Table 1:	Invited	Peer	Reviewer	Comments
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Reviewer ¹	Section ²	Reviewer Comments	Author Response ³
1	NA	The inclusion/exclusion criteria assigned by the requisitioners were rigorously applied to the literature that was elicited by way of the systematic review guide terms in the selected data bases	Thank you
1	NA	The inclusion/exclusion criteria were unfortunately narrow in an already-limited field of science. Key rigorously-developed research studies were not reviewed due to the narrowness of the criteria and yet certain of these published reports addressed key questions of the MedCAC program and key concerns articulated by the panel members on November 18. Key sources not retrievable from searched data bases (such as those studies reported in <i>Journal of Lymphoedema</i> , which might have required hand-searching) or set aside as supplements (conference proceedings) to <i>Lymphology</i> contribute considerable evidence to the field. For example, key epidemiological studies documenting the natural history of secondary lymphedema (such as those by Mahamaneerat et al, 2008, Armer et al, 2009) were not cited although their approach and findings addressed key concerns of the panel. These studies are informative to the concerns about the true incidence and prevalence of secondary lymphedema following breast cancer treatment, specifically, with potential for extrapolating findings to other cancer-related treatments involving lymph node dissection and/or radiation. These excluded studies also serve to bring order to the field of lymphedema measurement where historically multiple criteria, methodologies, and time-points are applied in clinical and research settings with a diversity of individual patient characteristics. Rather than accepting the diversity of findings as solely a worrisome lack of consensus as was done in the technology assessment, inclusion of these studies applying various methodologies (i.e., perometry, circumferences, self- reported symptoms), various criteria (i.e., 200 mL, 10% limb volume change, 2 cm girth change, and self-reported symptoms of heaviness and swelling), over various time-points (from pre-operative baseline, through post-operative, every three months for twelve months, then every six months to thirty months (as published), [and now every six months to seven years post-diagnosis] (Armer et al, 2005, 2	 We based our search on the parameters defined by the key questions. We use a professional librarian at the McMaster Evidence Based Practice Center who is trained in advanced searching techniques. We hand searched the reference lists of several recently published review articles and searched the bibliographies of included articles to identify key sources of data that may not have been captured in our database searches. Our literature search captured 198 articles published in Lymphology. We screened these articles as per our methods and would have included any that met our inclusion criteria. Although the Journal of Lymphoedema is not indexed in most major databases (including Medline), our hand searches would have identified any important articles published in this journal (none were identified). The technology assessment (TA) was commissioned to report on the state of the lymphedema literature. The TA was not intended to address the specific questions put to the MedCAC panel. The report was not meant to convey a 'worrisome' attitude toward the heterogeneity evident in the lymphedema literature. Rather, we indicate that the heterogeneity prevents us from drawing overall conclusions about the key questions that the TA was commissioned to answer.

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1	NA	Additional studies were excluded because secondary lymphedema was not specified in the title or abstract or the stratification of patients into those with primary and secondary lymphedema was not reported. This omission is unfortunate on multiple counts. Treatment for lymphedema, primary or secondary, is very similar as a standard of care. To exclude studies reporting effective treatment for primary lymphedema patients is unfortunate as the body of literature is limited and principles of effective management of primary and/or combined primary and secondary caseloads are highly relevant to best management of secondary lymphedema (and vice versa). Additionally, studies excluded for failure to specify secondary lymphedema but which reported participants with lymphedema following breast cancer clearly are studying secondary lymphedema (e.g., A. Sanders et al, 2002) and should have been included in the systematic review. Persistence in clarifying this information with the authors would have allowed the findings from these studies to be included in the systematic review analysis. Similarly, failure to report study or tool characteristics, such as validity and reliability, the index for comparison, the preparation of the interventionist(s), and other such study details (which may have been an author oversight or an omission due to space limitations) could have been remedied by contacting the authors for these data rather than discarding the studies.	The pathophysiology of primary and secondary lymphedema is different and one cannot assume that benefits found in one population are transferable to another population. There are many examples in medicine where treatment is dependent on the cause of the condition. For example, ankle edema (not lymphedema) can be caused by heart, liver or kidney failure through different mechanisms and the treatments are quite different. Since the scope of the TA was secondary lymphedema, we excluded studies of primary lymphedema or studies that contained a 'mixed' sample (i.e., some primary and some secondary lymphedema patients). We would have included any mixed sample study if the results were presented in such a way as to allow us to partition the primary and secondary lymphedema patients into two subgroups, each with a separate set of results (we would report the results for the secondary lymphedema subgroup).
			Studies that specified they were studying lymphedema patients would have been picked up by our literature search. A study was not included in the review if it did not meet one or more of our inclusion/exclusion criteria. We included studies that would answer the key questions; we were never tasked with including all lymphedema studies, nor did we choose to include case series (or before-after studies) because they occupy a position that is low on the hierarchy of medical evidence (primarily because they lack a comparator treatment and therefore cannot be used to evaluate the efficacy of a new/novel treatment).
			We were tasked with examining studies that reported sensitivity/specificity or reliability/validity data. As

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			per standard systematic review methodology, only studies that clearly reported on these issues were included. Contacting authors is done when a study appears to satisfy the inclusion criteria, but presents information in such a way that frustrates the extraction of data into tables. Study authors are not routinely contacted to see if they have done relevant work if there is no indication in any articles that such work was actually done.
1	NA	Omission of the foundational non-English literature from Germany and France is a significant oversight and gap in this systematic review. There are multiple rigorously-applied research studies by historic leaders in the field of lymphedema published in our peer- reviewed literature which have been or could have been translated into English for analysis. These European-origin research articles provide the solid foundation for the current clinical practice in the U.S. and around the world and support the clinical experts' testimony in this area. For example, the European traditions and research (published data from 1892) form the basis for the current standard of care in secondary lymphedema, complete decongestive therapy (CDT).	On the advice of the peer reviewers, we have included non-English literature. The information in this non-English literature did not change the initial conclusions of the TA. We were mandated to include publications between 1990 and January 2010. Therefore, any article published before 1990—regardless of language— was excluded from the review.
1	NA	Certain identified articles were labeled 'unavailable' to the reviewers at McMaster University. An article not available through local sources could have been ordered by inter-library-loan or by direct contact with sister institutions and/or authors and journals. To delete a selected manuscript meeting the inclusion criteria because of "unavailability" is simply not acceptable for a comprehensive review.	Inter-library loan and direct contact were attempted. In addition to the regular library retrievals, attempts were made to locate the articles by ordering through the RACER system, searching Google, and approaching the authors directly. Some articles are still on order and will be considered if they come in prior to the submission of the final report.
1	NA	Similarly, searching additional data bases, conference proceedings, and journal supplements, and the gray literature contributes to a more thorough systematic review. These literature sources are included in the respected Johanna Briggs Institute guidelines for systematic reviews which will capture relevant literature which can be subjected to levels-of-evidence grading.	We selected our databases following consultation with our EPC librarian, who examined existing lymphedema reviews to ensure our selections were consistent with the literature. We searched journal supplements, but we excluded conference proceedings and the grey literature because they would be unlikely to yield additional information.

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1	NA	The second key point focuses on the concepts of efficacy versus effectiveness. As was discussed by the panel and audience, the efficacy demonstrated by the standard randomized control trial is imperative for intervention(s) which can potentially bring harm to the patient. An example is pharmaceutical drug trials where a new agent must meet or surpass the standard of care in terms of efficacy without introducing greater harm. As eloquently expressed by one MedCAC panel member, the half-century of lymphedema care documented as clinically effective by expert clinicians in manuscripts which pre-date our MedCAC meeting cannot be allowed to be excluded when treatment has been shown to be effective and not harmful. The most knowledgeable therapists may be unwilling for ethical reasons to deny a patient the standard of care treatment shown over decades to be effective for secondary lymphedema in order to randomly control for an assessment of efficacy of a lesser studied intervention which may indeed lead to harm. Randomization may be highly appropriate for determination of dosage and interval with the standard therapies and for the addition of adjunct therapies to the standard protocol. In this systematic review, the exclusion of literature not reporting randomization of the intervention or without a cohort group, as prescribed in the charge by the Institutes of Medicine/AHRQ is a severe limitation for this methodology and these findings. To include this literature and then to evaluate the level of evidence as done with the application of Melnyck's (Evidence-Based Practice in Nursing and Healthcare: A Guide to Best Practice, 2004) criteria for levels of evidence in the Oncology Nursing Society's Putting Evidence into Practice (PEP) cards is recommended.	We did in fact search for (and include) non- randomized studies, provided they had a control group. We excluded studies without control groups because the efficacy or effectiveness of treatment cannot be adequately assessed without a comparator. Refer to Chapter 2: inclusion/exclusion criteria.
1	NA	The exclusion of early intervention studies as preventive is a major oversight if we accept the International Society of Lymphology diagnostic grading for Stages 0 to 3 with Stage 0 being latent, not-yet-emergent lymphedema. The well-designed study by Stout Gergich et al (2008) assigned an early intervention for those with post-operative edema and reported a lesser occurrence of a higher-stage lymphedema at later measurement points. This is a promising study which should be included in the review.	The assigned scope of this review did not include prevention. The question of prevention is an excellent topic for future work. Patients who have undergone surgery and radiation for breast cancer are at risk for developing lymphedema, but do not have the condition. Stage 0 is an entity of unknown clinical significance.
1	NA	Additional points to be made include the provision of standard of care treatment in the clinical setting in the U.S. by not only physical therapists but occupational therapists, nurses, and licensed massage therapists, all of whom should have completed specialized training in lymphedema assessment and management. It is important that we not exclude from provision of care those trained health professionals eligible for certification by the Lymphology Association of North America.	Thank you for your comment. Clarification has been added in the TA in Chapter 1, page 20.
2	NA	Thank you for the opportunity to review this assessment. I found this to be a wonderful review of the evidence as well as a clarion call for good quality studies. Bravo!	Thank You
2	p 14	"Infection in the lymphatics from a variety of sources, including venipuncture," There is to my knowledge no evidence, infection rates, etc reported on venipuncture for blood draws. The	Some sources do report an increased risk of infection from venipuncture. Clarification added in text of TA

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		prohibition is actually more valid for intravenous infusions where a catheter is left in place. I point this out because patients have been told to avoid venipuncture at all costs in the affected arm which has at times led to them refusing diagnostic scans. Simple blood tests in the affected arm are unlikely to lead to infection in developed countries.	on page 14.
2	p 15	No mention of reverse axillary node mapping as an emerging procedure to prevent arm edema.	We ran a search for this term and it was found however, it was excluded as it related to prevention.
2	p 18	Typo error in the 1st line bolded under heading "Non-pharmacological" Line at end of same paragraph does not make logical sense. "During exercise, there may be decreases in the pressure exerted by high stretch bandages, which could obstruct lymph flow." I would think that this should read increases.	High stretch bandages often lose pressure with exercise and thus do less to assist muscle pump than low stretch bandages. This typo was corrected on page 18
2	p 20	Re US - I would suggest adding a statement that US safety has not been established in patients with breast cancer and that US has shown enhanced tumor growth in mice.	Clarification has been added to text on page 20.
2	NA	Missed studies: Pappas, Christos, O'donnell, Thomas. Long-term results of compression treatment for lymphedema. J Vasc Surg 1992; 16: 555-64	In order to be included in the TA, studies needed to have a control group. This study by Pappas did not have a control group and thus was excluded from the TA.
3	NA	Per my oral comment during the panel, I feel the search was narrow in use of search terms and therefore narrow in literature captured for review. Using "breast neoplasm" and "upper limb morbidity" I captured several articles that were not identified in this technical report. This search does not include all the other cancers and conditions that result in secondary lymphedema such as prostate cancer and the gynecological cancers, peripheral vascular disease, etc When I used breast neoplasm and upper limb morbidity" in pub med central I yield 124 cites and when I use "arm morbidity" 553 cites. When I searched on "Breast neoplasm" and "morbidity" excluding the "upper limb" modifier, the search yields 3,040 reports. When I search on "neoplasm" and "morbidity" the results include 20,593 reports. This is a significant body of literature.	We based our search on the parameters defined by the key questions. We use a professional librarian at the McMaster Evidence Based Practice Center who is trained in advanced searching techniques. The reviewer's proposed search includes many broad terms that are at best tangentially related to lymphedema and therefore prone to return many citations that are beyond the scope of the TA (large noise-to-signal ratio). We ran the proposed search and did not find any articles that were missed in our initial search.
3	NA	I have included the first 100 cites here from the "breast neoplasm and upper limb morbidity" keyword search to give you an idea of the reports yielded followed by the first 100 cites from the "breast neoplasm and arm morbidity" keyword search. So the question is how many of these reports were not included in the review for the technical assessment?	We examined the 100 citations that you provided and none of them would have been included in the TA given the inclusion/exclusion criteria for the TA (see criteria p 21).
3	NA	I have inserted below the two sets of citations a table (table 2) from a recent systematic review on breast cancer and morbidity published by Lui et al in 2009 that demonstrates the issue. Lymphedema was not in the title or keys words for almost all of these articles included in the systematic review including the systematic review itself, yet lymphedema is one of the major	The reviewer mentions a series of articles that reported lymphedema as a morbidity associated with breast cancer. These studies do not examine diagnostic tests or treatments for lymphedema, and

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		morbidities reported in each of these studies. The physician literature does not routinely use the term "lymphedema" instead the term "morbidity" or "arm volume" are frequently used.	are therefore beyond the scope of the TA. Had these studies evaluated diagnostic tests or treatments for lymphedema, they would have been captured in our search and included in the TA (provided they met our other inclusion criteria).
3	NA	In the Cochrane Reviews at <u>http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003475/frame.html</u> the authors of a review protocol included their search strategy and I have pasted it below.	The TA was updated and some additional search terms were added to the search (see Chapter 2 and Appendix A).
		A computerized search of the medical literature will be undertaken. Medline, EMBASE, Cinahl, and Health Star will be searched from 1950 to present. The text term "physiotherapy" will be searched. Also, the text terms "lymphedema" or "lymphoedema" and "drainage" will be combined. Additionally, "lymphedema" or "lymphoedema" and "physical therapy," will be combined as well as "lymphedema" or "lymphoedema" and "massage." References from these studies will also be searched for relevant clinical trials. Additionally, these databases will be searched on text words "Complete Decongestive Physiotherapy," "Complex Physical Therapy," "Complex Lymphatic Therapy," "Complex Lymphedema Therapy," and "Complex Decongestive Physical Therapy," because these are all terms that have been used to describe decongestive therapy. We will also search on "Foldi," "Vodder," "Casley-Smith," "Lerner," and "Leduc," which are proper nouns commonly associated with brand names of the intervention. The Cochrane Library CENTRAL/CCTR will also be searched. Additionally the Bodywork Knowledge Base, a database specifically housing citations of the various aspects of massage, will be searched on keywords "lymphedema," "lymphoedema," "edema," "swelling," and "manual lymphatic drainage." Additionally, the Specialised Register maintained by the Cochrane Breast Cancer Group will be searched. (Details of search strategies used by the group for the identification of studies are outlined in the group's module). Handsearching of journals with the highest number of studies published on the treatment of lymphedema using CDP will be handsearched. This will involve a handsearching of "Lymphology." (Any relevant trials identified will be forwarded to CENTRAL/CCTR if these trials are not already included in the Cochrane Library). Lymphedema-associated websites which will be searched for additional references are: The British Lymphology Society www.lymphnet.org Lymphoedema Association of Australia www.lymphoedema.org/bls The National Lymphedema Network www.lymphnet	The specific research question that guided the search strategy in the cited Cochrane Review was also different from the key research questions in the TA. All search strategies must be guided by the research questions at hand and they cannot simply be transferred between different systematic reviews.

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		Investigators who have completed research on LE in the past will be contacted to determine if	
		there are any studies that are currently under review for publication and to identify any	
		additional randomized studies not previously identified in the systematic literature search."	
		In examining theses authors search strategy, several terms not utilized in the search used to	
		produce this technical assessment are used which yield additional reports: "Physiotherapy,	
		Physical therapy, Complete Decongestive Physiotherapy, Complete Decongestive Therapy,	
		Complex Physical Therapy, and Complex Decongestive Physical Therapy"	
3	NA	A second Cochrane review at	Please see our response to the immediately
		http://www.mrw.interscience.wiley.com/cochrane/clsysrev/articles/CD003141/frame.html also	preceding comment.
		included their search strategy and I have pasted it below.	
		Index terms	
		Medical Subject Headings (MeSH)	
		*Physical Therapy Modalities; Bandages; Lymphedema [*rehabilitation]; Randomized	
		Controlled Trials as Topic	
		MeSH check words	
		Humans	
		Appendices	
		Appendix 1. Search strategy for CENTRAL (Issue 1, 2008)	
		1. Lymphoedema or lymphedema or lymphodema or elephantiasis	
		2. exercise/	
		3. physical therapy	
		4. bandage	
		5. hosiery or hose	
		6. compression	
		7. 5 or 6 or 7 or 8 or 9	
		8. 1 and 7 Annendin 2. Second strategy for CINATH (Orid) (1982 to February 2008)	
		Appendix 2. Search strategy for CINAHL (Ovid) (1982 to February 2008) 1. Lymphedema/ or elephantiasis/	
		2. Lymph?dema or elephantiasis	
		3. 1 or 2	
		4. Physical therapy/	
		5. Bandages and dressings/	
		6. Compression garments/	
		7. physical therapy	
		8. bandage	
		9. hosiery or hose	

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		10. compression	
		11. 4 or 5 or 6 or 7 or 8 or 9 or 10	
		12. 3 and 11	
		Appendix 3. Search strategy for MEDLINE (Ovid) (1960 to February 2008)	
		1. Lymphedema/ or elephantiasis/	
		2. Lymph?dema or elephantiasis	
		3. 1 or 2	
		4. Physical therapy modalities/	
		5. Bandages/	
		6. Intermittent pneumatic compression devices/	
		7. physical therapy	
		8. bandage	
		9. hosiery or hose	
		10. compression	
		11. 4 or 5 or 6 or 7 or 8 or 9 or 10	
		12. 3 and 11	
		Appendix 4. Search strategy for EMBASE (Ovid) (1980 to February 2008)	
		1. Lymphedema/ or elephantiasis/	
		2. Lymph?dema or elephantiasis	
		3. 1 or 2	
		4. Physiotherapy/	
		5. Bandage/	
		6. Kinesiotherapy/	
		7. Intermittent pneumatic compression device/	
		8. Compression therapy/	
		9. physical therapy 10. bandage	
		11. hosiery or hose	
		12. compression	
		13. 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12	
		14. 3 and 13	
		Appendix 5. Search strategy for National Research Register (NRR) (February 2008)	
		1. lymphedema or lymphoedema or lymphodema	
		Appendix 6. Search strategy British Nursing Index, British Library Index, UnCover,	
		PASCAL (September 2003)	
		Lymph?edema OR elephantiasis	
		a) AND physical therapy	

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		b) AND bandage* OR (compression bandage*)	
		c) AND hosiery OR hose	
		d) OR hosiery OR hose NEAR compression	
		e) OR (compression stocking*) OR (compression sleeve*)	
		f) AND (pneumatic compression) OR (compression pump)	
		AND	
		g) (reduc* limb volume)	
		h) OR (reduc* limb size)	
		i) OR (reduc* excess volume)	
		j) OR (reduc* excess limb volume)	
		k) OR (reduc* oedema OR edema volume)	
		Lymph?edema OR elephantiasis	
		1) AND physical therapy	
		m) AND bandage*	
		n) AND (compression bandage*)	
		o) AND hosiery OR hose	
		p) AND (compression hosiery OR hose)	
		q) AND (compression stocking*) OR (compression sleeve*)	
		AND	
		r) (Quality of Life measure*) OR (Quality of Life tool*)	
3	NA	Additional studies relative to breast cancer that appear to me to meet the criteria for inclusion	Two of the articles were actually included in the
		are as follows (I have attached pdfs of articles to e-mail):	review (Bertelli, Damstra).
			The others were excluded because they failed to
			meet our inclusion criteria.
		Andersen 2000	
		Andersen L, Højris I, Erlandsen M, Andersen J. Treatment of breast-cancer-related	Andersen 2000, Bertelli 1991 and Damstra 2009
		lymphedema with or without manual lymphatic drainagea randomized study. <u>Acta Oncol.</u>	were included in the TA.
		2000;39(3):399-405.	
		Badger 2000	
		Badger CMA, Peacock JL, Mortimer PS. A randomized, controlled, parallel-group clinical	Badger 2000 was excluded because of mixed
		trial comparing multilayer bandaging followed by hosiery versus hosiery alone in the	population.
		treatment of patients with lymphedema of the limb. Cancer 2000;88(12):2832-7. Links	
		Bertelli 1991	
		Bertelli G, Venturini M, Forno G, Macchiavello F, Dini D. Conservative treatment of	
		postmastectomy lymphedema: a controlled randomised trial. Annals of Oncology 1991;2:575-	
		8. Links	

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		<i>Damstra 2009</i> <u>Damstra RJ, Partsch H</u> .Compression therapy in breast cancer-related lymphedema: A randomized, controlled comparative study of relation between volume and interface pressure changes. <u>J Vasc Surg.</u> 2009 May;49(5):1256-63.	
		Hammer 2007 Hamner JB, Fleming MD. Lymphedema therapy reduces the volume of edema and pain in patients with breast cancer. <u>Ann Surg Oncol.</u> 2007 Jun;14(6):1904-8. Epub 2007 Mar 8.	Hammer 2007, Karadiback 2008, Kim 2007, Kim 2008, Vignes 2007 and Weiss 2002 were excluded because they did not have a control group.
		<i>Hornsby 1995</i> Hornsby R. The use of compression to treat lymphoedema. <i>Professional Nurse</i> 1995; 11 (2):127-8.	Hornsby 1995 was excluded because it was an overview.
		<i>Irdesel 2007</i> Irdesel J, Kahram an Celiktas S. Effectiveness of exercise and compression garments in the treatment of breast cancer related lymphedema. <i>Turkiye Fiziksel Tip ve Rehabilitasyon Dergisi</i> 2007; 53 (1):16-21.	Irdesel 2007 was reviewed in non-English update and has been included.
		Johansson 2005 Johansson K, Tibe K, Weibull A, Newton RC. Low intensity resistance exercise for breast cancer patients with arm lymphedema with or without compression sleeve. <i>Lymphology</i> 2005; 38 (4):167-180. Links	Johansson 2005 was excluded because it was not on topic.
		<i>Karadibak 2008</i> <u>Karadibak D, Yavuzsen T, Saydam S</u> . Prospective trial of intensive decongestive physiotherapy for upper extremity lymphedema. <u>J Surg Oncol.</u> 2008 Jun 1;97(7):572-7.	
		<i>Kim 2007</i> <u>Kim SJ, Yi CH, Kwon OY</u> . Effect of complex decongestive therapy on edema and the quality of life in breast cancer patients with unilateral leymphedema. <u>Lymphology</u> . 2007 Sep;40(3):143-51.	
		<i>Kim 2008</i> <u>Kim SJ, Park YD</u> . Effects of complex decongestive physiotherapy on the oedema and the quality of life of lower unilateral lymphoedema following treatment for gynecological cancer. <u>Eur J Cancer Care (Engl).</u> 2008 Sep;17(5):463-8. Epub 2008 Jul 10.	

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		Vignes 2007 <u>Vignes S, Porcher R, Arrault M, Dupuy A</u> .Long-term management of breast cancer-related lymphedema after intensive decongestive physiotherapy. <u>Breast Cancer Res Treat.</u> 2007 Mar;101(3):285-90. Epub 2006 Jul 7.	
10		<i>Weiss 2002</i> <u>Weiss JM, Spray BJ</u> . The effect of complete decongestive therapy on the quality of life of patients with peripheral lymphedema. <u>Lymphology</u> . 2002 Jun;35(2):46-58.	

Peer reviewers are not listed in alphabetical order.

² If listed, page number, line number, or section refers to the draft report.

³ If listed, page number, line number, or section refers to the final report.