While earlier studies evaluated the validity of such approaches to identify and mitigate patient safety risks, so far only little attention has been given to their inputs, such as structured brainstorming and use of system mapping approaches (SMAs), to understand their impact in the risk identification process. To address this gap, this study evaluates the inputs of well-known systems approach, Failure Modes and Effects Analysis (FMEA), in identifying patient safety risks in a real healthcare setting.

Design: This study was conducted in a newly established Adult Attention Deficit Hyperactivity Disorder (ADHD) service at Cambridge and Peterborough Foundation Trust in the UK. Three stakeholders of the chosen service together with the facilitators conducted an FMEA exercise along with a particular system diagram that was initially found as the most useful SMA by eight stakeholders of the service.

Findings: In this study, it was found that the formal structure of FMEA adds value to the risk identification process through comprehensive system coverage with the help of the system diagram. However, results also indicates that the structured brainstorming refrains FMEA participants from identifying and imagining new risks since they follow the process predefined in the system diagram given.

Conclusions: While this study shows the potential contribution of FMEA inputs, it also suggests that healthcare organisations should not depend solely on FMEA results when identifying patient safety risks; and therefore prioritising their safety concerns.

Key Words: Patient safety; risk identification; FMEA; system mapping approaches; brainstorming

Article Classification: Original research

Introduction

The problem of the high rate of medical errors and their serious consequences on patient safety and quality have been discussed in various studies since the pioneer report of the Institute of Medicine (IOM), *To Err Is Human: Building a Safer Health System* (IOM, 2000). In response to this problem, one of the recommendations was made on risk management to provide substantial and sustainable improvements in patient safety and quality (Card *et al.*, 2014).

Over the last few decades, risk management has gradually become a valuable tool to assist organisations in improving the effectiveness of care delivery (NPSA, 2006). As Vincent (2001) emphasized, risk management has matured in crucial ways, and has begun to have a positive impact on patient safety and quality of care, rather than simply addressing potential losses as a result of litigation. While retrospective methods, such as incident reporting and investigation, have been embedded in various healthcare contexts in the last two decades (Kurutkan *et al.*, 2015; Simsekler, Card, Ruggeri, *et al.*, 2015), proactive methods are still underused to identify patient safety risks (Simsekler, Card, Ward, *et al.*, 2015; Simsekler *et al.*, 2018a).

Proactive risk management methods are in general systems approaches broadly and successfully utilised in other safety-critical industries, including chemical and aerospace industries (Ward et al., 2010). As suggested by earlier studies, healthcare can potentially be improved by learning from the experiences and methods used in other safety-critical industries to identify a comprehensive list of risks proactively. Since the nature of health systems is dynamic and complex, such systems approaches embedded in proactive methods seem crucial to accelerate improvement in patient safety and quality of care delivered (Carayon *et al.*, 2014).

While more than a hundred systems approaches are used in a range of safety-critical industries; most of the methods have not been applied in the healthcare field (Simsekler, Card, Ward, et al., 2015). From such methods, FMEA has got greater recognition in healthcare since 1990s, and, in turn, it is one of the most widely known and practiced proactive risk assessment tool (Ward *et al.*, 2010).

Due to its popularity, FMEA has been extended and similar methods were developed on it. These methods are called FMECA (Failure Mode Effects and Criticality Analysis) and HFMEA (Healthcare Failure Mode and Effect Analysis). For instance, HFMEA was developed to make the structure of FMEA more appropriate to healthcare settings (Habraken *et al.*, 2009). Providing the system details are available, HFMEA aims to help analyse system factors to identify hazards at a functional level (DeRosier *et al.*, 2002).

As a prospective hazard analysis approach, FMEA is used to identify the ways components, systems, or processes could fail to fulfil the intention of their design (ISO 31010, 2009). This approach is a well-documented process, requiring in-depth knowledge of the system studied (NASA, 1998); it therefore needs a strong multidisciplinary team, including a leader and members from different professional backgrounds with wide collective experience (Alamry *et al.*, 2017).

Despite the benefit FMEA has brought to healthcare because of its prospective nature, many limitations were also noted in the literature. These limitations were mainly about time and cost constraints, and the difficulty of gathering a team for the analysis (Lago *et al.*, 2012). As Potts *et al.* (2014) emphasised, such issues may limit the effective use of FMEA in healthcare. For instance, van Tilburg *et al.* (2006) reported that the entire HFMEA process required more than seven meetings, a total of 140 man-hours, something generally difficult to arrange in healthcare settings where time and resources are limited.

Further discussions have also addressed the validity of FMEA in the healthcare context (Franklin *et al.*, 2012; Shebl *et al.*, 2012). Several studies have shown that different

professional teams identified different risks for the same healthcare setting, and some discrepancies were found in the grading of the same risks (Ashley and Armitage, 2010; Shebl *et al.*, 2009). Potts and colleagues (2014) also stated that it is not surprising that different outcomes can be reached by different teams in applying the same risk assessment tool because of the subjective nature of the analysis. Due to such issues, Shebl *et al.* (2012) proposed that healthcare organisations should not depend solely on the results of FMEA in prioritising patient safety issues. Apart from such issues, it was addressed that the tabular structure of an FMEA does not allow assessors to visualise the system and then identify some other potential risks in the system (Battles *et al.*, 2006; Ward *et al.*, 2010). As a result, the FMEA could not list all necessary risks and lead to unreliable risk identification unless it is supported by the use of system mapping approaches (SMAs, also known as process maps, process models and diagrams). In order to overcome such issues and improve the reliability of FMEA, use of SMAs are recommended along with FMEA exercises so as to visualise and capture potential failure points in a given system (Battles *et al.*, 2006; Ward *et al.*, 2010). In turn, a more comprehensive overview of risks could be identified and more reliable results could be achieved by the analysis.

As the primary research on SMAs in healthcare risk assessment, Jun *et al.* (2009) evaluated the applicability of various mapping approaches in patient safety context. Following this research, Clarkson and his colleagues identified and shortlisted six SMAs, as below, in the Prospective Hazard Analysis (PHA) toolkit to provide fundamental visual representations in the application of prospective hazard analysis approaches (Clarkson *et al.*, 2010).

1- ***Task diagrams*** describe a hierarchy of operations and plans
2- ***Information diagrams*** describe a hierarchy of information and/or material
3- ***Organisational diagrams*** describe a hierarchy of people and/or roles within organisation(s)
4- ***System diagrams*** represent how data are transferred through activities
5- ***Flow diagrams*** represent activities occurring in sequence or in parallel
6- ***Communication diagrams*** represent information and material flows between people and process

A recent study also provided guideline to understand the capability of these six SMAS in identifying different risk sources, such as equipment-related risks, task-related risks, patient-related risks, environmental risks, staff-related risks, communication risks, and organisational risks (Simsekler *et al.*, 2018b). While all these studies evaluated the usability of SMAs in different healthcare settings (Clarkson *et al.*, 2010; Jun *et al.*, 2010; Simsekler *et al.*, 2018), still only limited research results are available to validate the successful embedment of SMAs within the use of prospective hazard analysis tools, such as FMEA, and how helpful they are in risk identification within the scope of risk assessment.

One another important outcome was a result discovered during the HFMEA exercise conducted by Potts and his colleagues (2014). The team raised a central patient safety issue, patient understanding, during the discussion in the HFMEA. However, this issue was not included in the final results of the HFMEA, as it did not readily fit the nature of the structured brainstorming process in FMEA. Many other issues, related to health and safety, hygiene, and sharps, were also discussed; these were also largely absent in the HFMEA results. This may be an important result, demonstrating that structured brainstorming as an input in HFMEA may hinder the imagination of new risks, or may cause safety issues to be disregarded that need to be included in the final results of the chosen method.

Such issues lead us to address the question on the usability and utility of inputs - *structured brainstorming* and *systems mapping approaches* - in prospective risk management tools in

the healthcare context, particularly in the identification of patient safety risks. Therefore, in this study, we aim to understand how the use and selection of systems mapping approaches and the nature of brainstorming play a role in FMEA exercise. It is also vital to understand how such inputs are treated in the context of patient safety in the healthcare field. Therefore, this study integrates systems mapping approaches into a real FMEA exercise along with its brainstorming component to clarify how systems mapping approaches along with the structured brainstorming contribute to the FMEA in identifying risks in a real healthcare setting.

Methods

Study Setting and Participants

This study was carried out in a newly established service, called the Adult ADHD (Attention Deficit Hyperactivity Disorder) Service, based at the Cambridge Peterborough Foundation Trust (CPFT) in the UK. This service provides services to people experiencing ADHD after the age of seventeen. Having a multidisciplinary team of professionals, led by a consulting psychiatrist, the service provides specialist diagnostic services and delivers a range of pharmacological and psychosocial interventions for those with adult ADHD.

Table I shows the characteristics of each participant including job title, the years of experience in the British National Health Service (NHS), experience on the use of SMAs and experience on risk assessment.

Table I here

As the primary step in this study, eight participants from the chosen healthcare setting were involved in individual workshops to evaluate the usability of the SMAs in their healthcare setting with the help of two facilitators, as shown in Table I. We first shortlisted six of the SMAs in accordance with the Prospective Hazard Analysis (PHA) toolkit (Clarkson *et al.*, 2010) to determine their potential contribution to general risk identification and to assess their ability to identify different types of risk sources. For the purpose of this study, the aim in the SMA evaluation was to help the stakeholders of the chosen service to select the best matching SMA to use throughout the FMEA exercise.

As exclusively detailed in our recent study (Simsekler *et al.*, 2018), the results showed that the *system diagram* was the most useful SMA to identify patient safety risks in the chosen healthcare setting since it includes a comprehensive view on system components, such as stakeholders, tasks, and data transfers throughout the process, in one picture (see Appendix).

As the secondary step in this study, we conducted the FMEA exercise along with the most useful SMA – *system diagram* – identified in the primary step. For the FMEA exercise three participants and two facilitators were involved.

Procedure

At the beginning of the FMEA exercise, the facilitators, the research background, and the aim of the study were first introduced to the participants. The tabular structure of the FMEA process, as shown in Table II, was then introduced to the participants in greater detail as follows:

1. Describing the system; identifying system components and system functions in order, by following the chosen SMA; *system diagram*

2. Identifying the failure modes
3. Determining the potential cause of each failure mode
4. Determining the immediate effect of each failure mode
5. Determining the system consequences
6. Determining the current controls
7. Ranking the likelihood of failure mode effects
8. Ranking the severity of failure mode effects
9. Grading the risk (severity x likelihood; hence identifying low, medium, and high risks)

Table II here

The first two column headings in the FMEA table (component and function headings, as shown in Table II) were filled out by the facilitators by following the chosen *system diagram*. This served as the main component of the bridge to be constructed between the *system diagram* and FMEA. Following the activity stages in the *system diagram*, each system component and function were identified for each possible risk. A range of failure modes associated with the functions were then listed by the facilitators.

As shown in Table II, FMEA has no explicit risk identification process for identifying the risk components, such as *hazard*, *cause*, and *effect*. However, *failure mode, potential cause,* and *immediate effect* serve as equivalents that can be associated with risk identification. After identifying the failure modes, participants were asked to identify the potential cause, immediate effect, system consequence, and current control for each failure mode. After these, severity and likelihood dimensions were assessed for each component identified. These were then multiplied to arrive at the risk priority number, based on the grading matrix used by the Trust. Although Table II provides the whole process of the FMEA, in this study we focused solely on the first five steps, since they are the only ones relevant to risk identification within the scope of the risk assessment process.

After completing the FMEA exercise, the participants were also asked to provide further comments on the use of *system diagram* and structured brainstorming process during the FMEA. Due to the limited number of participants and possibility to obtain limited quantitative results via statistical analysis, we verbally asked the following statements to the participants to gather their opinions for the purpose of the evaluation in the study.

- Statement 1. I found FMEA is helpful in risk identification
- Statement 2. Listing all potential failure modes in FMEA is helpful in risk identification
- Statement 3. I found the use of system diagrams is helpful in risk identification
- Statement 4. Brainstorming through FMEA is helpful in risk identification
- Statement 5. The same risks can be identified without using FMEA
- Statement 6. FMEA helped me become more aware of system-wide safety risks

Results and Discussion

In general, the FMEA session was constructive and interactive, with valuable insights contributed by all participants. Team participation in risk identification, and then grading the risks, was high. The identified risks can be seen in Table III.

Table III here

In general, FMEA exercise provided a direct link between system components and risk components. We identified 22 risks (see Table III) from the part of the system that we were able to cover in the course of the FMEA exercise. It was helpful to rank the system elements in terms of risks. It was observed that the success of the risk identification process in FMEA was primarily related to the system description provided by the *system diagram*, which helped define system components, functions, and failure modes, in order. We also found that the FMEA success was related to the motivation of the participants in the brainstorming session. It was noted that participants' positive motivation could enhance the risk identification process by identifying multiple causes and effects for each failure mode.

During the FMEA exercise, the participants found the *system diagram* very helpful. It is a relatively new finding of this study that service users were given freedom to select the most suitable SMA; a valuable insight into the study was gained because the users chose the diagram. Although the use of the *system diagram* provided a contribution to this research, it was also determined that this helped identify known risks, within the limits of its capability, as found in an earlier study (Colligan *et al.*, 2010). Due to the nature of the *system diagram*, no external risks were captured — a fact criticised by the participants concerned with critical safety issues in the service. It can therefore be assumed that the validity of FMEA is relevant to the chosen SMA, and its power to represent the system. It should also be noted that with FMEA, the role of facilitators is in general very important. In this case, although the facilitators had had experience with PHA in general, the current study was the first in which they had served as facilitators; this too might have had an impact on the quality of the results.

At the end of the FMEA session, we verbally asked six statements to gather the participants' opinions on the overall study. As mentioned in the first statement, the participants found the FMEA to be an acceptable and positive approach towards identifying risks proactively. Throughout the FMEA exercise, listing all potential failure modes in a spreadsheet was helpful in identifying risks in a useful manner. Further, the participants indicated that the *system diagram* was helpful in guiding the analysis of risk identification though it was limited to identify environmental risks. They also stated that while they became more aware of system-wide safety risks, they were still not sure whether FMEA was helpful in covering all relevant risks in their healthcare service. Further, participants mentioned that they had expected to be able to address some important concerns they had about the service, but following the structure given in the *system diagram* prevented them from raising these concerns and even imagining new risks. The participants also pointed out the importance of the facilitators' role in completely considering all system functions within the time allotted for the FMEA exercise.

As experienced in an earlier study (Potts *et al.*, 2014), a potential limitation of FMEA was found in the identification of external and environmental risks, as they were not addressed in the chosen *system diagram*. For instance, during the FMEA exercise one participant highlighted an issue regarding the physical environment of the service. However, this issue was not included in the FMEA result, since the failure modes were only identified based on the process steps shown in the *system diagram*, and no identification of external risks was allowed. Therefore it can be shown that the structured brainstorming through the use of *system diagram* or any other types of diagrams, such as work flow diagram, in FMEA may refrain participants from identifying some other types of risks that are out of the scope of the chosen diagram. With such limitations, it can be said that the outputs from FMEA should not be relied upon in isolation as highlighted in earlier studies (Shebl *et al.*, 2009). Therefore, they should be treated as a valuable output supporting the overall risk identification in any chosen healthcare settings. Some recent studies also supported the value of FMEA in particular healthcare settings, and indicated that FMEA can be an effective approach for quality improvement (Alamry *et al.*, 2017; Rosen *et al.*, 2015).

As experienced in earlier studies (Ashley and Armitage, 2010; Shebl *et al.*, 2009), it can be said that different results might be obtained with different and/or more participants in another longer study, but it was observed that the limited number of participants allowed for more accurate capture of the perceptions of the participants. As shown in earlier studies (Ashley and Armitage, 2010; Potts *et al.*, 2014), although participants had differing views on potential risks in some cases, they were easily able to reach a consensus during the analysis of each failure mode. Considering how little time for risk assessment is often allotted in healthcare, it is worth remembering that a small group of people can often reach consensus quickly.

It can be concluded that the efficacy of FMEA was directly affected by the chosen SMA (*system diagram* in this study), time, the experience of facilitators and participants, the number of participants, and their motivation as a multidisciplinary team. Having better options available for these factors may provide better results on the validity of FMEA that was addressed in earlier studies (Potts *et al.*, 2014; Shebl *et al.*, 2012). Further, practical aspect of the FMEA will also be enhanced through a better use of inputs, such as selecting the most helpful system mapping approaches and using the knowledge and experience of facilitator and participants during the brainstorming session.

Conclusions

This study addressed and elaborated the impact of the primary inputs – SMAs and structured brainstorming – utilised throughout the FMEA exercise. Regarding the results of the FMEA exercise, it can be said that FMEA has merit in risk identification, but also had limitations experiences in this study.

It was concluded that FMEA provided a useful opportunity for detailed risk identification using *system diagram* along with *structured brainstorming*, but healthcare organisations should not depend solely on the results of the FMEA in identifying patient safety risks. However, the primary inputs of this approach, such as brainstorming and SMAs, would contribute to the improvement of current risk identification practices with a better adaptation to the healthcare context.

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Competing Interests

The authors declared no potential conflicts of interests with respect to the authorship and/or publication of this article.

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References

Alamry, A., Al Owais, S.M., Marini, A.M., Al-Dorzi, H., Alsolamy, S. and Arabi, Y. (2017), "Application of Failure Mode Effect Analysis to Improve the Care of Septic Patients Admitted Through the Emergency Department", *Journal of Patient Safety*, Vol. 13 No. 2, p. 76.

Ashley, L. and Armitage, G. (2010), "Failure Mode and Effects Analysis: An Empirical Comparison of Failure Mode Scoring Procedures", *Journal of Patient Safety*, Vol. 6 No. 4, pp. 210–215.

Battles, J.B., Dixon, N.M., Borotkanics, R.J., Rabin-Fastmen, B. and Kaplan, H.S. (2006), "Sensemaking of Patient Safety Risks and Hazards", *Health Services Research*, Vol. 41 No. 4 Pt 2, pp. 1555–1575.

Carayon, P., Wetterneck, T.B., Rivera-Rodriguez, A.J., Hundt, A.S., Hoonakker, P., Holden, R. and Gurses, A.P. (2014), "Human factors systems approach to healthcare quality and patient safety", *Applied Ergonomics*, Vol. 45 No. 1, pp. 14–25.

Card, A.J., Simsekler, M.C.E., Clark, M., Ward, J.R. and Clarkson, P.J. (2014), "Use of the Generating Options for Active Risk Control (GO-ARC) Technique can lead to more robust risk control options", *The International Journal of Risk & Safety in Medicine*, Vol. 26 No. 4, pp. 199–211.

Clarkson, P.J., Ward, J.R., Buckle, P. and Berman, J. (2010), *Prospective Hazard Analysis Toolkit*, No. 978-0-9545243-4–0, University of Cambridge, Cambridge.

Colligan, L., Anderson, J.E., Potts, H.W. and Berman, J. (2010), "Does the process map influence the outcome of quality improvement work? A comparison of a sequential flow diagram and a hierarchical task analysis diagram", *BMC Health Services Research*, Vol. 10 No. 1, p. 7.

DeRosier, J., Stalhandske, E., Bagian, J.P. and Nudell, T. (2002), "Using health care Failure Mode and Effect Analysis: the VA National Center for Patient Safety's prospective risk analysis system", *The Joint Commission Journal on Quality Improvement*, Vol. 28 No. 5, pp. 248–267, 209.

Franklin, B.D., Shebl, N.A. and Barber, N. (2012), "Failure mode and effects analysis: too little for too much?", *BMJ Quality & Safety*, Vol. 21 No. 7, pp. 607–611.

Habraken, M.M.P., Van der Schaaf, T.W., Leistikow, I.P. and Reijnders-Thijssen, P.M.J. (2009), "Prospective risk analysis of health care processes: a systematic evaluation of the use of HFMEA in Dutch health care", *Ergonomics*, Vol. 52 No. 7, pp. 809–819.

IOM. (2000), *To Err Is Human: Building A Safer Health System*, National Academy Press, Washington, available at: (accessed 1 November 2013).

ISO 31010. (2009), *IEC 31010:2009 Risk Management - Risk Assessment Techniques*, The International Organization for Standardization, Switzerland.

Jun, G.T., Ward, J. and Clarkson, P.J. (2010), "Systems modelling approaches to the design of safe healthcare delivery: ease of use and usefulness perceived by healthcare workers", *Ergonomics*, Vol. 53 No. 7, pp. 829–847.

Jun, G.T., Ward, J., Morris, Z. and Clarkson, J. (2009), "Health care process modelling: which method when?", *International Journal for Quality in Health Care*, Vol. 21 No. 3, pp. 214–224.

Kurutkan, M.N., Usta, E., Orhan, F. and Simsekler, M.C.E. (2015), "Application of the IHI Global Trigger Tool in measuring the adverse event rate in a Turkish healthcare setting", *The International Journal of Risk & Safety in Medicine*, Vol. 27 No. 1, pp. 11–21.

Lago, P., Bizzarri, G., Scalzotto, F., Parpaiola, A., Amigoni, A., Putoto, G. and Perilongo, G. (2012), "Use of FMEA analysis to reduce risk of errors in prescribing and administering drugs in paediatric wards: a quality improvement report", *BMJ Open*, Vol. 2 No. 6, available at:https://doi.org/10.1136/bmjopen-2012-001249.

NASA. (1998), *Other Hazard Analysis Methodologies*, No. NASA-STD-8719.7, NASA.

NPSA. (2006), *Risk Assessment Programme Overview*, National Patient Safety Agency, London, available at: http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59813 (accessed 1 November 2013).

Potts, H.W., Anderson, J.E., Colligan, L., Leach, P., Davis, S. and Berman, J. (2014), "Assessing the validity of prospective hazard analysis methods: a comparison of two techniques", *BMC Health Services Research*, Vol. 14 No. 1, p. 41.

Rosen, M.A., Chima, A.M., Sampson, J.B., Jackson, E.V., Koka, R., Marx, M.K., Kamara, T.B., Ogbuagu, O.U., Lee, B.H. (2015), "Engaging staff to improve quality and safety in an austere medical environment: a case–control study in two Sierra Leonean hospitals", *International Journal for Quality in Health Care*, Vol. 27 No. 4, pp. 320–327.

Shebl, N.A., Franklin, B.D. and Barber, N. (2009), "Is failure mode and effect analysis reliable?", *Journal of Patient Safety*, Vol. 5 No. 2, pp. 86–94.

Shebl, N.A., Franklin, B.D. and Barber, N. (2012), "Failure mode and effects analysis outputs: are they valid?", *BMC Health Services Research*, Vol. 12, p. 150.

Simsekler, M.C.E., Card, A.J., Ruggeri, K., Ward, J.R. and Clarkson, P.J. (2015), "A comparison of the methods used to support risk identification for patient safety in one UK NHS foundation trust", *Clinical Risk*, Vol. 21, pp. 37–46.

Simsekler, M.C.E., Card, A.J., Ward, J.R. and Clarkson, P.J. (2015), "Trust-Level Risk Identification Guidance in the NHS East of England", *The International Journal of Risk & Safety in Medicine*, Vol. 27 No. 2, pp. 67–76.

Simsekler, M.C.E., Ward, J.R. and Clarkson, P.J. (2018a), "Design For Patient Safety: A Systems-based Risk Identification Framework", *Ergonomics*, pp. 1–19.

Simsekler, M.C.E., Ward, J.R. and Clarkson, P.J. (2018b), "Evaluation of system mapping approaches in identifying patient safety risks", *International Journal for Quality in Health Care*, pp. 1–7.

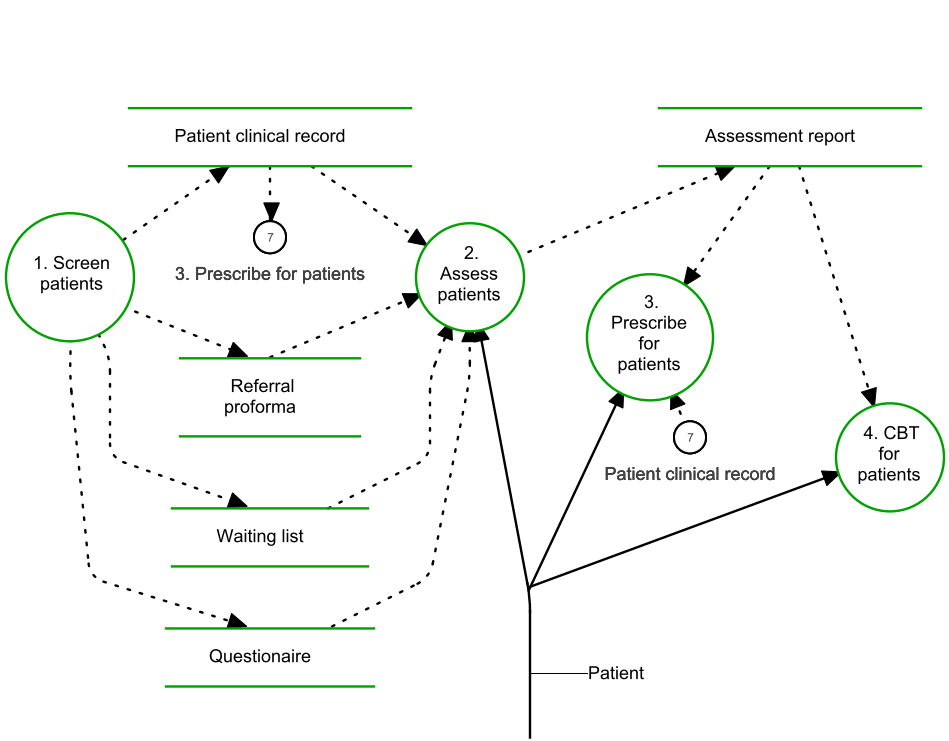
van Tilburg, C.M., Leistikow, I.P., Rademaker, C.M.A., Bierings, M.B. and van Dijk, A.T.H. (2006), "Health care failure mode and effect analysis: a useful proactive risk analysis in a pediatric oncology ward", *Quality & Safety in Health Care*, Vol. 15 No. 1, pp. 58–63.

Vincent, C. (Ed.). (2001), *Clinical Risk Management: Enhancing Patient Safety*, 2nd Edition., Wiley-Blackwell.

Ward, J.R., Clarkson, P.J., Buckle, P., Berman, J., Lim, R. and Jun, G.T. (2010), *Prospective Hazard Analysis: Tailoring Prospective Methods to a Healthcare Context*, Patient Safety Research Programme of the Department of Health, Cambridge.

Wynn, D.C., Wyatt, D.F., Nair, S.M.T. and Clarkson, P.J. (2010), "An introduction to the Cambridge Advanced Modeller", *1st International Conference on Modelling and Management of Engineering Processes*, presented at the MMEP, Cambridge.

Figure 0


Patient clinical record
Assessment report
1. Screen patients
7
3. Prescribe for patients
2. Assess patients
3. Prescribe for patients
Referral proforma
7
Patient clinical record
4. CBT for patients
Waiting list
Questionaire
Patient

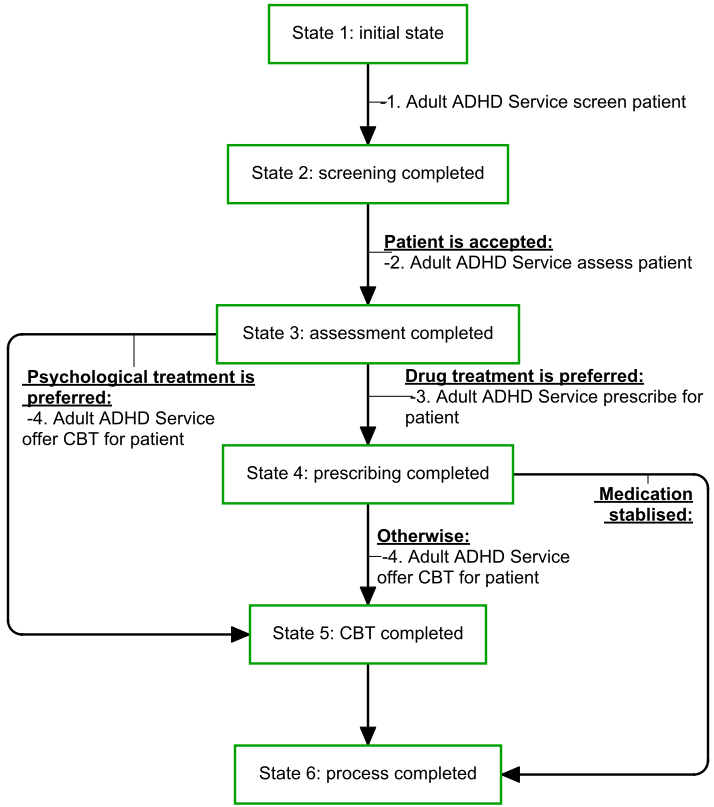
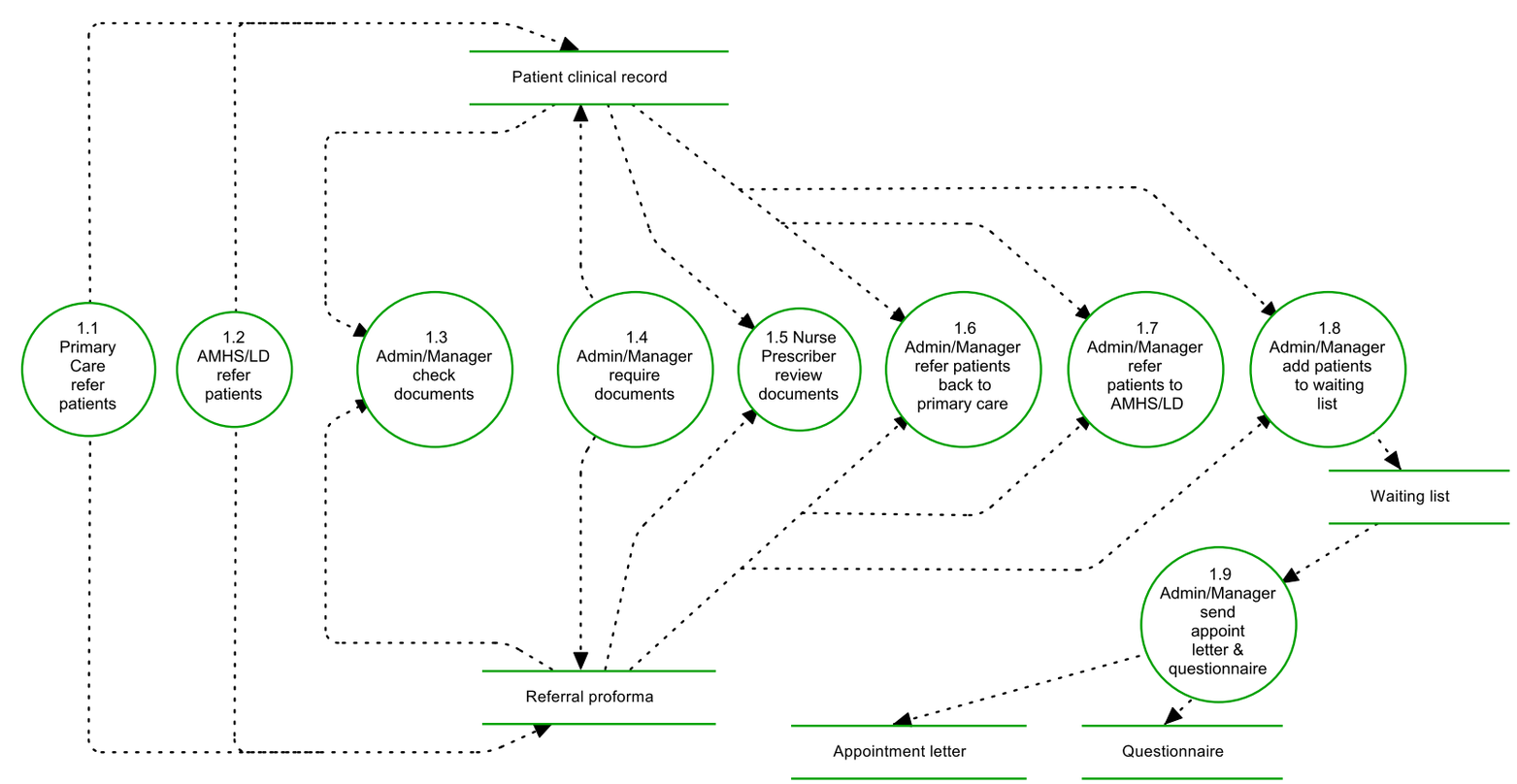

State 1: initial state
1. Adult ADHD Service screen patient
State 2: screening completed
Patient is accepted:
2. Adult ADHD Service assess patient
State 3: assessment completed
Psychological treatment is preferred:
4. Adult ADHD Service offer CBT for patient
Drug treatment is preferred:
3. Adult ADHD Service prescribe for patient
State 4: prescribing completed
Medication stablised:
Otherwise:
4. Adult ADHD Service offer CBT for patient
State 5: CBT completed
State 6: process completed

Figure 1


Patient clinical record
1.1 Primary Care refer patients
1.2 AMHS/LD refer patients
1.3 Admin/Manager check documents
1.4 Admin/Manager require documents
1.5 Nurse Prescriber review documents
1.6 Admin/Manager refer patients back to primary care
1.7 Admin/Manager refer patients to AMHS/LD
1.8 Admin/Manager add patients to waiting list
Waiting list
1.9 Admin/Manager send appoint letter & questionnaire
Referral proforma
Appointment letter
Questionnaire

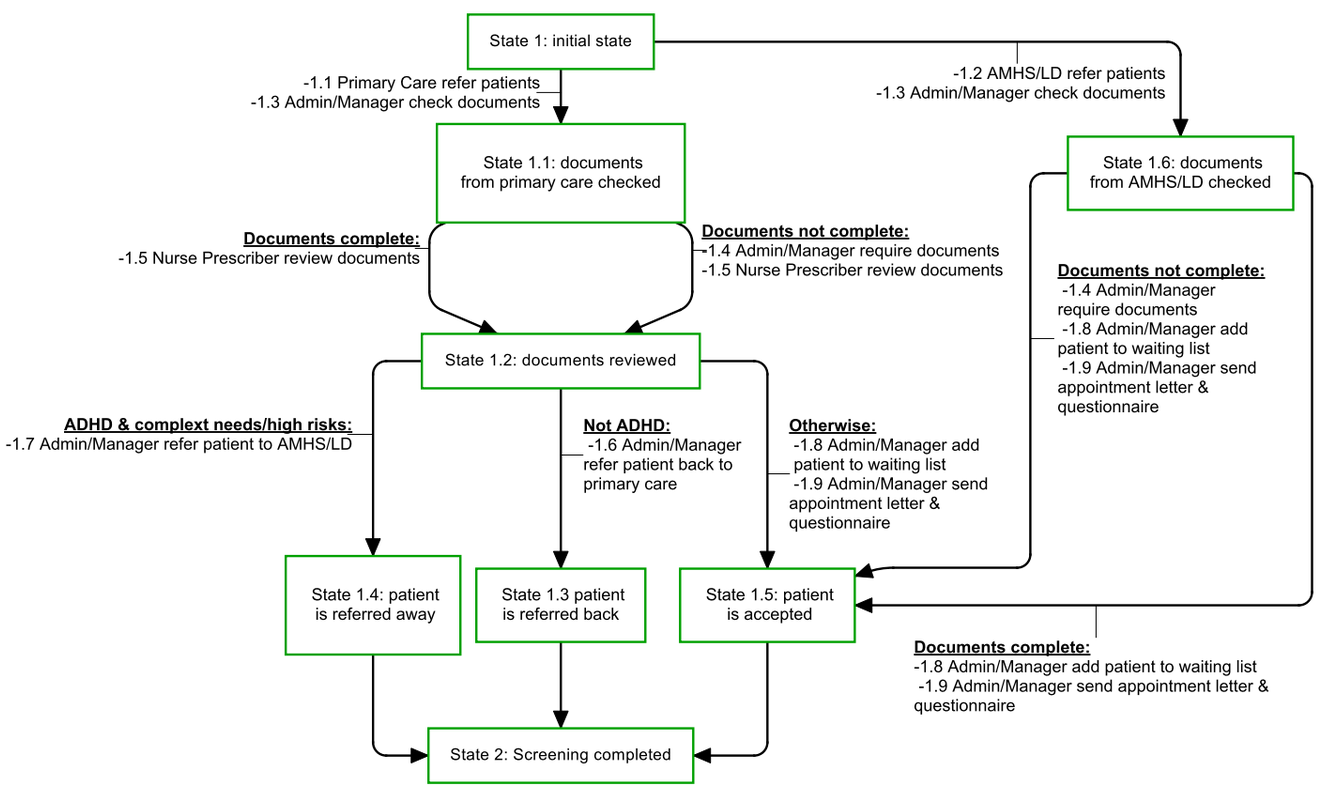

State 1: initial state
-1.1 Primary Care refer patients
-1.3 Admin/Manager check documents
-1.2 AMHS/LD refer patients
-1.3 Admin/Manager check documents
State 1.1: documents from primary care checked
State 1.6: documents from AMHS/LD checked
Documents complete:
-1.5 Nurse Prescriber review documents
Documents not complete:
-1.4 Admin/Manager require documents
-1.5 Nurse Prescriber review documents
Documents not complete:
-1.4 Admin/Manager require documents
-1.8 Admin/Manager add patient to waiting list
-1.9 Admin/Manager send appointment letter & questionnaire
State 1.2: documents reviewed
ADHD & complext needs/high risks:
-1.7 Admin/Manager refer patient to AMHS/LD
Not ADHD:
-1.6 Admin/Manager refer patient back to primary care
Otherwise:
-1.8 Admin/Manager add patient to waiting list
-1.9 Admin/Manager send appointment letter & questionnaire
State 1.4: patient is referred away
State 1.3 patient is referred back
State 1.5: patient is accepted
Documents complete:
-1.8 Admin/Manager add patient to waiting list
-1.9 Admin/Manager send appointment letter & questionnaire
State 2: Screening completed

Figure 2

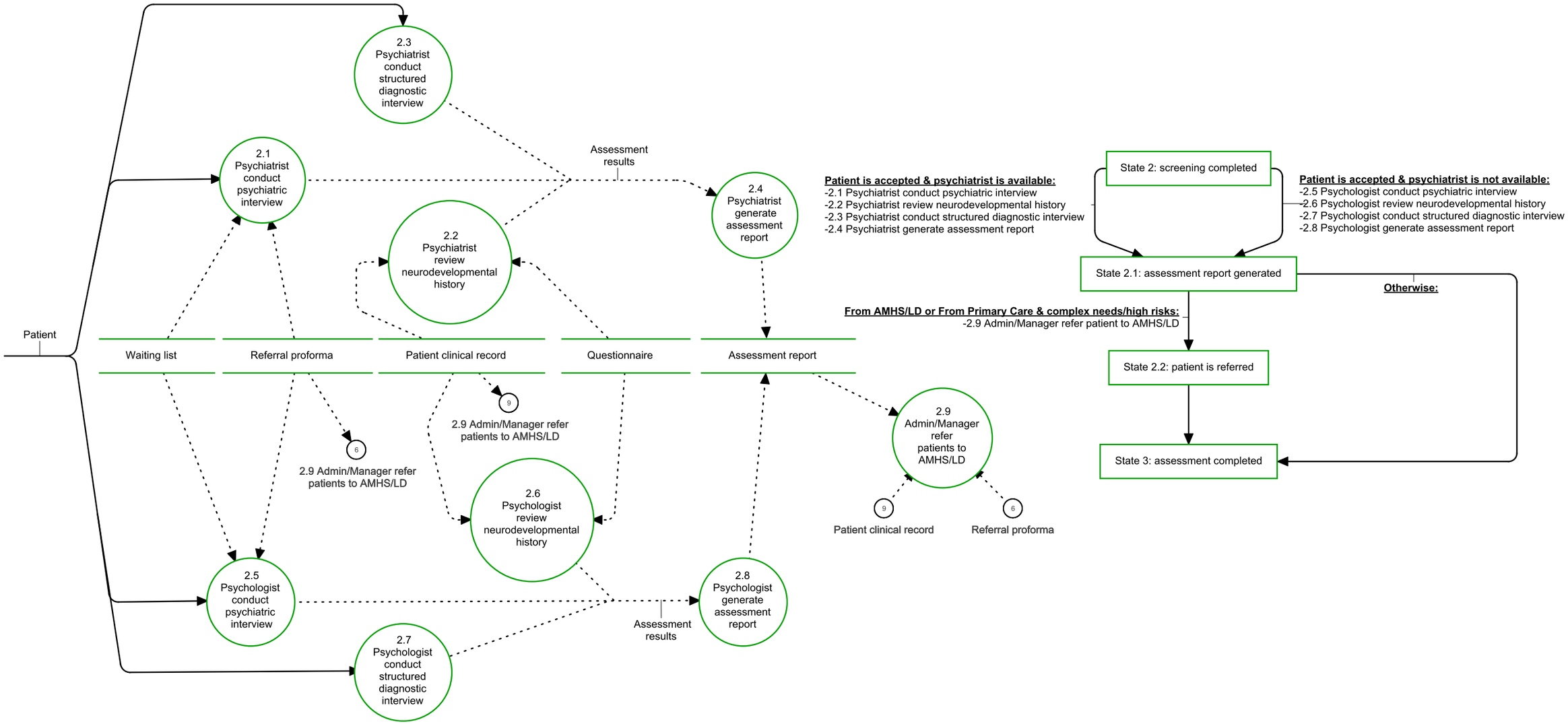

Patient
2.3 Psychiatrist conduct structured diagnostic interview
2.1 Psychiatrist conduct psychiatric interview
Assessment results
2.4 Psychiatrist generate assessment report
2.2 Psychiatrist review neurodevelopmental history
Waiting list
Referral proforma
Patient clinical record
Questionnaire
Assessment report
9
2.9 Admin/Manager refer patients to AMHS/LD
6
2.9 Admin/Manager refer patients to AMHS/LD
2.6 Psychologist review neurodevelopmental history
2.5 Psychologist conduct psychiatric interview
2.7 Psychologist conduct structured diagnostic interview
Assessment results
2.8 Psychologist generate assessment report
2.9 Admin/Manager refer patients to AMHS/LD
9
Patient clinical record
6
Referral proforma
Patient is accepted & psychiatrist is available:
-2.1 Psychiatrist conduct psychiatric interview
-2.2 Psychiatrist review neurodevelopmental history
-2.3 Psychiatrist conduct structured diagnostic interview
-2.4 Psychiatrist generate assessment report
State 2: screening completed
Patient is accepted & psychiatrist is not available:
-2.5 Psychologist conduct psychiatric interview
-2.6 Psychologist review neurodevelopmental history
-2.7 Psychologist conduct structured diagnostic interview
-2.8 Psychologist generate assessment report
State 2.1: assessment report generated
Otherwise:
From AMHS/LD or From Primary Care & complex needs/high risks:
-2.9 Admin/Manager refer patient to AMHS/LD
State 2.2: patient is referred
State 3: assessment completed

Figure 3

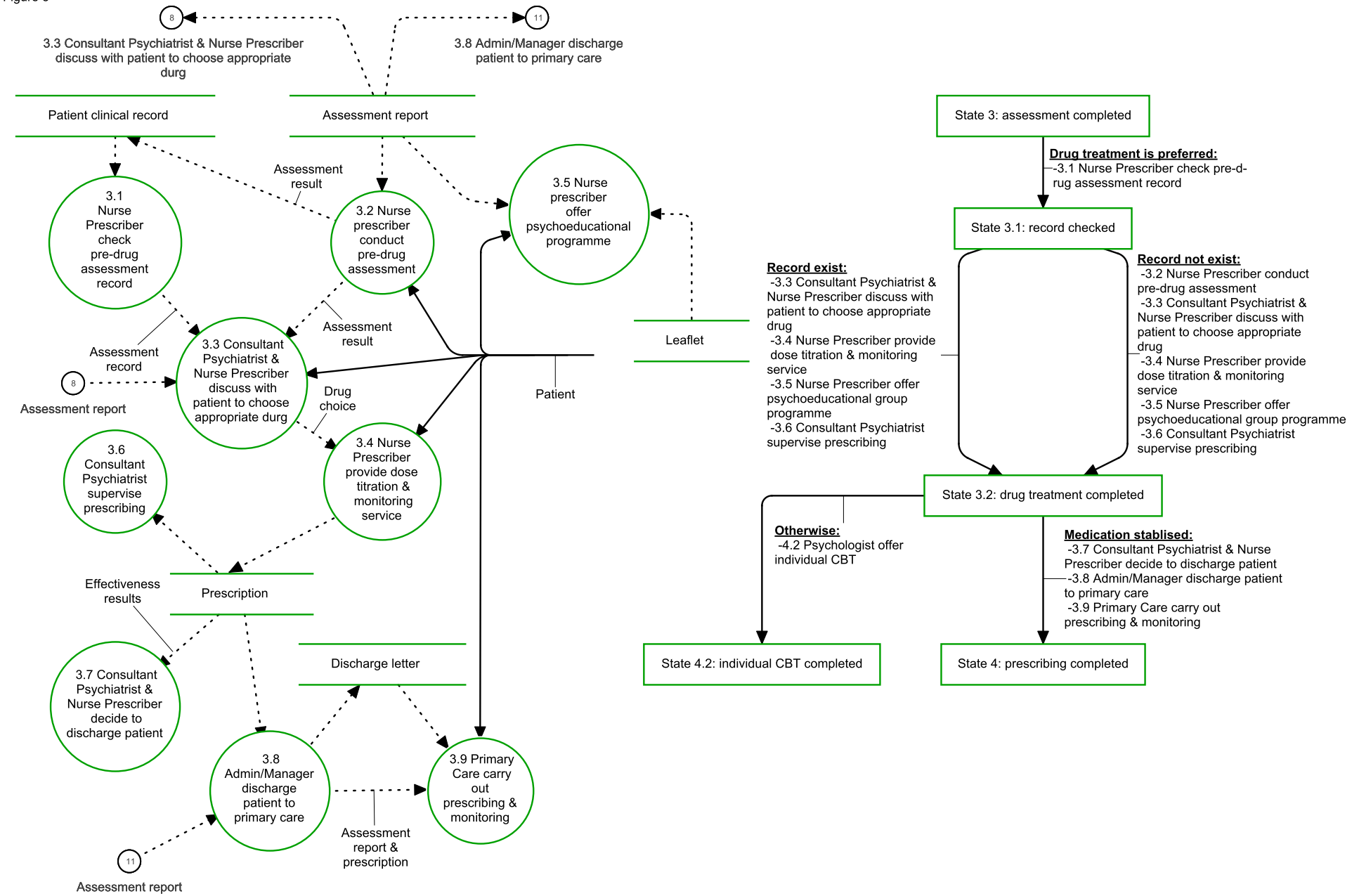
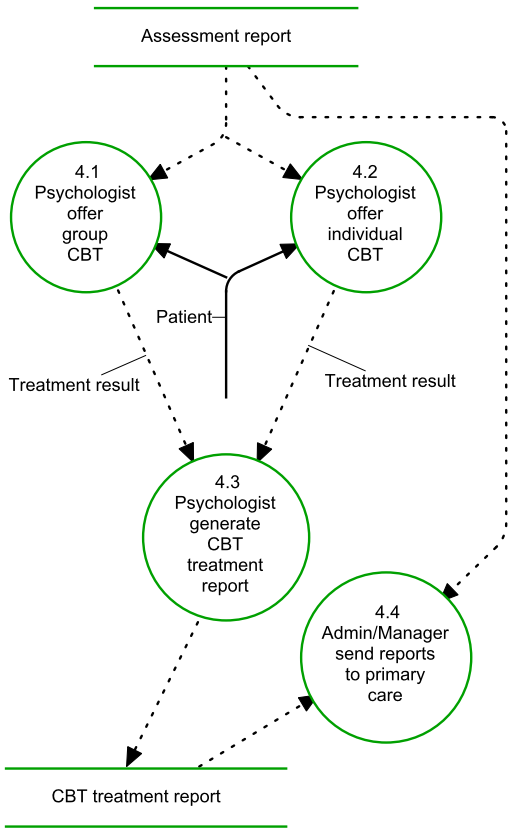
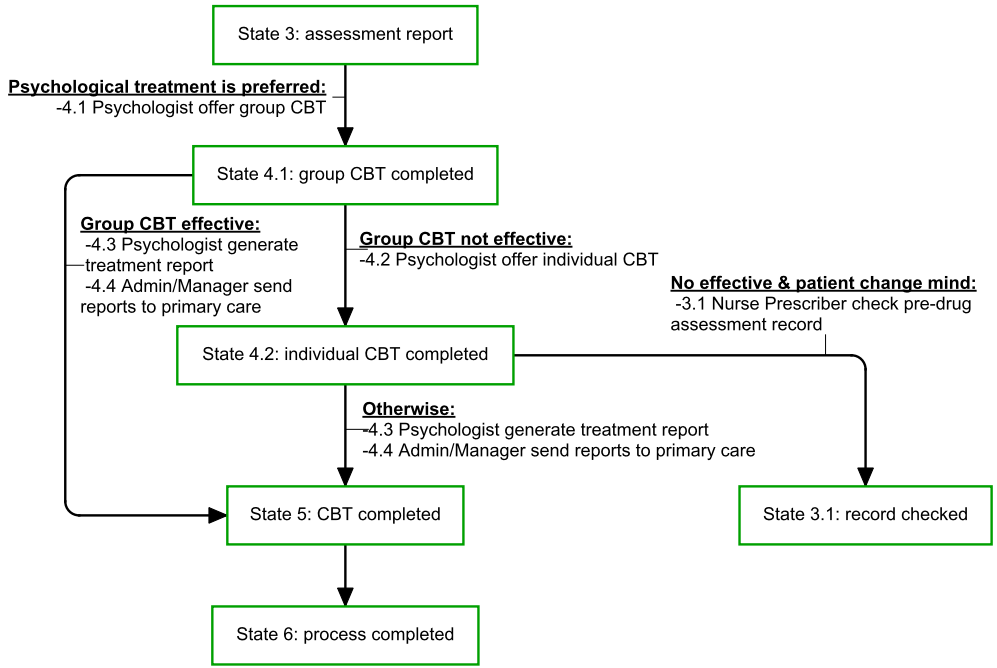

8
3.3 Consultant Psychiatrist & Nurse Prescriber discuss with patient to choose appropriate durg
11
3.8 Admin/Manager discharge patient to primary care
Patient clinical record
Assessment report
3.1 Nurse Prescriber check pre-drug assessment record
Assessment result
3.2 Nurse prescriber conduct pre-drug assessment
3.5 Nurse prescriber offer psychoeducational programme
Assessment record
8
Assessment report
3.3 Consultant Psychiatrist & Nurse Prescriber discuss with patient to choose appropriate durg
Assessment result
Drug choice
Patient
Leaflet
3.6 Consultant Psychiatrist supervise prescribing
3.4 Nurse Prescriber provide dose titration & monitoring service
Effectiveness results
Prescription
3.7 Consultant Psychiatrist & Nurse Prescriber decide to discharge patient
Discharge letter
3.8 Admin/Manager discharge patient to primary care
3.9 Primary Care carry out prescribing & monitoring
11
Assessment report
Assessment report & prescription
State 3: assessment completed
Drug treatment is preferred:
-3.1 Nurse Prescriber check pre-drug assessment record
State 3.1: record checked
Record exist:
-3.3 Consultant Psychiatrist & Nurse Prescriber discuss with patient to choose appropriate drug
-3.4 Nurse Prescriber provide dose titration & monitoring service
-3.5 Nurse Prescriber offer psychoeducational group programme
-3.6 Consultant Psychiatrist supervise prescribing
Record not exist:
-3.2 Nurse Prescriber conduct pre-drug assessment
-3.3 Consultant Psychiatrist & Nurse Prescriber discuss with patient to choose appropriate drug
-3.4 Nurse Prescriber provide dose titration & monitoring service
-3.5 Nurse Prescriber offer psychoeducational group programme
-3.6 Consultant Psychiatrist supervise prescribing
State 3.2: drug treatment completed
Otherwise:
-4.2 Psychologist offer individual CBT
Medication stablised:
-3.7 Consultant Psychiatrist & Nurse Prescriber decide to discharge patient
-3.8 Admin/Manager discharge patient to primary care
-3.9 Primary Care carry out prescribing & monitoring
State 4.2: individual CBT completed
State 4: prescribing completed

Figure 4





Appendix: System diagram used throughout the FMEA exercise (for further information on SMAs, please see Simsekler et al. 2018b)

Tables

No	Job title	Experience in the NHS	Familiarity with SMAs	SMA Evaluation	FMEA Evaluation	Experience in Risk Assessment
1	Service Manager	28 years	Medium	✓		
2	Consultant Psychiatrist	24 years	Very familiar	✓	✓	Medium
3	Specialist Psychiatrist	10 years	Medium	✓		
4	Admin Support	3.5 years	Not familiar at all	✓		
5	Clinical Psychologist	13 years	Not familiar at all	✓	✓	A little
6	Clinical Psychologist	5 years	Not familiar at all	✓	✓	A little
7	Specialty Registrar	12 years	Medium	✓		
8	Nurse Specialist	24 years	Medium	✓		

Table I Participants Information

ID	Component	Function	Failure mode	Potential cause	Immediate effect	System consequence	Current control	Likelihood	Severity	Risk
1										
2										

Table II Example FMEA worksheet

ID	Component	Function	Failure mode	Potential cause	Immediate effect
1	Admin or Manager	Check documents	Partial failure - fail to check all documents	Overtasking	Clinicians receive incomplete patient information
2	Admin or Manager	Check documents	Untimely operate - check documents late	Overtasking	Delay patient admission and assessment
3	Nurse prescriber	Review document	Untimely operate - review documents late	Overtasking	Delay patient admission and assessment
4	Admin or Manager	Add patient to waiting list	Complete failure - fail to add patient to WL	Inadequate IT facilities	Miss patient admission and assessment
5	Admin or Manager	Add patient to waiting list	Incorrectly operate - appointment date/time incorrectly added	Inadequate IT facilities	Delay patient assessment
6	Admin or Manager	Send appointment letter & questionnaires	Complete failure - fail to send	Inadequate IT facilities	Miss patient admission and assessment
7	Admin or Manager	Send appointment letter & questionnaires	Incorrectly operate - send incorrect appointment date/time	Inadequate IT facilities	Delay patient assessment
8	Admin or Manager	Send appointment letter & questionnaires	Incorrectly operate - send to incorrect address	Incorrect information from GP	Delay patient assessment
9	Psychiatrist	Conduct psychiatric interview	Incorrectly operate - conduct interview incorrectly	Inexperienced trainee	Incorrect diagnosis
10	Psychiatrist	Conduct psychiatric interview	Untimely operate - interview patient late	Overtasking	Delay patient assessment
11	Psychiatrist	Review neurodevelopmental history	Untimely operate - review history late	Incomplete neurodevelopmental history	Delay patient assessment
12	Psychiatrist	Generate assessment report	Untimely operate - generate report late	Overtasking	Delay patient treatment
13	Psychologist	Conduct psychiatric interview	Incorrectly operate - conduct interview incorrectly	Inexperienced trainee	Incorrect diagnosis
14	Psychologist	Conduct psychiatric interview	Untimely operate - interview patient late	Overtasking	Delay patient assessment
15	Psychologist	Review neurodevelopmental history	Untimely operate - review history late	Incomplete neurodevelopmental history	Delay patient assessment
16	Psychologist	Generate assessment report	Untimely operate - generate report late	Overtasking	Delay patient treatment
17	Nurse prescriber	Conduct pre-drug assessment	Untimely operate - conduct assessment late	Clinical equipment problem	Delay pre-drug assessment
18	Nurse prescriber	Provide dose titration & monitoring service	Partial failure - fail to provide complete monitoring service	Patients don't attend monitoring session	Complete medical treatment failure
19	Nurse prescriber	Provide dose titration & monitoring service	Incorrectly operate - titration is incorrect	Patients don't follow instructions	Overdosing
20	Psychiatrist	Supervising prescribing	Untimely operate - fail to supervise in time	Overtasking	Delay patient medical treatment
21	Admin or Manager	Discharge patient to primary care	Incorrectly operate - discharge patient without proper follow-up	No shared protocol with GP	GP is unable to carry out prescribing & monitoring
22	Admin or Manager	Discharge patient to primary care	Untimely operate - unable to send discharge documents in time	Inadequate IT facilities	Delay patient discharge

Table III Risks identified in the FMEA session