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Users' Perspectives in Good Clinical Practice (GCP): A case study of an Australian online training program

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Abstract

The

introduction of free, online training in Good Clinical Practice (GCP) was introduced in 2016 by

the Research and Education Training Program (RETP), an enabling platform of the Western Australian Health Translation Network (WAHTN)

for health and medical research professionals. The modules are accessible to all sta! and students within the 21 WAHTN partner institutions (including all major hospitals and universities) in the state of Western Australia. This report evaluates perceptions of the online participants of the GCP modules. After completing the GCP course, each participant was given an evaluation asking their opinion about the modules. Underpinned by a mixed-method approach, a multi-level analysis assisted the RETP to identify aspects which called for sustainable maintenance and improvement for improved delivery. Over 90 users participated in the online training. A case example describes that both of qualitative and quantitative data were useful to provide possible improvements within the course content presentation, technical issues, and management and operation issues. Keywords: Online training, Good Clinical Practice (GCP), research, education

Introduction The RETP is one of the many

enabling platforms of the Western Australia Health Translation Network (WAHTN). The RETP

provides health and medical practitioners with open access, online training in various research topics and allows participants to refresh their knowledge in research related topics. Building research capacity strengthens health practices and leads to a higher standard of studies, a greater likelihood of successful completion of research, and most importantly, better health outcomes for participants and the broader community (RETP, 2017). The RETP consists of multiple, short, free-standing courses across the research process, including Good

Clinical Practice (GCP). The courses are contextualised for an Australian and more speci"cally a Western Australian context (WAHTN, 2017a) to enable greater understanding of local policies across institutions and how the GCP principles are embedded in practice. Context: The Western Australian Health Translation Network The WAHTN includes Western Australia's (WAs) major hospitals, medical research institutes and "ve universities to capitalise on the substantial investment in health and medical expertise, resources and translation of knowledge (WAHTN, 2017b). In 2017, there are 21 partner organisations within the WAHTN. Research in the health and medical sector is an essential component for the continual improvement of clinical practice which directly contributes to the health and wellbeing of patients and

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in healthcare delivery. The RETP is funded by the WA government through its Department of Health (DoH) to develop and deliver online research training. Ensuring sta! receive the correct level of training and education is key to a high standard of health and medical research. Multiple face-to-face research training workshops are

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by individual partner institutions at various times and locations which

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valuable training to researchers who can attend such sessions if available when

o!ered.

RETP Online training in Good Clinical Practice (GCP) The RETP provides entry-level to advanced research training across the entire research process. A bene"t of online delivery is that the underpinning Learning Management System (LMS) gathers multiple aspects of data allowing for the measurement of impact. The "rst online training modules to be developed were the GCP modules ("ve in total). GCP is an international, ethical and

scienti"c

quality standard for conducting clinical trials (ICH Expert Working Group, 1996). Its principles can be applied to other clinical investigations and human research. GCP

also serves to protect the rights, integrity and con"dentiality of trial subjects.

The Declaration of Helsinki in 1964, was an outcome of unethical experimentation on human subjects leading to the development of international guidelines and policies on how to conduct safe and ethical human research to avoid future cases occurring (Vijayananthan & Nawawi, 2008).

In Australia, the ICH GCP (2016) international standards are encoded in the National Statement on Ethical Conduct in Human Research [The National Statement] (National Health and Medical Research Council [NHMRC], 2007 which suggests the ethical principles to be recommended to underpin all research on or with human subjects. However, though familiar with these principles is considered best practice in many "elds, training in the area of GCP in research is neither readily available, nor easily accessible for many researchers, clinicians and practitioners. Often, there is a high "nancial cost related to sta! enrolment in such courses including the cost of time away from work duties to attend courses if attending in person. The RETP GCP modules meet the

minimum criteria for ICH E6 (R2) GCP Investigator Site Personnel Training (Version 2, 2017) via the TransCelerate BioPharma

Inc. (2017)

approved mutual recognition. The current study explores the value of the online training in GCP by clinical and health professionals in this newly-commenced program, which started in September 2016. An ongoing evaluation during the program (Frye & Hemmer, 2012) was conducted to ascertain the quality of the program (Durning, Hemmer, & Pangaro, 2007; Faizal, Morin, & Parker, 2013). After completing each module of GCP, users of the online course are asked to participate in an online course evaluation reported in this paper including the standard evaluation "ve point scale rating and two open-ended questions. Studies on GCP and online training Vijayananthan & Nawawi (2008) signi"ed the importance of GCP by linking the historical background with the need of the formulation of GCP guidelines, especially in the US and Europe. The need for GCP training and compliance is internationally recognised and is endorsed by the International Council for Harmonisation as outlined in the introduction. Realising the need for GCP training, Arango et al. (2016) based their study on a Clinical Trials Transformation Initiative (CTTI) which intended to capture the key elements of GCP training. The recommendations included

the minimum key training elements, frequency, format, and evidence of training completion.

In a similar context, a study by Haeusler (2009) focusing on assessing the impact of formal training in GCP on the quality of clinical trials concluded that formal training in GCP has the potential to improve protocol adherence and clinical trial quality. In a

di!erent

setting, Vora and Shah (2011) conducted a study to evaluate the

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of GCP training among 125 medical teachers in India. They were given the survey before and after the GCP training. The "ndings showed that there was an improvement of the participants' knowledge of GCP after they undertook GCP training as well as an overall improvement in knowledge of GCP. In summary, studies have found considerable need to provide GCP training that is more accessible because the

bene"ts

are vast for health researchers, clinicians, quality of clinical trials and users of the health systems. However, there is a dearth in the studies, particularly about the perceptions of GCP online users. This study would be worth giving some understanding about the users' challenges and opinion on the e-learning GCP training.

Method Objective The objective of this study was to understand the users' perspectives of the online GCP training and their interplay with course content, structure, presentation and further needs. Case Study A case study was conducted to achieve the goal of the study. Although the research in this study focused on a single case, the adoption of a focus on users' perceptions suggests the possibility to the general use of the research design in other training programs; in particular other GCP courses. Participants The participants reported in this article were the online users of RETP courses. Participants" worksites included government health sites, universities, clinics, hospitals and private health organisations. A total of 90 participant feedback results were included in the data analysis. Data collection The data collection tool used in this study was an online survey within the Learning Management System (LMS) which is included within the online training on completion of each module. Key questions in the survey include the users' feeling and opinions about the online course, and other relevant areas about the content and presentation. The interview questions were matters surrounding management and operation issues. See Table 1 below. Table 1. Questions in online survey

Procedure From the time of logging in to the RETP website, data were collected automatically to assist assessing the strengths of RETP, and possible improvements to the system. The data collected includes the name, email address, institution, courses and modules enrolled in, and modules completed. The focus of this article is based on data of the users who took GCP course, taken on the 20 of February 2017, which was about six months after the course was launched online. A multi-level analysis was been used as an analytical tool in this study that includes the use of more than one method of data collection. A mixed-method approach (Creswell & Plano Clark, 2011) collecting, analysing and integrating quantitative (numerical data) and qualitative (participant observation) (see Table 2) was used as a methodology within the multi-level analysis to explore the users of GCP online learning. Underpinned by a mixed-method approach this research demonstrates that the multi-level analysis is a powerful tool to uncover users' perceptions across various organisations of GCP. The following table outlines the approach taken in several steps of evaluating the data. Table 2: Multi-level analysis: An application and technique for mixed-method approach. th

The table above describes the "ve-stage approach to assessment of the feedback data obtained through the Learning Management System (LMS). This representation of multi-level analysis is described on Figure 1.

Figure 1. Multi-level analysis mixed methods As indicated in the above "gure, this analysis was useful in addressing complex, multifaceted issues such as an evaluation of the online participants perceptions of the GCP modules. Figure 1 also presents how data obtained by both methods (quantitative and qualitative) was used to corroborate "ndings: statistical techniques were used to analyse numerical data whilst thematic analysis were used to analyse participants' observation in open ended questions. By comparing the data from quantitative and qualitative feedback through a cross-cutting analysis, the data were more deeply interrogated. The synthesis of these stages is re$ected in the discussion and conclusions sections. Results Quantitative data: Participant satisfaction with GCP course As described in the context, at the end of each module participants were asked to complete an evaluation form. This evaluation consists of "ve statements to which participants needed to respond, choosing a level of agreement (shown below). The statements are: 1. The course learning objectives were clear

2. The material was presented in a way which maintained my interest (e.g. text; images; visuals) 3. The content was well structured 4. The material challenged me to think more critically about the topic (covered at the right level). 5. The material presented extended my knowledge in this area. As can be seen from Table 3, the majority of the users chose 'agree' with the statements. More than 80 % of users either strongly agreed or agreed to the statement that 'the course learning objectives were clear' for all modules. At least 75% of users agreed with statements 2 to 5, suggesting that the material maintained user interest; the content was well structured; users felt they were challenged to think critically about the topic; and that the material generally extended the prior knowledge of users. The lowest score for agreement was 43.6% for statement 2 (that the 'material maintained user interest') in module 1, while the highest was 60.1% for statement 1 (that the 'course learning objectives were clear') for module 5. Overall, agreement averaged approximately 53% and strong

agreement averaged approximately 27%. Table 3: *Statistical results for the evaluation of the GCP Course (Module 1) *All source data is from the LMS reporting, RETP 2017 A visual graph to view the quantitative data* is displayed in Figure 2 below.

Figure 2: Cluster chart course satisfaction rating. *All source data is from the LMS reporting, RETP 2017 The same pattern of satisfaction was shown in all modules. Qualitative data: participants' opinion about the GCP course While the quantitative data shows a generally positive perspective of the online modules, this is interrogated more deeply in the two open-ended questions which accompany the statements: participants can freely express their thoughts are: Q 1: What were the best aspects of the online training? Q 2: What changes would you suggest? The cross-cutting analysis showed that the positive feedback from the quantitative data was mirrored in the qualitative data collected through Question 1. Grouping these data showed user satisfaction with

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aspects of the course design and content, which could be grouped by key themes. The groups showed course content; course presentation; and course accessibility to be areas with which users were

satis"ed.

The themes and areas of greatest satisfaction which were present in responses to Question 1 are shown in the Table 4 below: Table 4: Key themes in response to the *question 'What were the best aspects of the online training?'

*All source data is from the LMS reporting, RETP 2017 As can be seen in Table 4, there are three main areas users' commented on in evaluating the GCP course modules. These were: course content, course presentation, and course accessibility. Overall, users were satis"ed with all aspects of the online course. About 35 % - 38 % of the users considered the content in the GCP course to be one of its best aspects, and they considered the course informative. See references below: "Clear and informative" (79/M4); "Very informative" (67/Module 2)

Users also felt that the course content added to their current knowledge: "It signi"cantly extended my knowledge in this area" (73/Module 2) This satisfaction is reiterated through the statistical "ndings gathered from both the quantitative and qualitative data. As well as this more than 26% of users articulated positive responses towards the presentation of the content. Module 1 received the highest percentage of positive comments in this area on 'best aspects'. "Videos, examples to keep me interested in the topic" (20/Module 1) "Use of interesting videos." (65/Module 1) "I like the interactive part in Discussion board." (70/Module 3) Users indicated that the online course accessibility allowed them to manage their work /life

balance by being able to complete the course in their own time: "I could do it in my own time" (95/Module 2); "It is available as and when needed." (30/Module 5) Question two addressed improvements which users would like to see. Again, these were grouped according to themes: Table 5: Key themes in response to the *question 'What changes would you suggest?'

*All source data is from the LMS reporting, RETP 2017 As indicated in Table 5, users articulated three main issues in addressing the question of what changes could be implemented to improve the course. The "rst two issues reiterated the key areas raised in Q1, that is, the areas of course content and presentation. The third area of concern highlighted technical issues. Despite their satisfaction with the presentation of the materials (as seen on Table 5), users suggested improvements in the content, presentation and technical delivery of the course. Typical comments on the course content included: "Make modules shorter, key points could be summarized more succinctly" (06/Module 1) * "Better design" (72/Module 2)

Users emphasised the importance of employing a variety of text formats (slides, images, and video) and interactive activities within the modules: "Whilst the information was concise and easy to digest, perhaps more visual aids could be included - such as videos." (85/M2) In terms of the content of the material, users indicated some errors in content: "Quiz has mistake… …and correct the question." (24/M1) "I think the answer to question 10 regarding the SSA is incorrect." (94/M1) "Please change my quiz result attempt 2 to 100%" (24/M1) Other users suggested adding more examples in order to enrich their current knowledge: "More examples of poorly conducted research." (66/M1) "A good example of what a patient information booklet looks like" (75/M3) The frequency of evaluation quizzes was mentioned. One user suggested that there should be only one evaluation per course: "Only have one evaluation not one after every section" (80/S2). Of greater concern are the technical issues raised by some users. These issues often relate to

speci"c

workplaces where participants undertook online learning: "Web site seems very slow. Also, will not run on explorer" (88/M1) "Ensure WA Health computers can run embedded videos!" (76/M1) "Too slow to load" (74/M3) As can be seen in Table 5, this particular issue was raised by a signi"cant number of participants (approximately 8% of users) when doing Module 1 of the GCP course. These issues are an ongoing task for the technical team who work to resolve such issues. Lessons Learnt Consistency was found between the "ndings in quantitative and qualitative data. The majority of the users were satis"ed with the online GCP training. Some participants did articulate the training improved their knowledge about GCP. While this study evidenced the users' experience to this positive outcome, the studies by (Haeusler 2009) and (Vora and Shah 2011) in assessing the

impact of formal training in GCP on the quality of clinical trials would be useful for future studies of this GCP training. This study supports "ndings by Arango et al. (2016) study that

GCP online training could be one of the formats of training to o!er (Arango et al., 2016). The RETP training, feedback and ongoing evaluation can provide other training providers with necessary and relevant information for future users of GCP. There were lessons learnt around issues were raised by the participants. For example, more

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information provided and improvements to the overall presentation. The feedback has already been incorporated into the next version of the GCP training and will continue to be monitored for future improvements. Course presentation was the highest area of feedback followed by these

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requests for additional content. The evaluation conducted in this study could be improved in several ways. Firstly, an evaluation of participants before and after taking the GCP module followed by qualitative analysis of feedback through open-ended questions (Durning et al., 2007). Additional probing into asking why and how (Faisal et al., 2013) the online GCP program has or has not impacted their current practice in health associations is another area of future evaluation and highly useful for the knowledge translation and understanding impact. Another area participants raised concerns included technical issues, which were concerning the network and online software users used to access the GCP training. A considerable number of comments on this particular was raised during the "rst module of GCP. Supporting users with technical issues they encounter is an essential aspect of this service. The nature of the online training environment is that participants must be self-motivated to complete the training. They must also balance training with other leisure and life activities which can get in the way of completing online learning which is carried on at home or in work environments. Having an online learning program with less technical issues might increase users' motivation continue working on the program. The RETP online management system seems to capture this particular need because there was no such concern expressed by the participants on the last three modules of the GCP online course. As Cook (2012, p.309) staes: "If we teach them, they will learn. The question we face is how to make learning as painless, relevant, and e#cient as possible." Conclusion The objective of the study was to evaluate feedback from the users of GCP online training provided by RETP, WAHTN. Positive responses were obtained as this service had met the users' needs. Despite this, positive users made some suggestions for the improvements which are useful in guiding the ongoing course development at the RETP. This study is limited in that it was completed in a short time since its "rst launching. A study of a larger number of users will be undertaken in the future.

Take Home Messages Online Good Clinical Practice provides researchers with easy and $exible access to essential training. Ongoing evaluation of any training is critical for continuous improvement Techical issues will occur; having support sta! are critical during this time Evaluation of training allows for accumulated data to be analaysed about particlant satisfaction for continued improvement Notes On Contributors Dr. Rashmi Watson leads the Research Education and Training Program for the Western Australian Health Translation Network and has been involved as an educator for over 20 years. Dr. Nurmala Simbolon is both an educator and a researcher. Her research interests are the internationalisation of higher education and English medium instruction (EMI). Dr Edi Nuryatno is a specialist in the area of ICT business analyst/enterprise architecture at the Research Education and Training Program for the Western Australian Health Translation Network. Acknowledgements Bibliography/References Anonymous. (2008). Good Clinical Practice Research Guidelines Reviewed, Emphasis Given to Responsibilities of Investigators: Second Article in a Series. Journal of Oncology Practice, 4(5), 233 – 235, Accessed on March 21st, 2017 from http://ascopubs.org/doi/pdf/10.1200/JOP.0854601 https://doi.org/10.1200/JOP.0854601 Arango, J., Chuck, T., Ellenberg, S., Foltz, B., Gorman, C. Hinrichs, H., McHale, S., Merchant, K., Seltzer, J., Shapley, S., & Wild, G. (2016).

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An interesting paper covering an important aspect of the ever-increasing use of on-line learning. It was interesting to read of the authors' approaches using a mixed-methods approach. This approach seems valuable in being able to provide reason and opportunity to re-shape the programme according to the participants wants and needs. I thought that the authors described this well. My worries however is how these positive "ndings from these evaluation techniques provide us with a false positive view about the real outcome of the courses / events/ training activities described. I would have preferred to see how the authors now intend to structure a longer-term evaluation in how these activities really

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the participants impact upon future healthcare, either by extending the Kirkpatrick evaluation up to levels 3 and 4 or using an alternative model, such as that described by Maxwell (Maxwell R . Quality in Health Care 1992;1:171-1770 who looked more at the parameters of

E#ciency, Acceptability, E#ciency, Accessibility, Equity and most importantly Relevance. Appendices There are no con$icts of interest. Twitter: @RETP_WAHTN

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Rashmi Watson , Nurmala Simbolon , Edi

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Users' Perspectives in Good Clinical Practice (GCP): A case study of an Australian online training program

Rashmi Watson[1], Nurmala Simbolon[2], Edi Triono Nuryatno[1]

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The University of Western Australia, Corresponding Author: Dr Rashmi Watson rashmi.watson@uwa.edu.au Categories: Medical Education (General), Teachers/Trainers, Teaching and Learning DOI: https://doi.org/10.15694/mep.2017.000195 Abstract

The

The University of Western Australia, 2. Curtin University Corresponding Author: Dr Rashmi Watson (rashmi.watson@uwa.edu.au) Categories: Medical Education (General), Teachers/Trainers (including Faculty Development), Teaching and Learning DOI: https://doi.org/10.15694/mep.2017.000195 Published Date: 03/11/2017

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The WAHTN includes Western Australia's (WAs) major hospitals, medical research institutes and five universities to capitalise on the substantial investment in health and medical expertise, resources and translation of knowledge (WAHTN, 2017b). In 2017, there are 21 partner organisations within the WAHTN. Research in the health and medical sector is an essential component for the continual improvement of clinical practice which directly contributes to the health and wellbeing of patients and

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RETP Online training in Good Clinical Practice (GCP) The RETP provides entry-level to advanced research training across the entire research process. A bene"t of online delivery is that the underpinning Learning Management System (LMS) gathers multiple aspects of data allowing for the measurement of impact. The "rst online training modules to be developed were

RETP Online training in Good Clinical Practice (GCP) The RETP provides entry-level to advanced research training across the entire research process. A benefit of online delivery is that the underpinning Learning Management System (LMS) gathers multiple aspects of data allowing for the measurement of impact. The first online training modules to be developed were

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The Declaration of Helsinki in 1964, was an outcome of unethical experimentation on human subjects leading to the development of international guidelines and policies on how to conduct safe and ethical human research to avoid future cases occurring (Vijayananthan & Nawawi, 2008).

In Australia, the ICH GCP (2016) international standards are encoded in the National Statement on Ethical Conduct in Human Research [The National Statement] (National Health and Medical Research Council [NHMRC], 2007 which suggests the ethical principles to be recommended to underpin all research on or with human subjects. However, though familiar with these principles is considered best practice in many "elds, training in the area of GCP in research is neither readily available, nor easily accessible for many researchers, clinicians and practitioners. Often, there is a high "nancial cost related to sta! enrolment in

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minimum criteria for ICH E6 (R2) GCP Investigator Site Personnel Training (Version 2, 2017) via the TransCelerate BioPharma

Inc. (2017)

approved mutual recognition. The current study explores the value of the online training in GCP by clinical and health professionals in this newly-commenced program, which started in September 2016. An ongoing evaluation during the program (Frye & Hemmer, 2012) was conducted to ascertain the quality of the program (Durning, Hemmer, & Pangaro, 2007; Faizal, Morin, & Parker, 2013). After completing each module of GCP, users of the online course are asked to participate in an online course evaluation reported in this paper including the standard evaluation "ve point scale rating and two open-ended questions. Studies on GCP and online training Vijayananthan & Nawawi (2008) signi"ed the importance of GCP by linking the historical background with the need of the formulation of GCP guidelines, especially in the US and Europe. The need for GCP training and compliance is internationally recognised and is endorsed by the International Council for Harmonisation as outlined in the introduction. Realising the need for GCP training, Arango et al. (2016) based their study on a Clinical Trials Transformation Initiative (CTTI) which intended to capture the key elements of GCP training. The recommendations included

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setting, Vora and Shah (2011) conducted a study to evaluate the

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of GCP training among 125 medical teachers in India. They were given the survey before and after the GCP training. The "ndings showed that there was an improvement of the participants' knowledge of GCP after they undertook GCP training as well as an overall improvement in knowledge of GCP. In summary, studies have found considerable need to provide GCP training that is more accessible because the

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are vast for health researchers, clinicians, quality of clinical trials and users of the health systems. However, there is a dearth in the studies, particularly about the perceptions of GCP online users. This study would be worth giving some understanding about the users' challenges and opinion on the e-learning GCP training.

Method Objective The objective of this study was to understand the users' perspectives of the online GCP training and their interplay with course content, structure, presentation and further needs. Case Study A case study was conducted to achieve the goal of the study. Although the research in this study focused on a single case, the adoption of a focus on users' perceptions suggests the possibility to the general use of the research design in other training programs; in particular other GCP courses. Participants The participants reported in this article were the online users of RETP courses. Participants" worksites included government health sites, universities, clinics, hospitals and private health organisations. A total of 90 participant feedback results were included in the data analysis. Data collection The data collection tool used in this study was an online survey within the Learning Management System (LMS) which is included within the online training on completion of each module. Key questions in the survey include the users' feeling and opinions about the online course, and other relevant areas about the content and presentation. The interview

questions were matters surrounding management and operation issues. See Table 1 below. Table 1. Questions in online survey

Procedure From the time of logging in to the RETP website, data were collected automatically to assist assessing the strengths of RETP, and possible improvements to the system. The data collected includes the name, email address, institution, courses and modules enrolled in, and modules completed. The focus of this article is based on data of the users who took GCP course, taken on the 20 of February 2017, which was about six months after the course was launched online. A multi-level analysis was been used as an analytical tool in this study that includes the use of more than one method of data collection. A mixed-method approach (Creswell & Plano Clark, 2011) collecting, analysing and integrating quantitative (numerical data) and qualitative (participant observation) (see Table 2) was used as a methodology within the multi-level analysis to explore the users of GCP online learning. Underpinned by a mixed-method approach this research demonstrates that the multi-level analysis is a powerful tool to uncover users' perceptions across various organisations of GCP. The following table outlines the approach taken in several steps of evaluating the data. Table 2: Multi-level analysis: An application and technique for mixed-method approach. th

The table above describes the five-stage approach to assessment of the feedback data obtained through the Learning Management System (LMS). This representation of multi-level analysis is described on Figure 1.

Figure 1. Multi-level analysis mixed methods As indicated in the above figure, this analysis was useful in addressing complex, multifaceted issues such as an evaluation of the online participants perceptions of the GCP modules. Figure 1 also presents how data obtained by both methods (quantitative and qualitative) was used to corroborate findings: statistical techniques were used to analyse numerical data whilst thematic analysis were used to analyse participants' observation in open ended questions. By comparing the data from quantitative and qualitative feedback through a cross-cutting analysis, the data were more deeply interrogated. The synthesis of these stages is reflected in the discussion and conclusions sections. Results Quantitative data: Participant satisfaction with GCP course As described in the context, at the end of each module participants were asked to complete an evaluation form. This evaluation consists of five statements to which participants needed to respond, choosing a level of agreement (shown below). The statements are: • The course learning objectives were clear • The material was presented in a way which maintained my interest (e.g. text; images; visuals) • The content was well structured • The material challenged me to think more critically about the topic (covered at the right level). • The material presented extended my knowledge in this area. As can be seen from Table 3, the

from Table 3, the majority of the users chose 'agree' with the statements. More than 80 % of users either strongly agreed or agreed to the statement that 'the course learning objectives were clear' for all modules. At least 75% of users agreed with statements 2 to 5, suggesting that the material maintained user interest; the content was well structured; users felt they were challenged to think critically about the topic; and that the material generally extended the prior knowledge of users. The lowest score for agreement was 43.6% for statement 2 (that the 'material maintained user interest') in module 1, while the highest was 60.1% for statement 1 (that the 'course learning objectives were clear') for module 5. Overall, agreement averaged approximately 53% and strong agreement averaged approximately 27%. Table 3: *Statistical results for the evaluation of the GCP Course (Module 1) *All source data is from the LMS reporting, RETP 2017 A visual graph to view the quantitative data* is displayed in Figure 2 below.

Figure 2: Cluster chart course satisfaction rating. *All source data is from the LMS reporting, RETP 2017 The same pattern of satisfaction was shown in all modules. Qualitative data: participants' opinion about the GCP course While the quantitative data shows a generally positive perspective of the online modules, this is interrogated more deeply in the two open-ended questions which accompany the statements: participants can freely express their thoughts are: Q 1: What were the best aspects of the online training? Q 2: What changes would you suggest? The cross-cutting analysis showed that the

positive feedback from the quantitative data was mirrored in the qualitative data collected through Question 1. Grouping these data showed user satisfaction with

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aspects of the course design and content, which could be grouped by key themes. The groups showed course content; course presentation; and course accessibility to be areas with which users were

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The themes and areas of greatest satisfaction which were present in responses to Question 1 are shown in the Table 4 below: Table 4: Key themes in response to the *question 'What were the best aspects of the online training?'

*All source data is from the LMS reporting, RETP 2017 As can be seen in Table 4, there are three main areas users' commented on in evaluating the GCP course modules. These were: course content, course presentation, and course accessibility. Overall, users were satis"ed with all aspects of the online course. About 35 % - 38 % of the users considered the content in the GCP course to be one of its best aspects, and they considered the

course informative. See references below: "Clear and informative" (79/M4); "Very informative" (67/Module 2)

Users also felt that the course content added to their current knowledge: "It signi"cantly extended my knowledge in this area" (73/Module 2) This satisfaction is reiterated through the statistical "ndings gathered from both the quantitative and qualitative data. As well as this more than 26% of users articulated positive responses towards the presentation of the content. Module 1 received the highest percentage of positive comments in this area on 'best aspects'. "Videos, examples to keep me interested in the topic" (20/Module 1) "Use of interesting videos." (65/Module 1) "I like the interactive part in Discussion board." (70/Module 3) Users indicated that the online course accessibility allowed them to manage their work /life balance by being able to complete the course in their own time: "I could do it in my own time" (95/Module 2); "It is available as and when needed." (30/Module 5) Question two addressed improvements which users would like to see. Again, these were grouped according to themes: Table 5: Key themes in response to the *question 'What changes would you suggest?'

*All source data is from the LMS reporting, RETP 2017 As indicated in Table 5, users articulated three main issues in addressing the question of what changes could be implemented to improve the course. The "rst two issues reiterated the key areas raised in Q1, that is, the areas of course content and presentation. The third area of concern highlighted technical issues. Despite their satisfaction with the presentation of the

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materials (as seen on Table 5), users suggested improvements in the content, presentation and technical delivery of the course. Typical comments on the course content included: "Make modules shorter, key points could be summarized more succinctly" (06/Module 1) * "Better design" (72/Module 2)

Users emphasised the importance of employing a variety of text formats (slides, images, and video) and interactive activities within the modules: "Whilst the information was concise and easy to digest, perhaps more visual aids could be included - such as videos." (85/M2) In terms of the content of the material, users indicated some errors in content: "Quiz has mistake……and correct the question." (24/M1) "I think the answer to question 10 regarding the SSA is incorrect." (94/M1) "Please change my quiz result attempt 2 to 100%" (24/M1) Other users suggested adding more examples in order to enrich their current knowledge: "More examples of poorly conducted research." (66/M1) "A good example of what a patient information booklet looks like" (75/M3) The frequency of evaluation quizzes was mentioned. One user suggested that there should be only one evaluation per course: "Only have one evaluation not one after every section" (80/S2). Of greater concern are the technical issues raised by some users. These issues often relate to

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workplaces where participants undertook online learning: "Web site seems very slow. Also, will not run on explorer" (88/M1) "Ensure WA Health computers can run embedded videos!" (76/M1) "Too slow to load" (74/M3) As can be seen in Table 5, this particular issue was raised by a signi"cant number of participants (approximately 8% of users) when doing Module 1 of the GCP course. These issues are an ongoing task for the technical team who work to resolve such issues. Lessons Learnt Consistency was found between the "ndings in quantitative and qualitative data. The majority of the users were satis"ed with the online GCP training. Some participants did articulate the training improved their knowledge about GCP. While this study evidenced the users' experience to this positive outcome, the studies by (Haeusler 2009) and (Vora and Shah 2011) in assessing the

impact of formal training in GCP on the quality of clinical trials would be useful for future studies of this GCP training. This study supports "ndings by Arango et al. (2016) study that GCP online training could be one of the formats of training to o!er (Arango et al., 2016). The RETP training, feedback and ongoing evaluation can provide other training providers with necessary and relevant information for future users of GCP. There were lessons learnt around issues were raised by the participants. For example, more

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information provided and improvements to the overall presentation. The feedback has already been incorporated into the next version of the GCP training and will continue to be monitored for future improvements. Course presentation was the highest area of feedback followed by these

requests for additional content. The evaluation conducted in this study could be improved in several ways. Firstly, an evaluation of participants before and after taking the GCP module followed by qualitative analysis of feedback through open-ended questions (Durning et al., 2007). Additional probing into asking why and how (Faisal et al., 2013) the online GCP program has or has not impacted their current practice in health associations is another area of future evaluation and highly useful for the knowledge translation and understanding impact. Another area participants raised concerns included technical issues, which were concerning the network and online software users used to access the GCP training. A considerable number of comments on this particular was raised during the "rst module of GCP. Supporting users with technical issues they encounter is an essential aspect of this service. The nature of the online training environment is that participants must be self-motivated to complete the training. They must also balance training with other leisure and life activities which can get in the way of completing online learning which is carried on at home or in

work environments. Having an online learning program with less technical issues might increase users' motivation continue working on the program. The RETP online management system seems to capture this particular need because there was no such concern expressed by the participants on the last three modules of the GCP online course. As Cook (2012, p.309) staes: "If we teach them, they will learn. The question we face is how to make learning as painless, relevant, and e#cient as possible." Conclusion The objective of the study was to evaluate feedback from the users of GCP online training provided by RETP, WAHTN. Positive responses were obtained as this service had met the users' needs. Despite this, positive users made some suggestions for the improvements which are useful in guiding the ongoing course development at the RETP. This study is limited in that it was completed in a short time since its "rst launching. A study of a larger number of users will be undertaken in the future.

Take Home Messages Online Good Clinical Practice provides researchers with easy and $exible access to essential training. Ongoing evaluation of any training is critical for continuous improvement Techical issues will occur; having support sta! are critical during this time Evaluation of training allows for accumulated data to be analaysed about particlant satisfaction for continued improvement Notes On Contributors Dr. Rashmi Watson leads the Research Education and Training Program for the Western Australian Health Translation Network and has been involved as an educator for over 20 years. Dr. Nurmala Simbolon

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• Online Good Clinical Practice provides researchers with easy and flexible access to essential training. • Ongoing evaluation of any training is critical for continuous improvement • Techical issues will occur; having support staff are critical during this time • Evaluation of training allows for accumulated data to be analaysed about particlant satisfaction for continued improvement Notes On Contributors

is both an educator and a researcher. Her research interests are the internationalisation of higher education and English medium instruction (EMI). Dr Edi Nuryatno is a specialist in the area of ICT business analyst/enterprise architecture at the Research Education and Training Program for the Western Australian Health Translation Network. Acknowledgements Bibliography/References Anonymous. (2008). Good Clinical Practice Research Guidelines Reviewed, Emphasis Given to Responsibilities of Investigators: Second Article in a Series. Journal of Oncology Practice, 4(5), 233 – 235, Accessed on March 21st, 2017 from http://ascopubs.org/doi/pdf/10.1200/JOP.0854601 https://doi.org/10.1200/JOP.0854601 Arango, J., Chuck, T., Ellenberg, S., Foltz, B., Gorman, C. Hinrichs, H., McHale, S., Merchant, K., Seltzer, J., Shapley, S., & Wild, G. (2016).

Good Clinical Practice Training: Identifying Key Elements and Strategies for Increasing Training

Dr. Rashmi Watson leads the Research Education and Training Program for the Western Australian Health Translation Network and has been involved as an educator for over 20 years. Dr. Nurmala Simbolon is both an educator and a researcher. Her research interests are the internationalisation of higher education and English medium instruction (EMI). Dr Edi Nuryatno is a specialist in the area of ICT business analyst/enterprise architecture at the Research Education and Training Program for the Western Australian Health Translation Network. Acknowledgements

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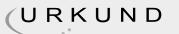
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An interesting paper covering an important aspect of the ever-increasing use of on-line learning. It was interesting to read of the authors' approaches using a mixed-methods approach. This approach seems valuable in being able to provide reason and opportunity to re-shape the programme according to the participants wants and needs. I thought that the authors described this well. My worries however is how these positive findings from these evaluation techniques provide us with a false positive view about the real outcome of the courses / events/ training activities described. I would have preferred to see how the authors now intend to structure a longer-term evaluation in how these activities really

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the participants impact upon future healthcare, either by extending the Kirkpatrick evaluation up to levels 3 and 4 or using an alternative model, such as that described by Maxwell (Maxwell R . Quality in Health Care 1992;1:171-1770 who looked more at the parameters of

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