

Title Registration for a Systematic Review: Psychosocial, Pharmacological, and Legal Interventions for Improving the Psychosocial Outcomes of Children with Substance- Misusing Parents

Elizabeth Eggers, Sharon Dawe, & David B. Wilson

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TITLE OF THE REVIEW

Psychosocial, Pharmacological, and Legal Interventions for Improving the Psychosocial Outcomes of Children with Substance-misusing Parents: Systematic Review and Network Meta-Analysis

BACKGROUND

The impact of parental substance misuse on children is a significant public health issue. Global estimates indicate that approximately 5-10 per cent of all children are being raised in families with one or more parent who misuses alcohol or other drugs (Dawe et al., 2006; Jääskeläinen et al., 2015; Manning et al., 2009; Raninen et al., 2015; SAMHSA, 2014). Decades of research demonstrate the pervasive impact of parental substance misuse on child and adolescent development. Specifically, parental substance misuse is associated with an array of detrimental child outcomes, including: child abuse and neglect (Wekerle et al., 2007; Williams et al., 2011), poor cognitive development and educational attainment (Lambert & Bauer, 2012; Park & Schepp, 2014; Richardson et al., 2015), psychopathology (Bountress & Chassin, 2015; Marmostein et al., 2009; Vidal et al., 2012), and adolescent substance misuse and antisocial behaviour (Clark et al., 2005; King et al., 2009; Lambert et al., 2012; Taplin et al., 2014; Walden et al., 2007).

Parental substance misuse often co-occurs with risk factors across multiple domains, including parental psychopathology and criminality, domestic violence, and severe poverty (e.g., see Grella et al., 2006; Hser et al., 2015; Miller et al., 2013; Skinner et al., 2010). A number of scholars suggest that it is the accumulation and interplay between risk factors, rather than parental substance abuse per se, that generates poor child outcomes (e.g., see Connors et al., 2004; Nair et al., 2003; Velleman & Templeton, 2007). Neger and Prinz (2015) propose a conceptual framework with multiple interrelated pathways to explain how parental substance misuse can lead to child maltreatment. For example, parents with substance misuse issues often have difficulty regulating negative emotional states or experience co-occurrence of mental health disorders (Whitaker et al., 2006; Smith et al., 2009), which can impact their capacity to assess and attend to their child's emotional wellbeing and needs (Borelli et al., 2010, 2012; Siqveland et al., 2014). Moreover, substance misuse affects the capacity to responsively parent their child according to child developmental needs (Velez et al., 2004; Slesnick et al., 2014). Importantly, deficits in parent emotional regulation and the capacity to responsively parent are key predictors of child abuse and maltreatment (Stith et al., 2009). Neger and Prinz's model highlights how parental substance misuse can directly and indirectly impact risk factors predictive of poor child outcomes (see also Dunn et al., 2002; Eiden et al., 2014; Finger et al., 2011; Miller et al., 2014; Shorey et al., 2013; Twomey et al., 2013). Ultimately, the accumulation of negative outcomes in the lives of children with substance-misusing parents can position these children onto developmental trajectories that are characterised by poor cognitive development and educational achievement, substance misuse, and antisocial behaviour

(Burlew et al., 2013; Christofferson & Soothill, 2003; Fisher et al., 2011; Hser et al., 2014; King et al., 2006; Lambert et al., 2013; Park & Schepp, 2014; Vellerman & Templeton, 2007).

The detrimental impact and prevalence of parental substance misuse reinforces the critical importance of intervening to improve the psychosocial wellbeing of children being raised by substance-misusing parents. Indeed, recent estimates suggest that for every dollar invested into substance misuse treatment, there are significant cost savings for society (Dalziel et al., 2015; National Institute of Drug Abuse, 2012; Public Health England, 2014). Psychosocial, pharmacological, and legal intervention models have been developed to alleviate the impact of parental substance misuse on child outcomes. Generally, these interventions either target parental substance misuse directly, risk factors associated with parental substance misuse, or substance misuse in combination with associated risk factors (e.g., parenting, housing, parental wellbeing).

A critical limitation of the current evaluation and review literature is the lack of integration and synthesis of the *relative* effectiveness of different intervention models that aim to improve the outcomes for children with substance-misusing parents. Without a clear understanding of the relative effectiveness of different intervention approaches, practitioners and policy-makers are limited in their ability to make informed and reliable choices between intervention models. Therefore, the proposed review aims to provide a comprehensive, up-to-date review of psychosocial, pharmacological and legal interventions in the context of parental substance misuse and the impact of these interventions on child psychosocial outcomes. Moreover, the review will provide a unique contribution by using network meta-analysis to synthesise the comparative effectiveness of these different intervention approaches (see Hutton et al., 2015; Mavridis et al., 2015; Saltani, 2012; Wilson et al., 2015).

OBJECTIVES

The overarching objective of this review is twofold. First, we aim to enhance and update existing reviews (see next section) by comprehensively synthesising the full array of psychosocial, pharmacological and legal interventions that aim to improve the psychosocial outcomes of children with substance-misusing parents. Second, we aim to use network meta-analysis to integrate and examine the comparative impact of these interventions. Specifically, the review will address the following research questions:

- What is the relative impact of psychosocial, pharmacological, and legal interventions for improving the psychosocial outcomes of children with substance-misusing parents?
- Does the impact of interventions vary according to the type of (a) outcome measure; (b) substance misuse; (c) practitioner implementing the intervention; or (d) intervention setting?
- Does the impact of interventions vary by the country of implementation?

EXISTING REVIEWS

There are 16 existing reviews that (a) focus on interventions specifically for substance-misusing parents and (b) have captured one or more studies that have assessed the impact of an intervention on child psychosocial outcomes. Although not all of these reviews adhere to full systematic review methodologies, each employs at least two systematic review techniques (e.g., systematic search, specific inclusion criteria, qualitative or quantitative synthesis of studies) and can be considered less biased than narrative reviews in the area (e.g., see Choi, 2012; Marsh et al., 2011; Oliveros & Kaufman, 2011; Renk et al., 2015). Importantly, these reviews highlight the range of interventions and large number of studies that are necessary for conducting a network meta-analysis. It is this network meta-analysis, in addition to an updated and enhanced search, that positions the proposed review for making a significant and unique contribution to the existing systematic review literature.

Existing reviews differ according to the specific intervention under consideration and whether only child outcomes or multiple different types of outcomes are included. Existing reviews can be summarised as follows (interventions described in following section):

- One review examines the impact of home-visiting interventions during pregnancy and the postnatal period for women with substance misuse issues and their impact across a range of parental and child outcomes (Turnbull and Osburn, 2012);
- Two reviews focus on Family Treatment Drug Courts for substance-misusing parents with and their impact on child out-of-home placement (Lloyd, 2015) or child maltreatment outcomes (Eldred & Gifford, 2016);
- One review examines the impact of multidimensional interventions for substance-misusing mothers and their impact on multiple child outcomes (Niccols et al., 2012);
- Two reviews focus on parenting interventions for substance-misusing parents across multiple parent and child outcomes (Bowie, 2005; Neger & Prinz, 2015);
- Two reviews and one Cochrane protocol concentrate on child-focused preventative interventions for improving outcomes for children of substance-misusing parents (Bröning et al., 2012) or alcohol misusing parents (Cuijpers, 2005; McLaughlin et al., 2014);
- Two Cochrane reviews examine the impact of pharmacological interventions during pregnancy on maternal and child outcomes in the context of alcohol misuse (Smith et al., 2009) and opioid dependence (Minozzi et al., 2013); and
- Several reviews capture a broad range of psychosocial interventions for parental substance misuse and their impact on multiple outcomes (including child outcomes) for either alcohol misuse during pregnancy (Lui et al., 2008; Stade et al., 2009) or all types of parental substance misuse (Calhoun et al., 2015; Mitchell & Burgess, 2009; Austin & Osterling, 2006; Templeton et al., 2010).

Although the existing review literature is extensive, there is variation in the degree of methodological quality and content coverage. Methodological quality issues and gaps in content coverage reduce the ability to draw reliable conclusions about the effectiveness of

interventions for improving psychosocial outcomes for children with substance-misusing parents. It is for these reasons that the proposed review will both (a) enhance and update the existing body of reviews, and (b) synthesise the comparative impact of interventions on the psychosocial outcomes of children with substance-misusing parents.

Methodological Limitations of Existing Reviews

Perhaps the most important methodological limitation of existing reviews is the lack of quantitative syntheses. Only three reviews with sufficient studies use meta-analysis to synthesise the evaluation evidence (Minozzi et al., 2013; Niccols et al., 2012; Turnbull & Osburn, 2012), despite the availability of multiple studies suitable for meta-analysis across many of the reviews. Rather, authors provide qualitative summaries of intervention effectiveness that are based on the raw differences, statistical significance, or effect sizes of individual studies. Although qualitative summaries are useful for assessing the breadth and qualities of intervention research, this methodology is inadequate for providing a reliable and precise estimate of an intervention impact (Borenstein et al., 2009; Littell et al., 2008).

Additional methodological limitations of existing reviews also highlight the need for an updated and more comprehensive systematic search. Firstly, existing reviews may not provide an accurate representation of the most up-to-date intervention evidence because between five and ten years have passed since the searches were conducted for many of the reviews. Secondly, there may be potential biases in the existing reviews. Some authors excluded studies that found negative intervention effects (e.g., Calhoun et al., 2015) or only reported study outcomes if they were statistically significant (e.g., Lloyd, 2015). Others have introduced publication bias by either explicitly excluding documents not published in peer-reviewed journals (e.g., Bröning et al., 2012; Eldred & Gifford, 2016), neglecting to search for unpublished literature, limiting their searches to very few sources, or omitting important search strategies such as hand-searching and contacting experts (e.g., Bowie, 2005; Calhoun et al., 2015; Cuijpers, 2005; Neger & Prinz, 2015; Turnbull & Osborn, 2012). Thirdly, much of the current body of reviews lacks transparency in the reporting of searches and sensitive search strategies. Many authors do not explicitly report their exact search and how it was implemented during their systematic search (e.g., what search fields were used). In addition, some authors have implemented restrictive searches by failing to incorporate multiple relevant synonyms within their search syntax or by using multiple Boolean AND terms (e.g., Austin & Osterling, 2006; Niccols et al., 2012).

Content Gaps in Existing Reviews

The current corpus of reviews does not provide complete coverage of the extant literature. Some reviews explicitly omit studies that include substance-misusing fathers (e.g., Niccols et al., 2012), focus only on the prenatal period (e.g., Minozzi et al., 2013; Smith et al., 2009), or omit studies that contain child outcomes in the absence of parent-level outcomes (e.g., Neger & Prinz, 2015). Others focus on alcohol misuse and do not capture equivalent interventions for populations with illicit drug misuse issues (e.g., Cuijpers, 2005; Lui et al., 2008; Smith et al., 2009; Stade et al., 2009; Templeton et al., 2010).

However, the most important limitation is that the existing review literature does not permit valid conclusions to be made about the *comparative* impact of these interventions for children with substance-misusing parents. Yet understanding the relative impact of different interventions for a particular population is a crucial for informing the decision-making of both practitioners and policy-makers (Hutton et al., 2015; Mavridis et al., 2015; Saltani, 2012). A recent methodological development, called network meta-analysis, provides an avenue for addressing this important question. Network meta-analysis (NMA), also known as multiple treatments meta-analysis, has been referred to as “the next generation evidence synthesis tool” (Saltani, 2012, p. 80) and extends traditional pairwise meta-analytic techniques. NMA provides an approach for (a) quantitatively synthesising both direct and indirect effects of multiple interventions for a particular population or condition; and (b) ranking interventions according to their effectiveness, even in the absence of trials that have directly compared the treatments (Saltani, 2012; Mavridis et al., 2015). Provided sufficient data are available and the underlying analytical assumptions are satisfied, the proposed review will provide the first NMA that synthesises the relative impact of multiple interventions on the psychosocial outcomes for children with substance-misusing parents.

INTERVENTION

In order to conduct a NMA, this review will include all possible interventions that explicitly aim to improve the psychosocial wellbeing of families characterised by parental substance misuse. However, the focus of the review will be studies that examine the impact of interventions on child psychosocial outcomes. Examples of eligible interventions are briefly described below (not exhaustive). Based on existing literature in the area, we anticipate that the majority of the included studies will utilise a treatment-as-usual comparison condition (e.g., methadone maintenance, case-management without the intervention under consideration).

Interventions will be included irrespective of whether it is initiated during the prenatal or postnatal period and there will be no restrictions on the intervention setting or treatment format (e.g., inpatient, outpatient, community settings, family home, one-on-one or group settings). In addition, studies will be included if the intervention focuses on the misuse of alcohol, illicit drugs, and/or prescription drugs.

Home-Visiting

Home-visiting interventions are characterised by regular home visits by health practitioners or paraprofessionals and aim to improve the psychosocial and health outcomes for mothers and infants (Segal et al., 2012; Turnbull & Osburn, 2012). This category of interventions generally begins in either the prenatal or early postpartum period and the duration of the intervention can span from weeks to many months (Segal et al., 2012). The specific content of home-visiting interventions varies and can include psychoeducation, health surveillance, connection with community resources, parent training, and/or counselling components (Turnbull & Osburn, 2012). Home-visiting interventions with substance-misusing parents

have been evaluated with randomised controlled trials using child psychosocial outcomes, in US and non-US locations (e.g., Butz et al., 2001; Quinlivan et al., 2003; Schuler, 2003).

Family Treatment Drug Courts

Family Treatment Drug Courts (FTDC) use a non-adversarial and treatment-oriented approach for managing child welfare cases where parental substance misuse has been identified as an issue (Gifford et al., 2014, 2015; Lloyd, 2015). Cases dealt within FTDCs have a dual focus on promoting the safety and wellbeing of children and families and also treatment of parents' substance misuse, whereby withdrawal or retention of parental rights is used as leverage for treatment compliance (Dakof et al., 2010; Gifford et al., 2014; 2015; Lloyd, 2015). Although the exact process and content differs slightly across jurisdictions, common FTDC components include: (a) multidisciplinary teams of professionals who collaborate with families to devise a holistic case-plan to address parental substance misuse and child welfare issues; (b) frequent court hearings and drug testing to monitor treatment adherence and case progress; (c) incentives or rewards for compliance; and (d) sanctions for non-compliance (Chuang et al., 2012; Edwards & Ray, 2005; Haack et al., 2005). FTDCs have been most widely evaluated in the United States (e.g., Ashford, 2004; Worcel et al., 2008), yet have recently emerged in the United Kingdom (Bambrough et al., 2013) and Australia (Marshall, 2015).

Multidimensional Interventions

In order to address the accumulation of risks across the multiple ecological domains that are characteristic of families with parental substance misuse issues, a large number intervention models integrate substance misuse treatment with other biopsychosocial treatments (Marsh et al., 2011; Niccols et al., 2012; Uziel-Miller & Lyons, 2000). These multidimensional interventions aim to comprehensively treat parental substance misuse, alleviate other psychosocial risks, and minimise barriers to treatment by simultaneously providing intervention components across different ecological domains (Niccols et al., 2012). Common components include: substance misuse treatment (pharmacological and/or psychological support around substance misuse), mental health services, flexible and accessible delivery (e.g., providing transportation and childcare or visiting homes), medical services for family members (e.g., prenatal care, immunisations for children), parenting programs, vocational and education assistance, and other support services (e.g., housing, financial or legal services). Multidimensional interventions have been evaluated or are currently registered for evaluation using randomised controlled or quasi-experimental trials and child psychosocial outcomes measures in a number of countries (e.g., Barlow et al., 2013; Catalano et al., 1999; Dawe & Harnett, 2007; Field et al., 1998; Noether et al., 2007)

Family, Parent or Child Focused Interventions

Interventions within this category can be distinguished from those in the abovementioned categories based on their narrower intervention focus. Generally, these interventions target the family unit, parents, or children in the absence of more intensive case-management components. For example, the 'Strengthening Families' program consists of concurrent

parent training, child training to promote coping, communication and resistance skills, and joint family sessions to facilitate the transfer of acquired knowledge and skills (see Renk et al., 2015 for a review). Other interventions aim to improve psychosocial outcomes of children with substance-misusing parents through Behavioural Couples Therapy with parents, sometimes with a parent-training component (e.g., Kelley & Fals-Stewart, 2002). Other interventions in this focused category include pharmacological treatment of the parent's substance misuse (e.g., Coyle et al., 2012; Fischer et al., 1999), school-based psychoeducational programs (e.g., Dore et al., 1999; Gance-Cleveland & Mays, 2008), and attachment-based parenting programs (e.g., Luthar et al., 2007; Suchman et al., 2011). In many instances, these interventions are delivered alongside and compared to standard treatment (e.g., methadone maintenance or usual case-management practices).

POPULATION

This review will focus on families with children under the age of 18 who have one or more currently substance-misusing parents. The primary research participants used in eligible impact evaluations must be either substance-misusing parent(s), children of substance-misusing parents, or entire families characterised by parental substance misuse issues. For the purposes of this review, a parent is defined as an individual who is responsible for providing physical, emotional and/or financial care for a child. Teenage, biological, foster, adoptive, or kinship caregivers are eligible for inclusion. A child is defined as an individual between the ages of 0 – 18 years who is under the care of at least one a parent, and a family is defined as at least one child and one parent.

Parents will be classified as 'currently substance-misusing' if they have been classified as such via standardised diagnostic criteria (e.g., DSM, ICD 10) or a self-report measure (e.g., AUDIT). In the absence of classification supported by diagnostic or self-report measures, studies will be included if the authors explicitly identify the research population as substance-misusing parents. For example, a study would be included if the authors note that all study participants are methadone-maintained mothers, even if the authors do not report formal diagnoses or baseline levels of substance use. Parents will be classified as substance-misusing if they are misusing alcohol, illicit drugs and/or prescription drugs. If the study sample is not comprised completely of substance-misusing parents, we will follow Turnbull and Osborn's (2012) approach, whereby the study sample must include at least 50 per cent substance-misusing parents to be included in the review.

OUTCOMES

In order to comprehensively synthesise the impact of eligible interventions on children with substance-misusing parents, this review will include a broad range of outcomes nested under the banner of 'psychosocial wellbeing'. Outcomes will be considered eligible if they are measured using standardised or non-standardised instruments or consist of official,

diagnostic, observation or self-report data. Examples of primary outcomes include, but are not limited to:

- Child development (e.g., attachment, language, cognitive functioning, educational outcomes)
- Child psychopathology (e.g., externalising/internalising behaviour, mental health diagnoses)
- Child maltreatment, abuse or neglect
- Child antisocial behaviour (e.g., truancy, delinquency, illicit drug use)
- Other child psychosocial wellbeing outcomes (e.g., self-esteem)

The decision to utilise one intervention over another may rest on other considerations beyond the effectiveness of the intervention, such as intervention cost, resource intensity, or degree to which participants accept or complete treatment. Therefore, if reported in eligible studies, the following secondary outcomes will also be coded and analysed: cost-effectiveness, treatment completion, length of time in treatment, and acceptability of treatment (e.g., participant perspectives of the intervention).

STUDY DESIGNS

Studies will be included in the review if they report on a quantitative impact evaluation of an eligible intervention using eligible participants and outcome measures. The impact evaluation must also utilise a randomised experimental design or methodologically robust quasi-experimental design with an eligible comparison condition. Eligible comparison conditions are: placebo, no treatment, waitlist control, treatment-as-usual, and alternative treatment.

Key research synthesists advise against using traditional research design labels when delineating an inclusion threshold for non-randomised studies in a systematic review (e.g., Higgins et al., 2012; Reeves et al., 2011). Rather, the suggestion is that inclusion thresholds should be based on the design features of studies due to (a) the variation and possible ambiguity across disciplines in relation to research design terminology; and (b) the likelihood that risk of bias will affect specific design features versus an overall research design category. For the purposes of this review, methodologically robust quasi-experimental designs are defined as those which permit causal inference by minimising threats to internal validity. For example, maximising treatment and comparison group equivalence through matching (e.g., propensity score matching), measurement of outcomes multiple times pre- and post-intervention to reduce maturation threats (e.g., interrupted time-series, cohort panel designs), or adjusting for confounding factors through statistical modelling (e.g., multiple regression, propensity score modelling). Due to serious threats to internal validity, single group studies with one pre-intervention and one post-intervention outcome measure will be excluded from the review.

To be included in the meta-analyses, there must be sufficient data available for each study to calculate a standardised mean difference effect size. Where data are not available in the document reporting on the study, the required data will be sought by contacting the document authors.

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REVIEW AUTHORS

Lead review author:

Name: Elizabeth Eggins

Title: Ms

Affiliation: Griffith University

Address: School of Applied Psychology

Building 24, Room 4.07

176 Messines Ridge Road

City, State, Province or County: Mount Gravatt, Queensland

Postal Code: 4122

Country: Australia

Phone: +61 (0)7 3735 3387

Email: liz.eggins@griffithuni.edu.au

Co-author(s):

Name: Sharon Dawe

Title: Professor

Affiliation: Griffith University

Address: School of Applied Psychology
Building 24, Room 4.06
176 Messines Ridge Road

City, State, Province or County: Mount Gravatt, Queensland

Postal Code: 4122

Country: Australia

Phone: +61 (0)7 3735 3371

Email: s.dawe@griffith.edu.au

Name: David B Wilson

Title: Professor

Affiliation: George Mason University

Address: Department of Criminology, Law and Society
4400 University Drive, MS 4F4

City, State, Province or County: Fairfax, Virginia

Postal Code:	22030
Country:	United States
Phone:	+1.703.993.4701
Email:	dwilsonb@gmu.edu

ROLES AND RESPONSIBILITIES

Collectively, the authors of the proposed review provide a distinctive combination of policy, practice, program evaluation, and systematic review expertise. As part of a larger review team based at the University of Queensland, Elizabeth Eggins has co-authored and assisted with a range of research projects grounded in systematic review methodology, including Campbell Collaboration and industry funded systematic reviews and scoping or qualitative research that uses systematic search, screening and coding techniques. Her PhD research focuses on building the evidence-base for interventions implemented with families characterised by parental substance misuse. Sharon Dawe is a Professor of Clinical Psychology with substantial expertise in addiction science. Professor Dawe has made, and continues to make, significant contributions across research, policy and practice arenas (e.g., by serving on expert panels, training practitioners, and publishing addiction science research). Professor David Wilson an expert in research synthesis, who has made significant contributions in relation to systematic review methodology, program evaluation, and systematic reviews in the area of crime and justice (including substance misuse).

The distribution of review tasks is summarised as follows:

- Content: Dawe, Eggins, Wilson
- Systematic review methods: Eggins, Wilson, Dawe
- Statistical analysis: Wilson, Eggins
- Information retrieval: Eggins, Dawe

FUNDING

This review has been submitted for consideration in the Jacob's Foundation "Better Evidence for Children and Youth" call for funding applications. If successful, the final review is due in December 2016.

POTENTIAL CONFLICTS OF INTEREST

Professor Sharon Dawe has been involved in the development and evaluation of the Parents under Pressure program (PuP). PuP has been evaluated in families with parental substance misuse issues and would meet the inclusion criteria for the review. She has also been an author on commissioned monographs focusing on the impact of parental substance misuse on child outcomes and on the impact of substance misuse on other family members. To minimise any potential biases, other review authors will screen and code any eligible studies co-authored by Professor Dawe.

PRELIMINARY TIMEFRAME

- Date you plan to submit a draft protocol: October 2016
- Date you plan to submit a draft review: October 2017

AUTHOR DECLARATION

Authors' responsibilities

By completing this form, you accept responsibility for preparing, maintaining, and updating the review in accordance with Campbell Collaboration policy. The Coordinating Group will provide as much support as possible to assist with the preparation of the review.

A draft protocol must be submitted to the Coordinating Group within one year of title acceptance. If drafts are not submitted before the agreed deadlines, or if we are unable to contact you for an extended period, the Coordinating Group has the right to de-register the title or transfer the title to alternative authors. The Coordinating Group also has the right to de-register or transfer the title if it does not meet the standards of the Coordinating Group and/or the Campbell Collaboration.

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Publication in the Campbell Library

The support of the Coordinating Group in preparing your review is conditional upon your agreement to publish the protocol, finished review, and subsequent updates in the Campbell Library. The Campbell Collaboration places no restrictions on publication of the findings of a Campbell systematic review in a more abbreviated form as a journal article either before or after the publication of the monograph version in *Campbell Systematic Reviews*. Some journals, however, have restrictions that preclude publication of findings that have been, or

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Form completed by:

Elizabeth Eggins, with input by all authors.

Date:

29th July 2015