Summary Report

Quinacrine

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Table of Contents

REVIEW OF NOMINATION 4
METHODOLOGY 4
Background information 4
Systematic literature review 4
Outreach to medical specialists and specialty organizations 7
Survey 7
CURRENT AND HISTORIC USE 9
Summary of background information 9
Summary of literature review 9
Summary of focus groups/interviews of medical experts and specialty organizations 18
Summary of survey results 19
CONCLUSION 21
APPENDICES 22
Appendix 1. References 22
Appendix 2. Survey instrument 35

Table of Tables

Table 1. Participating associations 8
Table 2. Associations that declined participation 8
Table 3. Currently approved products – US 9
Table 4. Currently approved products – select non-US countries and regions 9
Table 5. Types of studies 9
Table 6. Number of studies by country 9
Table 7. Number of studies by combinations 11
Table 8. Dosage by indication – US 12
Table 9. Dosage by indication – non-US countries[a] 14
Table 10. Compounded products – US 16
Table 11. Compounded products – non-US countries 17
Table 12. Overview of interviewee 18
Table 13. Characteristics of survey respondents 19
Table 14. Types of products used, prescribed, or recommended 19
Table 15. Compounded use of quinacrine in practice 19
Table 16. Indications for which quinacrine is considered a standard therapy 20
Table 17. Reasons for using compounded product instead of the FDA-approved products 20
Table 18. Change in frequency of compounded quinacrine usage over the past 5 years 20
Table 19. Do you stock non-patient specific compounded quinacrine in your practice? 20
Table 20. Questions related to stocking non-patient specific compounded quinacrine 20

REVIEW OF NOMINATION

Quinacrine (UNII code: 81A613ZZ6X) was not nominated for inclusion on the 503B Bulks List.

METHODOLOGY

Background information

The national medicine registers of 13 countries and regions were searched to establish the availability of quinacrine products in the United States (US) and around the world. The World Health Organization, the European Medicines Agency (EMA), and globalEDGE were used to identify regulatory agencies in non-US countries. The medicine registers of non-US regulatory agencies were selected for inclusion if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information, specifically, product trade name, active ingredient, strength, form, route of administration (ROA), and approval status, provided in a useable format. Based on these criteria, the medicine registers of 13 countries/regions were searched: US, Canada, European Union (EU), United Kingdom (UK), Ireland, Belgium, Latvia, Australia, New Zealand, Saudi Arabia, Abu Dhabi, Hong Kong, and Namibia. Both the EMA and the national registers of select EU countries (Ireland, UK, Belgium, and Latvia) were searched because some medicines were authorized for use in the EU and not available in a member country and vice versa.

Each medicine register was searched for quinacrine; name variations of quinacrine were entered if the initial search retrieved no results. The following information from the search results of each register was recorded in a spreadsheet: product trade name; active ingredient; strength; form; ROA; status and/or schedule; approval date. Information was recorded only for products with strengths, forms, and/or ROA similar to those requested in the nominations.

In addition to the aforementioned medicine registers, the DrugBank database (version 5.1.4) and the Natural Medicines database were searched for availability of over-the-counter (OTC) products containing quinacrine. The availability of OTC products (yes/no) in the US and the ROA of these products were recorded in a spreadsheet. Individual product information was not recorded.

Systematic literature review

Search strategy

Two databases (PubMed and Embase) were searched including any date through March 25, 2019. The search included a combination of (quinacrine[tiab] OR Acrichine[tiab] OR Atabrine[tiab] OR Atebrin[tiab] OR Mepacrine[tiab]) AND (treat*[tiab] OR therap*[taib] OR clinic*[tiab] OR malaria*[tiab] OR immuno*[tiab] OR leishmaniasis[tiab] OR malignant[tiab] OR giardiasis[tiab] OR cancer[tiab] OR tumor[tiab] OR carcinoma[tiab]) AND (humans[MeSH Terms] AND English[lang] NOT autism). Peer-reviewed articles as well as grey literature were included in the search. Search results from each database were exported to Covidence®, merged, and sorted for removal of duplicate citations.

Study selection

Articles were not excluded on the basis of study design. Articles were considered relevant based on the identification of a clinical use of quinacrine or the implementation of quinacrine in clinical practice. Articles were excluded if not in English, a clinical use was not identified, incorrect salt

form, or if the study was not conducted in humans. Screening of all titles, abstracts, and full-text were conducted independently by two reviewers. All screening disagreements were reconciled by a third reviewer.

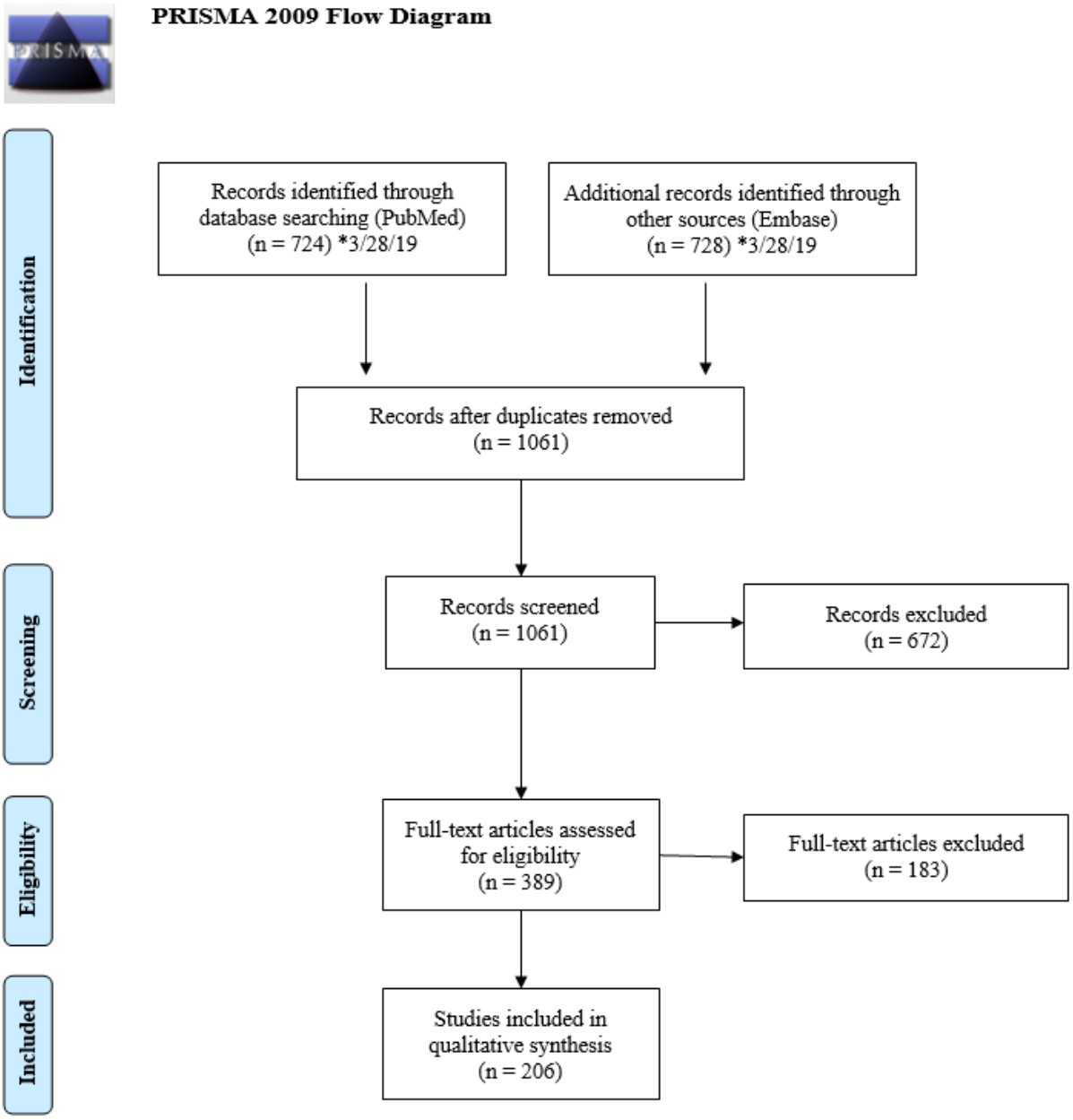
Data extraction

A standard data extraction form was used to collect study authors; article title; year published; journal title; country; indication for quinacrine use; dose; strength; dosage form; ROA; frequency and duration of therapy; any combination therapy utilized; if applicable, formulation of compounded products; study design; and any discussion surrounding the use of quinacrine compared to alternative therapies.

Results

Please refer to Figure 1.

Figure 1. Summary of literature screening and selection (PRISMA 2009 Flow Diagram)



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit www.prisma-statement.org.

Outreach to medical specialists and specialty organizations

Using the indications from the results of the literature review, fourteen (14) medical specialties that would potentially use quinacrine were identified: cardiology, dermatology, endocrinology, gastroenterology, hematology, hepatology, infectious disease, neurology, obstetrics and gynecology, oncology, pain management, primary care, pulmonology, and rheumatology. Semi-structured interviews were conducted with subject matter experts within these specialties. Interviews lasted from 30-75 minutes and were conducted either via telephone or in-person. Criteria for selecting subject matter experts included recommendations provided by specialty professional associations, convenient geographic location, authorship within the specialty, or referral by an interviewee. Up to nine (9) interviews were conducted per substance. Five (5) experts were contacted for interviews, of which one (1) accepted. Two (2) experts provided their response via email, one (1) expert specializing in hepatology stated that quinacrine is not used and one (1) expert specializing in gastroenterology stated that quinacrine is rarely used to treat giardiasis and other parasitic infections of the gut but would not consider it to be first-line, no additional follow-up was warranted. Two (2) experts, one (1) specializing in neurology and one (1) specializing in oncology, failed to respond to the interview request. The interview was recorded and transcribed via ©Rev.com. QSR International's NVivo 12 software was utilized for qualitative data analysis. The University of Maryland, Baltimore IRB and the Food & Drug Administration RIHSC reviewed the study and found it to be exempt. Subject matter experts provided their oral informed consent to participate in interviews.

Survey

General professional medical associations and specialty associations for cardiology, dermatology, endocrinology, gastroenterology, hematology, hepatology, infectious disease, neurology, obstetrics and gynecology, oncology, pain management, primary care, pulmonology, and rheumatology, identified from the literature review, were contacted to facilitate distribution of an online survey. A Google™ search was conducted to identify relevant professional associations within each specialty. Associations were included if their members are predominantly practitioners, national associations, and organizations focused on practice within the US. Organizations without practicing physicians and state or regional organizations were excluded. The association's website was searched in order to identify the email of the executive director, regulatory director, media director, association president, board members, or other key leaders within the organization to discuss survey participation. If no contact information was available, the "contact us" tab on the association website was used.

An online survey was created using Qualtrics® software (Provo, UT). The survey link was distributed to 17 associations. If an association had more than one (1) substance with indications relevant to that specialty, substances were combined into one (1) survey with no more than 14 substances per survey. Table 1 highlights the associations that agreed to distribute the survey link and Table 2 includes the associations that declined to participate. Additionally, single substance surveys were created and posted on the project website which was shared with survey participants.

Participation was anonymous and voluntary. The estimated time for completion was 30 minutes with a target of 50 responses per survey. The Office of Management and Budget (OMB) approved this project.

Table 1. Participating associations

Specialty	Association
Dermatology	American Academy of Dermatology (AAD)
	American Society for Dermatologic Surgery (ASDS)
Pain Medicine	American Academy of Pain Medicine (AAPM)
Primary Care	American Academy of Environmental Medicine (AAEM)
Rheumatology	American College of Rheumatology (ACR)

Table 2. Associations that declined participation

Specialty	Association	Reasons for Declining
Endocrinology	American Association of Clinical Endocrinologists (AACE)	Declined, "endocrinologists are not generally in the compounding space."
Gastroenterology	American Gastroenterological Association (AGA)	Failed to respond
Hematology	American Society of Hematology (ASM)	Failed to respond
Hepatology	American Association for the Study of Liver Diseases (AASLD)	Failed to respond
Medicine	American Medical Association (AMA)	Failed to respond
	American Osteopathic Association (AOA)	Failed to respond
Neurology	American Academy of Neurology (AAN)	Failed to respond
Obstetrics and Gynecology	American College of Obstetricians and Gynecologists (ACOG)	Declined, survey not approved for distribution
Oncology	American Society of Clinical Oncology (ASCO)	Declined
Primary Care	American Academy of Family Physicians (AAFP)	Failed to respond
	American College of Physicians (ACP)	Failed to respond
Pulmonology	American Thoracic Society (ATS)	Declined

CURRENT AND HISTORIC USE

Summary of background information

- Quinacrine is not available as an FDA-approved product.
- Quinacrine is not available as an OTC product in the US.
- There is no current United States Pharmacopeia (USP) monograph for quinacrine.
- Quinacrine is not available in any of the twelve foreign registries.

Table 3. Currently approved products – US

No approved products in the US

Table 4. Currently approved products – select non-US countries and regions

No approved products in the selected non-US countries and regions

Summary of literature review

- Total number of studies included: 206 (72 descriptive, 110 experimental, and 24 observational).
- Most of the studies were from the US (80).
  - Quinacrine was never formally approved by the FDA but it was used for a long time for malaria, especially during World War II. It was marketed until 1995 and was discontinued due to a decrease in demand.[1]
- The most common indications for the use of quinacrine in the US were malaria, giardiasis, and female sterilization. The most common indications from the non-US studies were female sterilization, lupus erythematosus, and giardiasis.
- Compounded products were identified from both US and non-US studies.

Table 5. Types of studies

Types of Studies	Number of Studies
Descriptive[2-73]	72
Experimental[74-183]	110
Observational[184-207]	24

Table 6. Number of studies by country

Country	Number of Studies
Australia[11,61,92,113,150]	5
Bangladesh[190]	1

Belgium[124,178]	2
Cameroon[94]	1
Canada[33,43,87,134,187]	5
Chile[73,183]	2
China[52,101,114,137]	4
Costa Rica[80]	1
Cuba[98]	1
Denmark[95,96,100,139]	4
Egypt[3,4,109,111]	4
Finland[131,148]	2
France[12,44,121]	3
Germany[189]	1
Honduras[123]	1
India[6,130,141,157,168,174,186]	7
Indonesia[65,66,74,75]	4
Iran[162,199]	2
Israel[51,170-172]	4
Italy[99]	1
Japan[146]	1
Kenya[27,120,138]	3
Libya[108]	1
The Netherlands[71]	1
Nigeria[97,126]	2
Norway[45,112,129,132,143]	5
Pakistan[84,90]	2
Panama[160]	1

Philippines[79]	1
Russia[169]	1
Saudi Arabia[7]	1
Singapore[147]	1
South Africa[59]	1
South Korea[17]	1
Spain[29,46,57,70,188,204-206]	8
Sudan[2]	1
Sweden[76-78,81,164,176,193]	7
Switzerland[115]	1
Syria[198]	1
Thailand[16,151,158,159]	4
UK[5,22,26,30,36-38,50,54,64,72,105,117,136,142,149,152,154,167,177,179,185,203]	23
US[8-10,13-15,18-21,23-25,28,31,32,34,35,39-42,47-49,55,56,58,60,62,63,67-69,82,83,86,88,89,91,93,102-104,106,107,110,118,119,125,127,128,133,135,140,145,153,155,156,161,163,165,166,173,175,180,182,184,191,194,195,200-202,207]	75
West Africa[116]	1
Multiple Countries • Brazil, Cuba[196] • Brazil, US[197] • Chile, US[181] • Egypt, US[85] • India, US[144] • Ireland, UK[53] • Kenya, US[122] • Norway, Sweden[192]	8
	Total US: 80 Total Non-US Countries: 131

[a]Studies 84, 121, 143, 180, and 196 counted in both US and non-US total.

Table 7. Number of studies by combinations

No combination product(s) were nominated

Table 8. Dosage by indication – US

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Malaria, treatment[41,82,83,102,104,106,119,122,125,153,165,173,180,201]	0.4-1g	–	Solution	Intravenous	Once
	0.4-0.7g/week	–	Tablet	Oral	1 month-1 year
	0.1-1.2g/day	–	–	Oral	6 days-8 months
	Daily	–	–	–	2 years
Malaria, suppressive[82,103,122,191,195]	0.21g/4 days-3.4g/week	–	–	–	4-7 days
Malaria, protective[104,106]	0.4-0.8g/day	–	–	–	11-25 days
Giardiasis[8,10,19,21,35,47,48,55,85,145,166,207]	200-300mg/day	–	Tablet	Oral	5 days-3 weeks
	6mg/kg/day	–	Suspension	Oral	5-10 days
Female sterilization[39,68,89,107,110,135,140,144,181,182,197]	240-252mg/month	–	Pellets	Intracervical, Intrauterine, Transvaginal	1-3 months
	1.5g	–	Powder	Intracervical	–
	3g	–	Suspension	Intrauterine	Once
Pneumothorax[15,40,42,58,62,133,163,202]	25-100mg/day	0.1-2%	Solution, Suspension	Intrapleural	3-4 days
Lupus erythematosus[9,13,20,155,175,194,200]	25-200mg/day	–	Tablet	Oral	15 months
	100-300mg/day	–	–	–	3 weeks-12 months
Pleural effusion[23,49,86,93,127,156]	100-1500mg/day	–	Solution	Intrapleural	Once-3 months
Dermatomyositis[14,18,184]	100mg/day	–	–	–	At least 5 months
Sarcoidosis[60,63,128]	0.1-2.7g/day	–	–	–	–

Amebiasis[56]	0.4g/day	–	–	–	15 days
Annular erythema of Sjogren's syndrome[34]	100mg/day	–	–	Oral	–
Ascites[23]	200-400mg/day	–	Solution	Intrapleural	4-6 days
Auricular fibrillation[31]	0.6g	6%	Solution	Intramuscular	Twice
	0.1-0.3g/day	–	–	Oral	6 days
Creutzfeldt-Jakob disease[118]	300mg/day	–	–	Oral	2 months
Dipylidiasis[69]	150mg	7.5%	–	Nasogastric tube	Once
HBsAg-positive chronic hepatitis[91]	100-400mg/day	–	Tablet	Oral	3 months
Light sensitive eruptions[155]	25-75mg/day	–	Tablet	–	At least 6 weeks
Non-small cell lung cancer[88]	50-150mg/day	–	–	Oral	84 days
Psoriasis[20]	100-300mg/day	–	–	–	3 weeks-3 months
Reticular erythematous mucinosis[67]	100mg/day	–	–	–	10 weeks
Supraventricular tachycardia[31]	0.1g	–	–	Intravenous	Once
Systemic sclerosis[28]	–	–	–	–	–
Teniasis[161]	0.2g/10 minutes	–	Tablet	–	4 doses
Torula meningitis[32]	0.2g/6 hours	–	–	Intramuscular	30 hours
	0.3-0.4g/day	–	–	Oral	18 days
Trichomonas vaginitis[24]	7.3g/treatment	–	Powder	Intravaginal	4 treatments over 2 days
Tularemia, undulant fever[25]	0.3g/day	–	Tablet	Oral	5 days

Abbreviations: "–", not mentioned; ROA, route of administration.

Table 9. Dosage by indication – non-US countries[a]

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Female sterilization[65,66,73-75,79,80,84,87,90,108,109,137,141,144,147,157,162,168,181,183,190,197,198]	180-500mg/month	–	Pellet, Solution	Intracervical, Intrauterine, Transcervical, Transvaginal	1-4 months
	50mg-1g	16-20%	Suspension	Intrauterine, Intravaginal	Once
Lupus erythematosus[12,17,22,29,33,38,44,54,70,99,100,115,170-172,189,204]	100mg/day	–	Tablet	Oral	8 months
	50mg-1.4g/week	–	–	–	2 weeks-11 months
	–	–	–	–	6 months-7 years
Malaria, treatment[2,30,45,71,92,94,97,113,116,120,154,169,174,179,186]	0.3-1.2g/day	–	Solution	Intramuscular	1 day-5 weeks
	5mL/day	4%	Solution	Intravenous	7 days
	0.1-1.2g/day	–	Tablet	Oral	1-17 days
	0.1-1g/day	–	–	–	Once-2 months
Pleural effusion[36,76-78,81,129,134,139,164,167,176,185,187,192,193]	180mg-28g/week	0.25-4%	Solution	Intrapleural	1 day-3 months
Giardiasis[7,12,51,57,85,98,131,143,158,177,196,199,205,206]	200-300mg/day	–	–	Oral	5-14 days
	6-8mg/kg/day	–	–	–	5 days-3 years
Tapeworm (Taenia[101,114,130,138] saginata[27,43,123] and solium[61], Hymenolepis nana[123], Raillietina siriraji[16])	0.4-1.2g/day	–	Tablet	Oral	1 day
Prion disease[50,105], Creutzfeldt-Jakob disease[46,121,146], Fatal familial insomnia[188]	300mg/day	–	Capsule	Oral	3 weeks-26 months
	100-600mg/day	–	–	–	15 days-3 months

Amebiasis[3,4,52]	0.1g	–	Solution	Injection	Once
	0.9g/day	–	–	Oral	10 days
	0.3-0.9g/day	–	–	–	7-15 days
Malaria, chloroquine-resistant[11,136,151]	150-800mg/day	–	Tablet	Oral	7 days
	2.5g/5 days	–	–	–	5 days
Rheumatoid arthritis[112,117,148]	100-300mg/day	–	Tablet	Oral	1 year
Sarcoidosis[72,203]	100mg/day	–	–	Oral	10 months
Annular elastolytic giant cell granuloma[53]	300mg/week	–	–	Oral	–
Collagenous colitis[150]	300mg/day	–	–	Oral	10 days
Common variable hypogammaglobulinemia[59]	300mg/day	–	–	–	1 month
Cutaneous sarcoid[37]	100-200mg/day	–	–	–	8 months
Dermatomyositis[5]	200mg/day	–	–	–	A few weeks
Gastroenteritis[26]	0.3g/day	–	–	–	5 days
Hymenolepis nana[111]	15mg/kg	–	Tablet	Oral	Once
Intestinal parasitism[160]	300mg/day	–	–	–	5 days
Jessner-Kanof disease[178]	300mg/week-100mg/day	–	–	–	7-10 months
Malaria, suppressive[6]	1 tablet/day	–	Tablet	–	7 months
Non-insulin-dependent diabetes mellitus[152]	300mg/day	–	–	Oral	7 days
Onchocerciasis[126]	400mg/day	–	–	–	5-7 days

Opisthorchis viverrini[159]	0.4-2g/day	–	–	Oral	5-8 days
Petit mal[142]	500mg/week	–	–	–	3-24 months
Pneumothorax[124]	100mg/day	–	Solution	Intrapleural	4 days
Polymorphic light eruptions, chronic[96]	25-200mg/day	–	–	–	31 days
Prevention against UV rays[132]	1mL	5%	Ointment	Topical	1-4 days
Reticular erythematous[64]	100mg/day	–	–	–	A few weeks
Rosacea[95]	100-200mg/day	–	Tablet	Oral	At least 31 days
Vitiligo[149]	0.1-0.3g/day	–	–	Oral	–

Abbreviations: "–", not mentioned; ROA, route of administration.
[a]Study 11 had more than one indication.

Table 10. Compounded products – US

Indication	Publication Year	Compounding Method	Dosage Form	Final Strength
Pneumothorax[40,42,62,133,202]	1973-1983	• Quinacrine in 5% glucose water or saline	Solution	0.1-2%
Pleural effusion[23,86,93,156]	1964-1978	• Quinacrine in saline or in pleural/ascitic fluids	Solution	0.33-2%
Ascites[23]	1967	• Quinacrine 200mg in saline or in pleural/ascitic fluids	Solution	2%
Auricular fibrillation and supraventricular tachycardia[31]	1947	• Quinacrine in 1% novocaine	–	6%
Dipylidiasis[69]	1962	• Quinacrine in water	–	7.5%
Female sterilization[182]	1976	• Quinacrine powder in 2% xylocaine	–	30%

Giardiasis[21]	1981	• Quinacrine suspension in 1.5M sucrose solution	Suspension	2%
Malaria[201]	1947	• Atabrine dissolved in distilled water and added to saline	Solution	–
Trichomonas vaginitis[24]	1948	• Atabrine with boric acid powder	Insufflation	–

Abbreviation: "–", not mentioned.

Table 11. Compounded products – non-US countries

Indication	Compounding Method	Dosage Form	Final Strength
Pleural effusion[36,76-78,129,134,167,176,185,193]	• Quinacrine dissolved in distilled water, saline, or pleural fluid	Solution	0.25-4%
	• Quinacrine dissolved in 0.25% bupivacaine	Solution	0.33%
Female sterilization[87,183]	• Quinacrine suspended in water	Suspension	16.7%
	• Quinacrine in 2% xylocaine	Solution	–
	• Quinacrine with epinephrine in 2% xylocaine	Solution	–
	• Quinacrine in water	Solution	–
	• Quinacrine with oxytocin in water	Solution	–
	• Quinacrine with tetracycline in 2% xylocaine	Solution	–
	• Quinacrine with cortisone in water	Solution	–
	• Quinacrine with versenate in water	Solution	–
Giardiasis[7]	• Mepacrine suspended in water	Solution	0.5%
Malaria[186]	• Quinacrine HCl tablets dissolved in distilled water, boiled for 3 minutes after adding 15mL distilled water to 700mL of solution and allowed to cool	Solution	3.3%

Pneumothorax[124]	• Quinacrine dissolved in sterile saline solution	Solution	0.2%
Taeniasis[61]	• Atabrine HCl dissolved in glass of water containing one teaspoonful of sodium bicarbonate	Solution	–

Abbreviation: "–", not mentioned.

Summary of focus groups/interviews of medical experts and specialty organizations

One (1) interview was conducted.

Table 12. Overview of interviewee

Interviewee	Level of Training	Specialty	Current Practice Setting	Experience with Quinacrine	Interview Summary Response
END_03	MD	Endocrinology	Academic medical institution	No	• Not familiar with quinacrine.

Abbreviation: MD, Doctor of Medicine.

Summary of survey results

Table 13. Characteristics of survey respondents [12 people responded to survey[a]]

Board Certification	DO	MD	No Response
Anesthesiology	0	1	0
Dermatology	0	2	0
Neurology	0	1	0
Pain Medicine	0	3	0
Rheumatology	1	0	0
No Response	0	0	6

Abbreviations: DO, Doctor of Osteopathic Medicine; MD, Doctor of Medicine.

Table 14. Types of products used, prescribed, or recommended

Types of Products	Respondents, n (N=2[a])
Compounded	2
FDA-approved	0
Over-the-counter	0
Dietary	0
Unsure	0
No Response	0

[a]Out of 12 respondents, 2 reported using, prescribing, or recommending quinacrine product.

Table 15. Compounded use of quinacrine in practice[a]

Indication	Strength	Dosing frequency	Dosage Form	ROA	Duration of Treatment	Patient Population
Lupus vulgaris	100mg	Daily	Tablet	Oral	Indefinitely	Adult
Systemic lupus	–	–	–	–	–	–

Abbreviations: "–", not mentioned; ROA, route of administration.
[a]Two (2) respondents.

Table 16. Indications for which quinacrine is considered a standard therapy

Indication	Standard Therapy	
	Compounded, n (N=2)	Non-compounded, n (N=0)
None[a]	1	0
No Response	1	0

[a]One (1) respondent wrote "adjunct to hydroxychloroquine in recalcitrant cutaneous lupus".

Table 17. Reasons for using compounded product instead of the FDA-approved products

Theme	Reasons
Availability	"Only available via compounding"
Intolerance	"Intolerance to FDA approved product"

Table 18. Change in frequency of compounded quinacrine usage over the past 5 years

	Respondents, n (N=2)
No–use has remained consistent	1
Yes–I use it LESS often now[a]	1
Yes–I use it MORE often now	0

[a]One (1) respondent wrote "shortage/unavailability".

Table 19. Do you stock non-patient specific compounded quinacrine in your practice?

	Respondents, n (N=2)
No	2
Yes	0

Table 20. Questions related to stocking non-patient specific compounded quinacrine

No survey respondents provided this information

CONCLUSION

Quinacrine (UNII code: 81A613ZZ6X) was not nominated for inclusion on the 503B Bulks List.

From the literature review conducted, the most common indications for the use of quinacrine in the US were malaria, giardiasis, and female sterilization. The most common indications from the non-US studies were female sterilization, lupus erythematosus, and giardiasis. Compounded products were identified from both the US and non-US studies.

From the interview, one (1) interviewee was not familiar with quinacrine.

From the survey responses, 2 out of 12 respondents used quinacrine. Respondents most commonly used compounded quinacrine for lupus vulgaris and systematic lupus. Availability and intolerance were the reasons provided for use of a compounded quinacrine product over an FDA-approved product. Zero (0) out of two (2) respondents who used the compounded product reported stocking non-patient specific compounded quinacrine in their practice.

APPENDICES

Appendix 1. References

1. Mishra S, Hull KM, Orleans RJ. Quinacrine hydrochloride. Slides presented at: Pharmacy Compounding Advisory Committee Meeting; March 8-9, 2016; Silver Spring, MD. https://www.fda.gov/media/96621/download. Accessed February 3, 2020.
2. Abbott PH. A case of blackwater fever during mepacrine therapy. *Transactions of the Royal Society of Tropical Medicine and Hygiene.* 1946;40(3):354-356.
3. Abd-El-Ghaffar V. Successful treatment of hepatic and splenic amebic abscesses with atabrine after failure of emetine, chloroquine and terramycin. *The Journal of the Egyptian Medical Association.* 1960;43:61-65.
4. Abdel-Ghaffar Y, Abdel-Ghaffar M. Atabrine in hepatic amebiasis. *The American journal of tropical medicine and hygiene.* 1955;4(1):9-12.
5. Abdul-Wahab A, Holden CA, Harland C, Patel S. Calcific panniculitis in adult-onset dermatomyositis. *Clinical and experimental dermatology.* 2009;34(8):e854-856.
6. Adhikari AK. Suppressive mepacrine treatment to the staff of B. A. Railway in 1945. *Indian journal of malariology.* 1947;1(2):337-345.
7. al Karawi M, Salam I, Mohamed AE. Combined oral and endoscopic mepacrine therapy in a case of persistent chronic symptomatic giardiasis. *Transactions of the Royal Society of Tropical Medicine and Hygiene.* 1988;82(4):581.
8. Andreae DA, Cunningham-Rundles C. Balancing inflammation and infection in a patient with common variable immunodeficiency (CVID) and chronic giardiasis. *Annals of Allergy, Asthma and Immunology.* 2014;113(5):A85.
9. Ashinoff R, Werth VP, Franks AG. Resistant discoid lupus erythematosus of palms and soles: successful treatment with azathioprine. *Journal of the American Academy of Dermatology.* 1988;19(5 Pt 2):961-965.
10. Babb RR, Peck OC, Vescia FG. Giardiasis. A cause of traveler's diarrhea. *JAMA (Chicago, Ill).* 1971;217(10):1359-1361.
11. Bowden DK, Bastien P, Douglas FP, Muir JW, Tambisari E. Chloroquine-resistant Plasmodium falciparum malaria in Vanuatu. *The Medical journal of Australia.*2(12):561-562.
12. Brasseur Y, Pallot D, Husson MC, et al. Quinacrine (dihydrochloride, dihydrate) tablets: Needs in human medicine in France. *International Journal of Clinical Pharmacy.* 2012;34(1):160.
13. Buchanan RN. Quinacrine in the treatment of discoid lupus erythematosus: a five year follow-up survey; results and evaluation. *Southern medical journal.* 1959;52(8):978-983.
14. Cadena I, Werth VP, Levine P, et al. Lasting pathologic complete response to chemotherapy for ovarian cancer after receiving antimalarials for dermatomyositis. *ecancermedicalscience.* 2018;12((Werth V.P.) University of Pennsylvania, Philadelphia, PA, United States).
15. Cattaneo SM, Sirak HD, Klassen KP. Recurrent spontaneous pneumothorax in the high-risk patient. Management with intrapleural quinacrine. *The Journal of thoracic and cardiovascular surgery.* 1973;66(3):467-471.
16. Charoenlarp P, Radomyos P. Treatment of Raillietina siriraji with atabrine. *The Southeast Asian journal of tropical medicine and public health.* 1973;4(2):288.

17. Chung HS, Hann SK. Lupus panniculitis treated by a combination therapy of hydroxychloroquine and quinacrine. *The Journal of dermatology.* 1997;24(9):569-572.

18. Cohen JB. Cutaneous involvement of dermatomyositis can respond to Dapsone therapy. *International journal of dermatology.* 2002;41(3):182-184.

19. Cooper RF, Allison B, Bowles CC, King M, Hopkins LG. Giardiasis: a common, sexually transmissible parasitic diarrhea with pitfalls in diagnosis. *Southern medical journal.* 1983;76(7):863-865.

20. Cormia FE, Noun MH. Treatment of pustular psoriasis and pustular bacterid with quinacrine (atabrine). *AMA archives of dermatology and syphilology.* 1953;68(3):337-338.

21. Craft JC, Murphy T, Nelson JD. Furazolidone and quinacrine. Comparative study of therapy for giardiasis in children. *American journal of diseases of children (1960).* 1981;135(2):164-166.

22. Dharmapalaiah C, Hassan N, Nandagudi A, Bharadwaj A, Skibinska M, Gendi N. A case of ulcerative lupus profundus responding to rituximab. *Rheumatology (United Kingdom).* 2013;52((Skibinska M.) Dermatology, Essex and Thurrock University Hospitals, NHS Foundation Trust, Essex, United Kingdom):i59-i60.

23. Dollinger MR, Krakoff IH, Karnofsky DA. Quinacrine (Atabrine) in the treatment of neoplastic effusions. *Annals of internal medicine.* 1967;66(2):249-257.

24. Dula FM. Atabrine in the treatment of trichomonas vaginitis. *North Carolina medical journal.* 1948;9(6):309.

25. Ecke DH. Tularemia and undulant fever treated with atabrine. *The Illinois medical journal.* 1948;93(6):318-320.

26. Freedman BJ. Epidemic gastroenteritis successfully treated with mepacrine. *British medical journal.* 1946;2:552.

27. Froyd G, Czyzewicz M. Incidence of multiple infestation with Taenia saginata in Kenya. *East African medical journal.* 1961;38(7):346-349.

28. Gale S, Mathew N, Lin CJ, Jahreis A, Sarsour K. Treatment patterns among adult systemic sclerosis patients in a US healthcare claims population. *Annals of the Rheumatic Diseases.* 2016;75((Gale S.; Mathew N.; Lin C.J.; Jahreis A.; Sarsour K.) Genentech, South San Francisco, United States):543.

29. García-Montero P, Del Boz J, Millán-Cayetano JF, de Troya-Martín M. Quinacrine: A Treatment Option That Should Not Be Overlooked. *Actas dermo-sifiliograficas.* 2016;107(10):867-870.

30. Gerring JM. Cerebral malaria treated with penicillin and mepacrine. *Nursing mirror and midwives journal.* 1947;85(2215):471.

31. Gertler MM, Yohalem SB. The effect of atabrine on auricular fibrillation and supraventricular tachycardia in man. *Journal of the Mount Sinai Hospital, New York.* 1947;13(6):323-327.

32. Goldberg FA. Torula meningitis. *Memphis Medical Journal.* 1948;23(7):129-130.

33. Green PJ, Pasternak S. Hypertrophic and ulcerated discoid lupus erythematosus. *Journal of cutaneous medicine and surgery.* 16(6):453-457.

34. Haimowitz JE, McCauliffe DP, Seykora J, Werth VP. Annular erythema of Sjögren's syndrome in a white woman. *Journal of the American Academy of Dermatology.* 2000;42(6):1069-1072.

35. Hauben M. Quinacrine and chronic fatigue syndrome. *American family physician.* 1994;49(6):1354.

36. Hickman JA, Jones MC. Treatment of neoplastic pleural effusions with local instillations of quinacrine (mepacrine) hydrochloride. *Thorax.* 1970;25(2):226-229.

37. Hughes JR, Pembroke AC. Cutaneous sarcoid treated with mepacrine [2]. *Clinical and Experimental Dermatology.* 1994;19(5):448.

38. Humphreys F, Marks JM. Mepacrine and pregnancy. *The British journal of dermatology.* 1988;118(3):452.

39. Israngkun C, Phaosavadi S, Neuwirth RS, Richart RM. Clinical evaluation of quinacrine hydrochloride for sterilization of the human female. *Contraception.* 1976;14(1):75-80.

40. Jones RE, Giammona ST. Intrapleural injection of quinacrine for pneumothorax in a child with cystic fibrosis. *American journal of diseases of children (1960).* 1976;130(7):777-778.

41. Jordan Jr WS. Primary attack ofvivax malaria occurring twenty-seven months after infection. *New England journal of medicine (Print).* 1948;239(11):397-399.

42. Kattwinkel J, Taussig LM, McIntosh CL, di Sant'Agnese PA, Wood RE. Intrapleural instillation of quinacrine for recurrent pneumothorax. Use in a patient with cystic fibrosis. *JAMA.* 1973;226(5):557-559.

43. Lewis FN. The treatment of taenia saginata. *Canadian services medical journal.* 1956;12(6):519-520.

44. Lipsker D, Piette JC, Cacoub P, Godeau P, Frances C. Chloroquine-quinacrine association in resistant cutaneous lupus. *Dermatology (Basel, Switzerland).* 1995;190(3):257-258.

45. Löken AC, Haymaker W. Pamaquine poisoning in man, with a clinicopathologic study of one case. *American Journal of Tropical Medicine.* 1949;29(3):341-352.

46. Martínez-Lage JF, Rábano A, Bermejo J, et al. Creutzfeldt-Jakob disease acquired via a dural graft: failure of therapy with quinacrine and chlorpromazine. *Surgical neurology.* 2005;64(6):542-545, discussion 545.

47. McCarthy VP, Nash TE, Hubbard VS. Severe giardiasis in a patient with cystic fibrosis. *Journal of pediatric gastroenterology and nutrition.* 1985;4(2):320-322.

48. McLaughlin LA. GIARDIAL DUODENITIS: CLINICAL MANIFESTATIONS OF GIARDIASIS IN CHILDREN (REPORT OF THREE CASES). *The Journal of the Louisiana State Medical Society : official organ of the Louisiana State Medical Society.* 1963;115:350-354.

49. McLoud TC, Isler R, Head J. The radiologic appearance of chemical pleurodesis. *Radiology.* 1980;135(2):313-317.

50. Mead S, Ranopa M, Gopalakrishnan GS, et al. PRION-1 scales analysis supports use of functional outcome measures in prion disease. *Neurology.* 2011;77(18):1674-1683.

51. Meltzer E, Lachish T, Schwartz E. Treatment of giardiasis after nonresponse to nitroimidazole. *Emerging infectious diseases.* 2014;20(10):1742-1744.

52. Meng HY, Chien TS, Chang KC. PLEUROPULMONARY AMEBIASIS. CLINICAL ANALYSIS OF 64 CASES. *Chinese medical journal.* 1965;84:117-124.

53. Molloy K, Hellen R, Nestor L, et al. Resolution of annular elastolytic giant cell granuloma with the glucagon-like peptide-1 agonist liraglutide. *British Journal of Dermatology.* 2017;177((Calonje E.) Dermatopathology Laboratory, Guy's and St Thomas' Hospital NHS Foundation Trust, London, United Kingdom):29-30.

54. Naidoo K, Carmichael AJ, Fatah S. Amicrobial pustulosis of the folds: A rare presentation of lupus erythematosus. *British Journal of Dermatology.* 2018;178(4):e286-e287.

55. Nash TE, Ohl CA, Thomas E, Subramanian G, Keiser P, Moore TA. Treatment of patients with refractory giardiasis. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America.* 2001;33(1):22-28.

56. Radke RA. Amebiasis with hepatic abscess and pleuropulmonary involvement treated with quinacrine (atabrine) and carbarsone. *Military surgeon.* 1952;110(5):343-345.

57. Requena-Méndez A, Goñi P, Lóbez S, et al. A family cluster of giardiasis with variable treatment responses: refractory giardiasis in a family after a trip to India. *Clinical microbiology and infection : the official publication of the European Society of Clinical Microbiology and Infectious Diseases.* 2014;20(2):O135-138.

58. Rich RH, Warwick WJ, Leonard AS. Open thoracotomy and pleural abrasion in the treatment of spontaneous pneumothorax in cystic fibrosis. *Journal of pediatric surgery.* 1978;13(3):237-242.

59. Ruttenberg D, Ress SR, Price SK, Girdwood AH, Marks IN. Common variable hypogammaglobulinemia. A case report. *Journal of clinical gastroenterology.* 1990;12(3):336-340.

60. Samitz MH, Satanove A, Kirshbaum B. Sarcoidosis involving the mucous membranes. *AMA archives of dermatology and syphilology.* 1953;68(4):473-474.

61. Sandars DF. Taenia solium, the pork tapeworm, in Australia. *Medical Journal of Australia.* 1958;45(18):607-608.

62. Schuster SR, McLaughlin FJ, Matthews WJ, Strieder DJ, Khaw KT, Shwachman H. Management of pneumothorax in cystic fibrosis. *Journal of pediatric surgery.* 1983;18(4):492-497.

63. Shaffer B, Cahn MM, Levy EJ. Sarcoidosis apparently cured by quinacrine (atabrine) hydrochloride. *AMA archives of dermatology and syphilology.* 1953;67(6):640-641.

64. Spierings N, Raweily E, Aslanian F. Reticular erythematous mucinosis: Two cases treated with mepacrine. *British Journal of Dermatology.* 2016;175((Spierings N.; Raweily E.; Aslanian F.) Epsom and St Helier NHS Trust, London, United Kingdom):30-31.

65. Suhadi A, Anwar M, Soejoenoes A. Four-year clinical evaluation of quinacrine pellets for non-surgical female sterilization. *Advances in contraception : the official journal of the Society for the Advancement of Contraception.* 1998;14(1):69-77.

66. Suhadi A, Soejoenoes A. Quinacrine pellet nonsurgical female sterilization in Wonosobo, Indonesia. *Fertility and sterility.* 1997;67(5):966-968.

67. Susok L, Kreuter A. Complete clearance of reticular erythematous mucinosis with quinacrine monotherapy. *Archives of dermatology.* 2012;148(6):768-769.

68. Thurmond AS, Jones MK, Mullick B, Kessel E. Reversal of sterilization due to application of quinacrine by means of transcervical tubal catheterization. *Journal of vascular and interventional radiology : JVIR.*6(1):147-149.

69. Turner JA. Human dipylidiasis (dog tapeworm infection) in the United States. *Journal of Pediatrics.* 1962;61(5):763-768.

70. Ugarte A, Porta S, Ríos R, et al. Combined mepacrine-hydroxychloroquine treatment in patients with systemic lupus erythematosus and refractory cutaneous and articular activity. *Lupus.* 2018;27(10):1718-1722.

71. Winckel CW. The efficacy of quinacrine and quinine in the treatment of Plasmodium malariae infections. *Documenta Neerlandica et Indonesica de morbis tropicis; quarterly journal of tropical medicine and hygiene.* 1949;1(1):93-96.

72. Yesudian PD, Azurdia RM. Scar sarcoidosis following tattooing of the lips treated with mepacrine [7]. *Clinical and Experimental Dermatology.* 2004;29(5):552-554.

73. Zipper J, Trujillo V. 25 years of quinacrine sterilization experience in Chile: review of 2,592 cases. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics.* 2003;83 Suppl 2:S23-29.

74. Agoestina T, Hoesni RH, Purwara BH, et al. Randomized trial of one versus two transcervical insertions of quinacrine pellets for sterilization. *Fertility and sterility.* 2002;77(5):1065-1068.

75. Agoestina T, Kusuma I. Clinical evaluation of quinacrine pellets for chemical female sterilization. *Advances in contraception : the official journal of the Society for the Advancement of Contraception.* 1992;8(2):141-151.

76. Agrenius V, Chmielewska J, Widström O, Blombäck M. Pleural fibrinolytic activity is decreased in inflammation as demonstrated in quinacrine pleurodesis treatment of malignant pleural effusion. *The American review of respiratory disease.* 1989;140(5):1381-1385.

77. Agrenius V, Chmielewska J, Widström O, Blombäck M. Increased coagulation activity of the pleura after tube drainage and quinacrine instillation in malignant pleural effusion. *The European respiratory journal.* 1991;4(9):1135-1139.

78. Agrenius V, Ukale V, Widsrom O, Kallenius G, Svenson SB. Quinacrine induced pleural inflammation in malignant pleurisy: Relation between drainage time of pleural fluid and local interleukin-1β levels. *Respiration.* 1993;60(6):366-372.

79. Alfonso LA, Albano HA. Quinacrine sterilization (QS) experience in the Philippines: a preliminary report. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics.* 2003;83 Suppl 2:S121-123.

80. Alpizar F. Quinacrine sterilization (QS) in Costa Rica: 694 cases. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics.* 2003;83 Suppl 2:S141-145.

81. Arvastson B, Boe J, Stiksa J, Simonsson BG. Mepacrine in malignant pleural effusion. *Scandinavian journal of respiratory diseases.* 1973;54(2):132-135.

82. Baker BM, Platt D. Vivax relapse rates following continued atabrine suppressive medication; observations on malaria in an infantry regiment. *Bulletin of the Johns Hopkins Hospital.* 1947;81(5):295-304.

83. Bang FB, Hairston NG. Treatment of acute attacks of vivax and falciparum malaria; a comparison of atabrine and quinine. *Bulletin of the US Army Medical Department United States Army Medical Department.* 1947;7(1):75-89.

84. Bashir A, Bashir M, Afzal S. The effect of special training for quinacrine sterilization (QS) in Faisalabad, Pakistan: a report on an 1833-women subset of 11,000 cases. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics.* 2003;83 Suppl 2:S67-71.

85. Bassily S, Farid Z, Mikhail JW, Kent DC, Lehman JS. The treatment of Giardia lamblia infection with mepacrine, metronidazole and furazolidone. *The Journal of tropical medicine and hygiene.* 1970;73(1):15-18.

86. Bayly TC, Kisner DL, Sybert A, Macdonald JS, Tsou E, Schein PS. Tetracycline and quinacrine in the control of malignant pleural effusions. A randomized trial. *Cancer.* 1978;41(3):1188-1192.

87. Benoît A, Melancon J, Gagnon MA. Chemically induced tubal occlusion in the human female using intrauterine instillation of quinacrine. *Contraception.* 1975;12(1):95-101.

88. Bhateja P, Dowlati A, Sharma N. Phase I study of the combination of quinacrine and erlotinib in patients with locally advanced or metastatic non small cell lung cancer. *Investigational new drugs.* 2018;36(3):435-441.

89. Bhatt R, Waszak CS. Four-year follow-up of insertion of quinacrine hydrochloride pellets as a means of nonsurgical female sterilization. *Fertility and sterility.* 1985;44(3):303-306.

90. Bilgrami M, Shah L. Marie Stopes Society, Pakistan: 1000 cases of quinacrine sterilization (QS). *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics.* 2003;83 Suppl 2((Bilgrami M.; Shah L.) Marie Stopes Society, Karachi, Pakistan.):S125-127.

91. Bodenheimer HC, Schaffner F, Vernace S, Hirschman SZ, Goldberg JD, Chalmers T. Randomized controlled trial of quinacrine for the treatment of HBsAg-positive chronic hepatitis. *Hepatology (Baltimore, Md).*3(6):936-938.

92. Boreham PF. Dreamtime, devastation and deviation: Australia's contribution to the chemotherapy of human parasitic infections. *International journal for parasitology.* 1995;25(9):1009-1022.

93. Borja ER, Pugh RP. Single-dose quinacrine (atabrine) and thoracostomy in the control of pleural effusions in patients with neoplastic diseases. *Cancer.* 1973;31(4):899-902.

94. Boroda C. Treatment on malaria with single doses of mepacrine, chloroquine and amodiaquin. *The West African medical journal.* 1955;4(3):144-148.

95. Brodthagen H. Mepacrine and chloroquine in the treatment of rosacea. *The British journal of dermatology.* 1955;67(12):421-425.

96. Brodthagen H, Christiansen JV. Chronic polymorphic light eruptions treated with mepacrine. *The British journal of dermatology.* 1955;67(4):146-148.

97. Bruce-Chwatt LJ. Evaluation of synthetic anti-malarial drugs in children from a hyperendemic area in West Africa. *Transactions of the Royal Society of Tropical Medicine and Hygiene.* 1951;44(5):563-592.

98. Canete R, Escobedo AA, Gonzalez ME, Almirall P. Randomized clinical study of five days apostrophe therapy with mebendazole compared to quinacrine in the treatment of symptomatic giardiasis in children. *World journal of gastroenterology.* 2006;12(39):6366-6370.

99. Cavazzana I, Sala R, Bazzani C, et al. Treatment of lupus skin involvement with quinacrine and hydroxychloroquine. *Lupus.* 2009;18(8):735-739.

100. Christiansen JV. Treatment of lupus erythematosus with chloroquine; therapeutic results and a comparison of the value of chloroquine and mepacrine. *The British journal of dermatology.* 1957;69(5):157-168.

101. Chung WC, Fan PC, Lin CY, Wu CC. Poor efficacy of albendazole for the treatment of human taeniasis. *International journal for parasitology.* 1991;21(2):269-270.

102. Clark-Cooper W, Coatney GR, Ruhe DS. Studies in human malaria. V. Homologous strain superinfection during latency in subjects with sporozoite-induced vivax malaria (St. Elizabeth strain). *American Journal of Hygiene.* 1947;46(1):141-148.

103. Coatney GR, Clark-Cooper W, Young MD, Burgess RW. Studies in human malaria. IV. The suppressive action of a phenanthrene amino alcohol, NIH-204 (SN-1796), against sporozoite-inductd vivax malaria (St. Elizabeth strain). *American Journal of Hygiene.* 1947;46(1):132-140.

104. Coatney GR, Cooper WC, Ruhe DS, Young MD. Studies in human malaria. XVII. Trials of guinacrine, colchicine (SN, 12,080) and quinine against Chesson strain vivax malaria. *American Journal of Hygiene.* 1949;50(2):194-199.

105. Collinge J, Gorham M, Hudson F, et al. Safety and efficacy of quinacrine in human prion disease (PRION-1 study): a patient-preference trial. *The Lancet Neurology.* 2009;8(4):334-344.

106. Cooper WC, Ruhe DS, Coatney GR, Josephson ES, Young MD. Studies in human malaria. VIII. The protective and therapeutic action of quinacrine against St. Elisabeth strain vivax malaria. *American Journal of Hygiene.* 1949;49(1):25-40.

107. el Kady AA, Nagib HS, Kessel E. Efficacy and safety of repeated transcervical quinacrine pellet insertions for female sterilization. *Fertility and sterility.* 1993;59(2):301-304.

108. el Mahaishi MS, Azzidani AM. Quinacrine sterilization in Libya: 200 cases. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics.* 2003;83 Suppl 2:S113-115.

109. el Sahwi S, Kamel M, el Faham M, el Makhzangy I. Hysteroscopic and hysterosalpingographic study after intrauterine insertion of quinacrine pellets for non-surgical sterilization: results in 180 women. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics.* 2003;83 Suppl 2:S101-106.

110. el-Kady AA, Mansy MM, Nagib HS, Kessel E. Histopathologic changes in the cornual portion of the fallopian tube following a single transcervical insertion of quinacrine hydrochloride pellets. *Advances in contraception : the official journal of the Society for the Advancement of Contraception.* 1991;7(1):1-9.

111. El-Masry NA, Farid Z, Bassily S. Treatment of Hymenolepis nana with niclosamide, mepacrine and thiabendazole. *East African medical journal.* 1974;51(7):532-535.

112. Engeset A. Treatment of rheumatoid arthritis with quinacrine and chloroquine. *Acta rheumatologica Scandinavica.* 1958;4(1):28-39.

113. Fairley NH. Experiments with antimalarial drugs in man. VI. The value of chloroquine diphosphate as a suppressive drug in volunteers exposed to experimental mosquito-transmitted malaria (new guinea strains). *Transactions of the Royal Society of Tropical Medicine and Hygiene.* 1957;51(6):493-501.

114. Fan PC, Chung WC, Chan CH, Chen YA, Cheng FY, Hsu MC. Studies on taeniasis in Taiwan. V. Field trial on evaluation of therapeutic efficacy of mebendazole and praziquantel against taeniasis. *The Southeast Asian journal of tropical medicine and public health.* 1986;17(1):82-90.

115. Feldmann R, Salomon D, Saurat JH. The association of the two antimalarials chloroquine and quinacrine for treatment-resistant chronic and subacute cutaneous lupus erythematosus. *Dermatology (Basel, Switzerland).* 1994;189(4):425-427.

116. Findlay GM. Blackwater fever in West Africa 1941-45. I. Blackwater fever in European military personnel. *Annals of Tropical Medicine and Parasitology.* 1949;43(2):140-154.

117. Freedman A, Bach F. Mepacrine and rheumatoid arthritis. *Lancet (London, England).* 1952;2(6729):321.

118. Geschwind MD, Kuo AL, Wong KS, et al. Quinacrine treatment trial for sporadic Creutzfeldt-Jakob disease. *Neurology.* 2013;81(23):2015-2023.

119. Gordon HH, Christianson HB, Lippincott SW. A comparison of quinine and quinacrine in the treatment of the clinical attacks of vivax malaria. *Southern medical journal.* 1946;39(8):631-634.

120. Grounds JG. Single dose treatment of malaria with amodiaquin chloroquine and mepacrine in a semi-immune poplation. *East African medical journal.* 1960;37:496-500.

121. Haïk S, Brandel JP, Salomon D, et al. Compassionate use of quinacrine in Creutzfeldt-Jakob disease fails to show significant effects. *Neurology.* 2004;63(12):2413-2415.

122. Handfield-Jones RP. Chloroquine, proguanil, mepacrine and quinine in the treatment of malaria caused by Plasmodium falciparum. *Annals of tropical medicine and parasitology.* 1949;43(3-4):345-348.

123. Hoekenga MT. Treatment of T. saginata and H. nana infestations with atabrine. *The American journal of tropical medicine and hygiene.* 1951;31(4):420-422.

124. Janzing HM, Derom A, Derom E, Eeckhout C, Derom F, Rosseel MT. Intrapleural quinacrine instillation for recurrent pneumothorax or persistent air leak. *The Annals of thoracic surgery.* 1993;55(2):368-371.

125. Jones R, Pullman TN, Whorton CM, Graioe B, Alvino AS, Eighelberger L. The therapeutic effectiveness of large doses ofpaludrine in acute attacks of sporozoiteinduced vivax malaria (Chesson strain). *Journal of Clinical Investigation.* 1948;27(3):51-55.

126. Kale OO. Mepacrine--ineffective in onchocerciasis. *Tropenmedizin und Parasitologie.* 1980;31(3):365-366.

127. Kisner D, Bayly T, Sybert A. Tetracycline and quinacrine in the control of malignant pleural effusion: a randomized clinical trial. *Proceedings of the American Association for Cancer Research.* 1977;Vol.18((Kisner D.; Bayly T.; Sybert A.) Georgetown Univ. Hosp., Washington, D.C. 20007):No.C-93.

128. Klauder JV. Sarcoid of the eyelids, conjunctiva, and uveal tract treated with quinacrine hydrochloride (atabrine dihydrochloride). *AMA archives of dermatology and syphilology.* 1953;68(4):474.

129. Koldsland S, Svennevig JL, Lehne G, Johnson E. Chemical pleurodesis in malignant pleural effusions: a randomised prospective study of mepacrine versus bleomycin. *Thorax.* 1993;48(8):790-793.

130. Koul PA, Wahid A, Bhat MH, Wani JI, Sofi BA. Mepacrine therapy in niclosamide resistant taeniasis. *The Journal of the Association of Physicians of India.* 2000;48(4):402-403.

131. Kyrönseppä H, Pettersson T. Treatment of giardiasis: relative efficacy of metronidazole as compared with tinidazole. *Scandinavian journal of infectious diseases.* 1981;13(4):311-312.

132. Langlo L. The efficiency of local application of chloroquine and mepacrine in preventing the effects of ultraviolet rays on human skin. *Acta dermato-venereologica.* 1957;37(1):85-87.

133. Larrieu AJ, Tyers GF, Williams EH, O'Neill MJ, Derrick JR. Intrapleural instillation of quinacrine for treatment of recurrent spontaneous pneumothorax. *The Annals of thoracic surgery.* 1979;28(2):146-150.

134. Lee M, Boyes DA. The use of quinacrine hydrochloride for the control of malignant serous effusions. *The Journal of obstetrics and gynaecology of the British Commonwealth.* 1971;78(9):843-844.

135. Lippes J, Brar M, Gerbracht K, Neff P, Kokkinakis S. An FDA phase I clinical trial of quinacrine sterilization (QS). *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics.* 2003;83 Suppl 2:S45-49.

136. Looareesuwan S, Phillips RE, Edwards G, et al. Mepacrine accumulation during treatment of chloroquine-resistant falciparum malaria. *Annals of tropical medicine and parasitology.* 1988;82(2):107-112.

137. Lu W, Zhu J, Zhong C, Zhao Y. A comparison of quinacrine sterilization (QS) and surgical sterilization (TL) in 600 women in Guizhou Province, China. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics.* 2003;83 Suppl 2:S51-58.

138. McKinnon JA. The mass treatment of tapeworm with mepacrine. *East African medical journal.* 1957;34(1):15-18.

139. Mejer J, Mortensen KM, Hansen HH. Mepacrine hydrochloride in the treatment of malignant pleural effusion. A controlled randomized trial. *Scandinavian journal of respiratory diseases.* 1977;58(6):319-323.

140. Merchant RN, Doctor VM, Thaku SS, et al. Clinico-pathological study of fallopian tubes after transcervical insertion of quinacrine hydrochloride pellets. *Advances in contraception : the official journal of the Society for the Advancement of Contraception.* 1986;2(1):79-90.

141. Merchant RN, Prabhu SR, Kessel E. Clinicopathologic study of fallopian tube closure after single transcervical insertion of quinacrine pellets. *International journal of fertility and menopausal studies.*40(1):47-54.

142. Miller RA. Mepacrine therapy for children with petit mal. *Scottish medical journal.* 1958;3(11):441-444.

143. Mørch K, Hanevik K, Robertson LJ, Strand EA, Langeland N. Treatment-ladder and genetic characterisation of parasites in refractory giardiasis after an outbreak in Norway. *The Journal of infection.* 2008;56(4):268-273.

144. Mullick BC, Kessel E, Mumford SD. A potential single insertion protocol for quinacrine pellet non-surgical female sterilization. *Advances in contraception : the official journal of the Society for the Advancement of Contraception.* 1995;11(3):239-244.

145. Murphy TV, Nelson JD. Five vs ten days' therapy with furazolidone for giardiasis. *American Journal of Diseases of Children.* 1983;137(3):267-270.

146. Nakajima M, Yamada T, Kusuhara T, et al. Results of quinacrine administration to patients with Creutzfeldt-Jakob disease. *Dementia and geriatric cognitive disorders.* 2004;17(3):158-163.

147. Ng AY, Chen C, Ratnam SS. Hysteroscopic sterilization with quinacrine sulphate and electrocoagulation. *The Australian & New Zealand journal of obstetrics & gynaecology.* 1976;16(1):38-39.

148. Oka MJ. Treatment of rheumatoid arthritis with atebrin. *Annales medicinae internae Fenniae.* 1953;42(3):215-220.

149. Pegum JS. Vitiligo treated with mepacrine. *The British journal of dermatology.* 1953;65(9):324-325.

150. Pieterse AS, Hecker R, Rowland R. Collagenous colitis: a distinctive and potentially reversible disorder. *Journal of clinical pathology.* 1982;35(3):338-340.

151. Powell RD, Brewer GJ, Alving AS, Millar JW. STUDIES ON A STRAIN OF CHLOROQUINE-RESISTANT PLASMODIUM FALCIPARUM FROM THAILAND. *Bulletin of the World Health Organization.* 1964;30:29-44.

152. Powrie JK, Watts GF, Smith GD, Sönksen PH, Jones RH. Short-term effects of mepacrine on serum lipids, lipoproteins, and apolipoproteins in patients with non-insulin-dependent diabetes mellitus. *Metabolism: clinical and experimental.* 1994;43(2):131-134.

153. Pullman TN, Craige B. Comparison of chloroquine, quinacrine (atabrine) and quinine in the treatment of acute attacks of sporozoite-induced vivax malaria, Chesson strain. *The Journal of clinical investigation.* 1948;27(3 Pt1):46-50.

154. Reid J. Mepacrine and falciparum malaria. *The Quarterly journal of medicine.* 1947;16(2):61-82.

155. Robinson RC, Smith GC. Triquin in the treatment of discoid lupus erythematosus and light sensitive eruptions. *Bulletin of the School of Medicine (Baltimore, Md).* 1958;43(4):97-99.

156. Rochlin DB, Smart CR, Wagner DE, Silva AR. THE CONTROL OF RECURRENT MALIGNANT EFFUSIONS USING QUINACRINE HYDROCHLORIDE. *Surgery, gynecology & obstetrics.* 1964;118:991-994.

157. Roy A. A 22-year experience with quinacrine sterilization in a rural private clinic in Midnapore, India: a report on 5 protocols and 1838 cases. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics.* 2003;83 Suppl 2:S87-91.

158. Sabchareon A, Chongsuphajaisiddhi T, Attanath P. Treatment of giardiasis in children with quinacrine, metronidazole, tinidazole and ornidazole. *The Southeast Asian journal of tropical medicine and public health.* 1980;11(2):280-284.

159. Sadun EH, Chamnarnkit C, Chetanasen S. Studies on the treatment of opisthorchis viverrini in human infections with quinacrine hydro chloride and chloroquine phosphate. *Amer JTropMedHyg.* 1955;4(6):1080-1087.

160. Sanchez JL, Rios C, Hernandez-Fragoso I, Ho CK. Parasitological evaluation of a foodhandler population cohort in Panama: risk factors for intestinal parasitism. *Military medicine.* 1990;155(6):250-255.

161. Schapiro MM. Tegucigalpa Observations on the treatment of human teniasis with auinacrine bydrocbloride (Atabrine). *Aimt J Trop Kwd.* 1951;31(6):833-835.

162. Soroodi-Moghaddam S. Quinacrine sterilization (QS) in Iran and the use of HSG as a measure of success. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics.* 2003;83 Suppl 2:S93-96.

163. Spector ML, Stern RC. Pneumothorax in cystic fibrosis: a 26-year experience. *The Annals of thoracic surgery.* 1989;47(2):204-207.

164. Stiksa G, Korsgaard R, Simonsson BG. Treatment of recurrent pleural effusion by pleurodesis with quinacrine. Comparison between instillation by repeated thoracenteses and by tube drainage. *Scandinavian journal of respiratory diseases.* 1979;60(4):197-205.

165. Taggart JV, Earle Jr DP, Berliner RW, et al. Studies on the chemotherapy of the human malarias. V. The antimalarial activity of quinacrine. *Journal of Clinical Investigation.* 1948;27(3-12):93-97.

166. Taylor GD, Wenman WM, Tyrrell DL. Combined metronidazole and quinacrine hydrochloride therapy for chronic giardiasis. *CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne.* 1987;136(11):1179-1180.

167. Taylor SA, Hooton NS, Macarthur AM. Quinacrine in the management of malignant pleural effusion. *The British journal of surgery.* 1977;64(1):52-53.

168. Thakur PS. Quinacrine sterilization in Tripura, India. *Contraception.* 2001;64(5):277-279.

169. Tiburskaja NA, Vrublevskaja OS. Clinical and experimental studies on quartan malaria following blood transfusion and methods for preventing its occurrence. *Bulletin of the World Health Organization.* 1965;33(6):843-851.

170. Toubi E, Kessel A, Rosner I, et al. Quinacrine added to ongoing therapeutic regimens attenuates anticardiolipin antibody production in SLE. *Lupus.* 2003;12(4):297-301.

171. Toubi E, Kessel A, Rosner I, Rozenbaum M, Paran D, Shoenfeld Y. The reduction of serum B-lymphocyte activating factor levels following quinacrine add-on therapy in systemic lupus erythematosus. *Scandinavian journal of immunology.* 2006;63(4):299-303.

172. Toubi E, Rosner I, Rozenbaum M, Kessel A, Golan TD. The benefit of combining hydroxychloroquine with quinacrine in the treatment of SLE patients. *Lupus.* 2000;9(2):92-95.

173. Trager W. The rate of asymptomatic malarial infection in white and Negro service troops taking suppressive atabrine. *American journal of hygiene.* 1947;46(3):336-340.

174. Tyagi N. Chemotherapy in malaria. *Journal of the Indian Medical Association.* 1955;25(7):261-262.

175. Tye MJ, White H, Appel B, Ansell HB. Lupus erythematosus treated with a combination of quinacrine, hydroxychloroquine and chloroquine. *The New England journal of medicine.* 1959;260(2):63-66.

176. Ukale V, Agrenius V, Hillerdal G, Mohlkert D, Widström O. Pleurodesis in recurrent pleural effusions: a randomized comparison of a classical and a currently popular drug. *Lung cancer (Amsterdam, Netherlands).* 2004;43(3):323-328.

177. Wright SG, Tomkins AM, Ridley DS. Giardiasis: clinical and therapeutic aspects. *Gut.* 1977;18(5):343-350.

178. Wuyts L, Dandelooy J, Siozopolou V, Lambert J, Aerts O. Mepacrine as successful monotherapy for refractory Jessner-Kanof disease: still an important drug in the dermatologic armamentarium. *The Journal of dermatological treatment.* 2017;28(3):276-278.

179. Wynne-Griffith G. Suppression of malaria by mepacrine. *Journal of the Royal Army Medical Corps.* 1947;89(3):112-121.

180. Young MD, Eyles DE. The efficacy of chloroquine, quinacrine, quinine and totaquine in the treatment of Plasmodium malariae infections (quartan malaria). *The American journal of tropical medicine and hygiene.* 1948;28(1):23-28.

181. Zipper J, Cole LP, Goldsmith A, Wheeler R, Rivera M. Quinacrine hydrochloride pellets: preliminary data on a nonsurgical method of female sterilization. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics.* 1980;18(4):275-279.

182. Zipper J, Medel M, Goldsmith A, Edelman D, Pastene L, Rivera M. The clinical efficacy of the repeated transcervical instillation of quinacrine for female sterilization. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics.* 1976;14(6):499-502.

183. Zipper J, Stacchetti E, Medel M. Transvaginal chemical sterilization: clinical use of quinacrine plus potentiating adjuvants. *Contraception.* 1975;12(1):11-21.

184. Ang GC, Werth VP. Combination antimalarials in the treatment of cutaneous dermatomyositis: a retrospective study. *Archives of dermatology.* 2005;141(7):855-859.

185. Banerjee AK, Willetts I, Robertson JF, Blamey RW. Pleural effusion in breast cancer: a review of the Nottingham experience. *European journal of surgical oncology : the journal of the European Society of Surgical Oncology and the British Association of Surgical Oncology.* 1994;20(1):33-36.

186. Basumullick KL, Gupta JC. Parenteral quinacrine in malarial fevers. *The Indian medical gazette.* 1947;82(4):193-195.

187. Beaudoin EL, Dumoulin E, Carrier N, Cantin AM, Poulin Y. Pleurodesis in spontaneous pneumothorax, a retrospective study comparing quinacrine to TALC and mechanical pleurodesis. *American Journal of Respiratory and Critical Care Medicine.* 2012;185((Beaudoin E.-L.; Dumoulin E.; Carrier N.; Cantin A.M.; Poulin Y., yannick.poulin@usherbrooke.ca) Centre Hospitalier, Universitaire De Sherbrooke, Sherbrooke, QC, Canada).

188. Benito-León J. Combined quinacrine and chlorpromazine therapy in fatal familial insomnia. *Clinical neuropharmacology.* 27(4):201-203.

189. Benoit S, Goebeler M. Mepacrine in Recalcitrant Cutaneous Lupus Erythematosus: Old-fashioned or Still Useful? *Acta dermato-venereologica.* 2015;95(5):596-599.

190. Bhuiyan SN, Begum R. Quinacrine non-surgical female sterilization in Bangladesh. *Contraception.* 2001;64(5):281-286.

191. Bianco AA, Saunders GM, Levine AS, Cohn R. Long-term observation of Plasmodium vivax malaria in the returned serviceman. (Relapses). *US Naval Medical Bulletin.* 1947;47(3):550-567.

192. Bjermer L, Gruber A, Sue-Chu M, Sandstrom T, Eksborg S, Henriksson R. Effects of intrapleural mitoxantrone and mepacrine on malignant pleural effusion - A randomised study. *European Journal of Cancer Part A: General Topics.* 1995;31(13-14):2203-2208.

193. Bjorkman S, Elisson LO, Gabrielsson J. Pharmacokinetics of quinacrine after intrapleural instillation in rabbits and man. *Journal of Pharmacy and Pharmacology.* 1989;41(3):160-163.

194. Chang AY, Piette EW, Foering KP, Tenhave TR, Okawa J, Werth VP. Response to antimalarial agents in cutaneous lupus erythematosus: a prospective analysis. *Archives of dermatology.* 2011;147(11):1261-1267.

195. Downs WG, Harper PA, Lisansky ET. Malaria and other insect-borne diseases in the South Pacific campaign 1942-1945. II. Epidemiology of insect-borne diseases in army troops. *American Journal of Tropical Medicine.* 1947;27(SUPPL. OF NO. 3):69-89.

196. Escobedo AA, Almirall P, Alfonso M, et al. Hospitalization of Cuban children for giardiasis: a retrospective study in a paediatric hospital in Havana. *Annals of tropical medicine and parasitology.* 2011;105(1):47-56.

197. Ferreira CR, Magalhaes DR, Lippes J. Sonographic recognition of three cases of septate uteri diminishes failures of quinacrine sterilization. *Contraception.* 2006;73(4):433-436.

198. Garabedian V. Quinacrine sterilization (QS) in Syria: a preliminary report on 297 cases. *International journal of gynaecology and obstetrics: the official organ of the International Federation of Gynaecology and Obstetrics.* 2003;83 Suppl 2:S133-135.

199. Kavousi S. Giardiasis in infancy and childhood: a prospective study of 160 cases with comparison of quinacrine (Atabrine) and metronidazole (Flagyl). *The American journal of tropical medicine and hygiene.* 1979;28(1):19-23.

200. Kennedy CB, Henington VM, Garvin WH, Bahcall C. Treatment of chronic discoid lupus erythematosus with atabrine. *The Journal of the Louisiana State Medical Society : official organ of the Louisiana State Medical Society.* 1954;106(3):89-92.

201. Machella TE, Kimmelman LJ, Lewis RA. The intravenous administration of atabrine in falciparum malaria. *Bulletin of the US Army Medical Department United States Army Medical Department.* 1947;7:1009-1021.

202. McLaughlin FJ, Matthews WJ, Strieder DJ, Khaw KT, Schuster S, Shwachman H. Pneumothorax in cystic fibrosis: management and outcome. *The Journal of pediatrics.* 1982;100(6):863-869.

203. Paolino A, Walsh S. Cutaneous sarcoidosis: Clinical spectrum in a tertiary referral centre. *British Journal of Dermatology.* 2018;179((Paolino A.; Walsh S.) King's College Hospital, London, United Kingdom):14.

204. Porta S, Martinez A, Ugarte A, Ríos R, Ortego N, Ruiz-Irastorza G. Response to a combined hydroxychloroquine-quinacrine treatment in SLE with cutaneous and/or joint disease. *Clinical and Experimental Rheumatology.* 2016;34(4):S14.

205. Requena-Méndez A, Goñi P, Rubio E, et al. The Use of Quinacrine in Nitroimidazole-resistant Giardia Duodenalis: An Old Drug for an Emerging Problem. *The Journal of infectious diseases.* 2017;215(6):946-953.

206. Requena-Méndez A, Goñi P, Treviño B, et al. Nitroimidazole-resistant Giardia intestinalis in European travellers and migrants. *Tropical Medicine and International Health.* 2015;20((Martínez-Montseny A.F.) Infectious and Imported Diseases, Paediatric Unit, Hospital Universitari Sant Joan de Deú, Barcelona, Spain):71.

207. Wright RA, Spencer HC, Brodsky RE, Vernon TM. Giardiasis in Colorado: an epidemiologic study. *American journal of epidemiology.* 1977;105(4):330-336.

Appendix 2. Survey instrument

Start of Block: Welcome Page

The University of Maryland Center of Excellence in Regulatory Science and Innovation (M-CERSI), in collaboration with the Food and Drug Administration (FDA), is conducting research regarding the use of certain bulk drug substances nominated for use in compounding by outsourcing facilities under section 503B of the Federal Food, Drug, and Cosmetic Act. In particular, we are interested in the current and historic use of these substances in clinical practice. This survey is for **quinacrine**. As a medical expert, we appreciate your input regarding the use of this substance in your clinical practice. This information will assist FDA in its development of a list of bulk drug substances that outsourcing facilities can use in compounding under section 503B of the Act. All responses are anonymous.

OMB Control No. 0910-0871
Expiration date: June 30, 2022

The time required to complete this information collection is estimated to average 30 minutes, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. If you have additional questions or concerns about this research study, please email: compounding@rx.umaryland.edu. If you have questions about your rights as a research subject, please contact HRPO at 410-760-5037 or hrpo@umaryland.edu.

End of Block: Welcome Page

Start of Block: Quinacrine

Q1. What type(s) of product(s) do you use, prescribe, or recommend for **quinacrine**? Please check all that apply.

- ☐ Compounded drug product
- ☐ FDA-approved drug product
- ☐ Over the counter drug product
- ☐ Dietary supplement (e.g. vitamin or herbal supplement products sold in retail setting)
- ☐ Unsure

Skip To: Q13 If What type(s) of product(s) do you use, prescribe, or recommend for quinacrine? Please check all th... != Compounded drug product

Skip To: Q2 If What type(s) of product(s) do you use, prescribe, or recommend for quinacrine? Please check all th... = Compounded drug product

Display This Question:

If What type(s) of product(s) do you use, prescribe, or recommend for quinacrine? Please check all th... = Compounded drug product

Q2. Please list any conditions or diseases for which you use compounded **quinacrine** in your practice. Please include the strength(s), dosing frequency(ies), dosage form(s), route(s) of administration, duration of therapy, and patient population (ex. age, gender, comorbidities, allergies, etc).

	Strength(s) (please include units)	Dosing frequency(ies)	Dosage form(s)	Route(s) of administration	Duration of therapy	Patient population
Condition 1 (please describe)						
Condition 2 (please describe)						
Condition 3 (please describe)						
Condition 4 (please describe)						
Condition 5 (please describe)						

Q3. Do you use compounded **quinacrine** as a single agent active ingredient, or as one active ingredient in a combination product? Please check all that apply.

- ☐ Single
- ☐ Combination

Skip To: Q5 If Do you use compounded quinacrine as a single agent active ingredient, or as one active ingredient... != Combination

Display This Question:

If Loop current: Do you use compounded quinacrine as a single agent active ingredient, or as one active ingredient... = Combination

Q4. Please list all combination products in which you use compounded **quinacrine**.

_____

Q5. For which, if any, diseases or conditions do you consider compounded **quinacrine** standard therapy?

_____

Q6. Does your specialty describe the use of compounded **quinacrine** in medical practice guidelines or other resources?

_____

Q7. Over the past 5 years, has the frequency in which you have used compounded **quinacrine** changed?

- ○ Yes - I use it **MORE** often now (briefly describe why) _____
- ○ Yes - I use it **LESS** often now (briefly describe why) _____
- ○ No - use has remained consistent

Q8. Why do you use compounded **quinacrine** instead of any FDA-approved drug product?

_____

Q9. Do you stock non-patient-specific compounded **quinacrine** in your practice location?

- o Yes
- o No

Skip To: End of Block If Do you stock non-patient-specific compounded [substance] in your practice location? = No

Display This Question:

If Do you stock non-patient-specific compounded [substance] in your practice location? = Yes

Q10. In what practice location(s) do you stock non-patient-specific compounded **quinacrine**? Please check all that apply.

- ☐ Physician office
- ☐ Outpatient clinic
- ☐ Emergency room
- ☐ Operating room
- ☐ Inpatient ward
- ☐ Other (please describe) _____

Q11. How do you obtain your stock of non-patient-specific compounded **quinacrine**? Please check all that apply.

- ☐ Purchase from a compounding pharmacy
- ☐ Purchase from an outsourcing facility
- ☐ Compound the product yourself
- ☐ Other (please describe) _____

Q12. Why do you keep a stock of non-patient-specific compounded **quinacrine**? Please check all that apply.

- ☐ Convenience
- ☐ Emergencies
- ☐ Other (please describe) _____

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded [substance]? Please check all that apply. = Convenience

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded [substance]? Please check all that apply. = Emergencies

Skip To: End of Block If Why do you keep a stock of non-patient-specific compounded [substance]? Please check all that apply. = Other (please describe)

Q13. For which, if any, diseases or conditions do you consider **quinacrine** standard therapy?

_____

Q14. Does your specialty describe the use of **quinacrine** in medical practice guidelines or other resources?

_____

End of Block: Quinacrine

Start of Block: Background Information

Q15. What is your terminal clinical degree? Please check all that apply.

- ☐ Doctor of Medicine (MD)
- ☐ Doctor of Osteopathic Medicine (DO)
- ☐ Doctor of Medicine in Dentistry (DMD/DDS)
- ☐ Naturopathic Doctor (ND)
- ☐ Nurse Practitioner (NP)
- ☐ Physician Assistant (PA)
- ☐ Other (please describe) _____

Q16. Which of the following Board certification(s) do you hold? Please check all that apply.

- ☐ No Board certification
- ☐ Allergy and Immunology
- ☐ Anesthesiology
- ☐ Cardiovascular Disease
- ☐ Critical Care Medicine
- ☐ Dermatology
- ☐ Emergency Medicine
- ☐ Endocrinology, Diabetes and Metabolism
- ☐ Family Medicine
- ☐ Gastroenterology
- ☐ Hematology
- ☐ Infectious Disease
- ☐ Internal Medicine
- ☐ Medical Toxicology
- ☐ Naturopathic Doctor
- ☐ Naturopathic Physician
- ☐ Nephrology
- ☐ Neurology
- ☐ Obstetrics and Gynecology
- ☐ Oncology
- ☐ Ophthalmology
- ☐ Otolaryngology
- ☐ Pain Medicine
- ☐ Pediatrics
- ☐ Psychiatry
- ☐ Rheumatology
- ☐ Sleep Medicine
- ☐ Surgery (please describe) _____
- ☐ Urology
- ☐ Other (please describe) _____

End of Block: Background Information