Summary Report

Lidocaine

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Food and Drug Administration
Clinical use of bulk drug substances nominated for inclusion on the 503B Bulks List
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REVIEW OF NOMINATIONS

Lidocaine (UNII code: 98PI200987) was nominated for inclusion on the 503B Bulks List by Outsourcing Facilities Association (OFA), Sincerus, AnazaoHealth, and David Smith. Lidocaine was nominated for use in combination with multiple active pharmaceutical ingredients (API), refer to Table 7 for the nominated combination formulations.

While the exact medical condition in which the compounded product is being requested is generally unknown, lidocaine is generally used to treat pain associated with wounds, neuropathy, and warts as well as used as a topical anesthetic prior to various procedures. Lidocaine was nominated for use via various topical dosage forms and strengths based on the prescriber's request; the therapeutic dose ranges from 2-30%. Additionally, lidocaine will be compounded as a 1-30% topical gel, cream, ointment, and emulsion for pain associated with wounds, neuropathy, warts, and as a topical anesthetic prior to procedures. Lastly, lidocaine will be compounded as a 2-6% topical dental gel for use as a topical numbing agent.

Reasons provided for nomination to the 503B Bulks List include:

- Compounding from bulk ensures that only the ingredients necessary to achieve the desired clinical outcome are utilized, eliminating any fillers, excipients, binders, dyes, preservatives, or other materials that may be hazardous or allergenic.
- Commercially available products have a considerable variance in the actual API, which has the potential to introduce unacceptable inaccuracies into the compounded product.
- To compound with other APIs that are not currently found in combination with one another in commercially available products.
- To compound in different strengths, dosage forms, and bases than the commercially available products.

METHODOLOGY

Background information

The national medicine registers of 13 countries and regions were searched to establish the availability of lidocaine 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 lidocaine; name variations of lidocaine 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 lidocaine. 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 May 10, 2019. The search included a combination of lidocaine[tiab] AND ("aloe vera"[tiab] OR mupirocin[tiab] OR tranilast[tiab] OR tetracaine[tiab] OR benzocaine[tiab] OR prilocaine[tiab] OR phenylephrine[tiab] OR cimetidine[tiab] OR "deoxy d glucose"[tiab] OR ibuprofen[tiab] OR "salicylic acid"[tiab] OR hydrocortisone[tiab]) AND (topica* OR gel OR cream OR ointment OR solution OR suspension OR emulsion OR denta*) AND (treat*[tiab] OR therap*[tiab] OR clinic*[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

Lidocaine is a component of an FDA-approved product, as a result, articles were excluded if lidocaine was utilized as the FDA-approved product or in the same concentration and formulation as the FDA-approved product. Articles were considered relevant based on the identification of a clinical use of lidocaine or the implementation of lidocaine 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. Additionally, cost-effectiveness, and epidemiological studies were excluded. Screening of all titles, abstracts, and full-text were conducted independently by two reviewers. All screening disagreements were reconciled by a third reviewer.

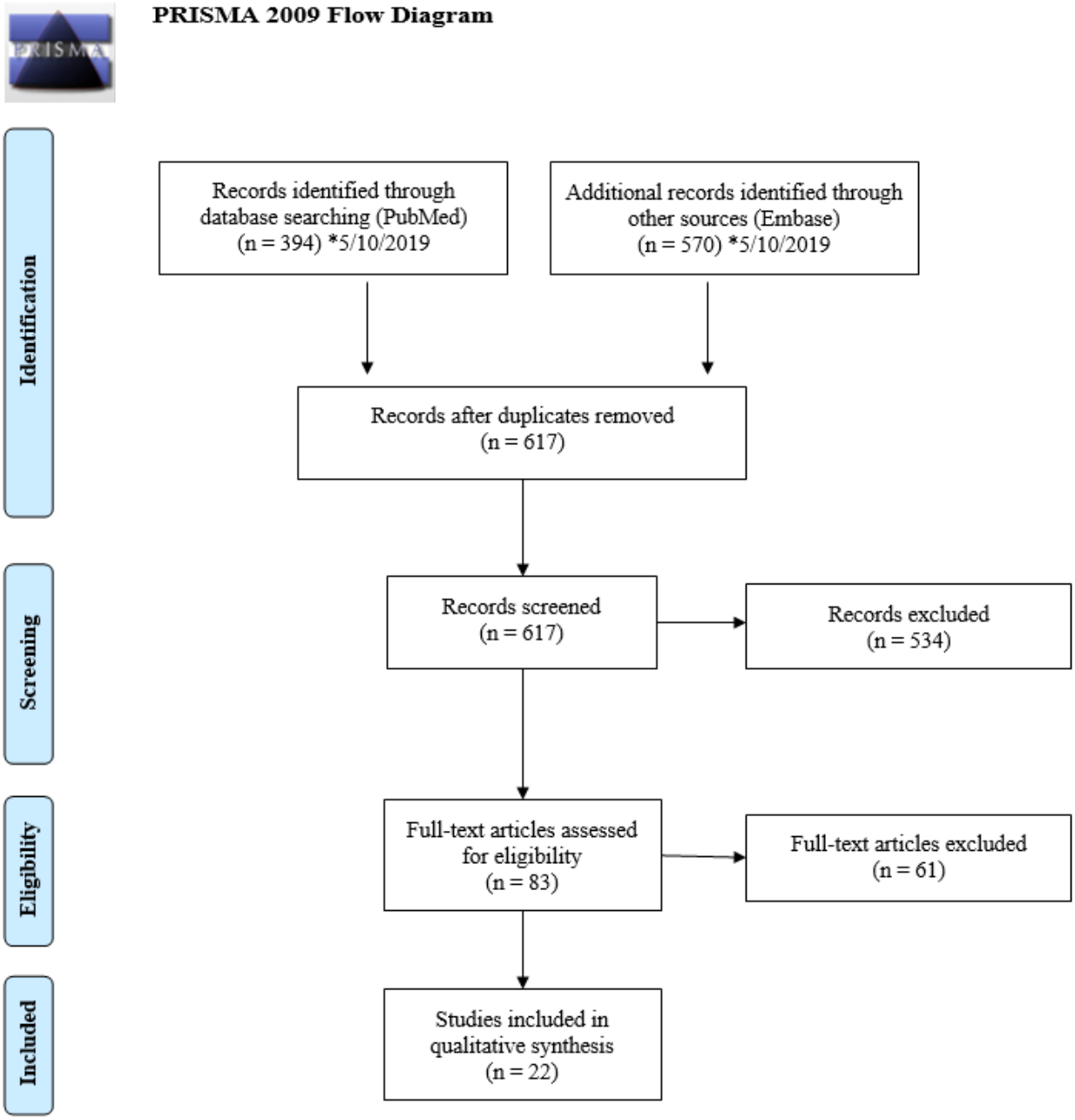
Data extraction

A standard data extraction form was used to collect study authors; article title; year published; journal title; country; indication for lidocaine 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 lidocaine 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 nominations and the results of the literature review, nine (9) medical specialties that would potentially use lidocaine were identified: anesthesiology, dermatology gastroenterology, neurology, pain management, primary care, proctology, surgery, and wound care. 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. Six (6) experts were contacted for interviews, of which three (3) accepted. Two (2) experts, one (1) specializing in otolaryngology and one (1) in neurology failed to respond to the interview request. One (1) expert specializing in gastroenterology replied that lidocaine is commonly used as a gargle prior to upper endoscopy but did not state a need for a compounded product. Most interviews were recorded and transcribed via ©Rev.com, one (1) interview was not recorded. 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 anesthesiology, dermatology gastroenterology, neurology, pain management, primary care, proctology, surgery, and wound care, identified from the nominations, literature review, and interviews, 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 fifteen (15) 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)

Table 2. Associations that declined participation

Specialty	Association	Reasons for Declining
Anesthesiology	American Society of Anesthesiologists (ASA)	Declined, requires a PI who is an ASA member
Gastroenterology	American Gastroenterological Association (AGA)	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
Primary Care	American Academy of Family Physicians (AAFP)	Failed to respond
	American College of Physicians (ACP)	Failed to respond
Proctology	American Society of Colon and Rectal Surgeons (ASCRS)	Declined, survey not approved for distribution
Surgery	American College of Surgeons (ACS)	Failed to respond
Wound Care	American Professional Wound Care Association (APWCA)	Failed to respond
	Wound Healing Society (WHS)	Failed to respond

CURRENT AND HISTORIC USE

Summary of background information

- Lidocaine is available as an FDA-approved product.
- Lidocaine is available as an OTC product in the US.
- There is a current United States Pharmacopeia (USP) monograph for lidocaine.
- Lidocaine is available in Abu Dhabi, Australia, Belgium, Canada, Hong Kong, Ireland, Latvia, Namibia, New Zealand, Saudi Arabia, and UK.

Table 3. Currently approved products – US[a]

Active Ingredient	Concentration	Dosage Form	ROA	Status	Approval Date[b]
Lidocaine	5%	Ointment	Topical	Prescription	Prior to 01/01/1982
Lidocaine HCl	2%	Jelly	Topical		Prior to 01/01/1982
	4%	Solution	Topical		Prior to 01/01/1982
	0.5mg	System	Intradermal		08/16/2007
Lidocaine / Prilocaine	2.5% / 2.5%	Cream	Topical		12/30/1992
	2.5% / 2.5%	Gel	Periodontal		12/19/2003
Lidocaine / Tetracaine	7% / 7%	Cream	Topical		06/29/2006

Abbreviation: ROA, route of administration; HCl, hydrochloride.
[a]Source: US FDA *Approved Drug Products with Therapeutic Equivalence Evaluations* (Orange Book).
[b]If multiple approval dates and/or multiple strengths, then earliest date provided.

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

Active Ingredient	Concentration	Dosage Form	ROA	Approved For Use		
				Country	Status	Approval Date[b]
Lidocaine, Lidocaine HCl	5%	Cream	–	Abu Dhabi	Active	–
	4%			Hong Kong	Pharmacy[c]	1/9/2014
			Topical	New Zealand		12/05/2013
				UK		11/20/2007
	0.2-4%			Australia	Schedule 2	3/10/2006
	2%	Gel	–	Abu Dhabi	Active	–
				Hong Kong	Pharmacy[c]	12/16/2003
			Topical	Canada	Ethical	12/31/1951
				New Zealand	Pharmacy[c]	12/31/1969
				Saudi Arabia	Prescription	–
	2-5%, 21.3g			Australia	Schedule 2	8/13/1991
	5%	Ointment	–	Abu Dhabi	Active	–
			Topical	Canada	Ethical	12/31/1954
				Saudi Arabia	Prescription	–
	5-10%			Australia	Schedule 2	8/13/1991
	4%, 0.02	Solution		Abu Dhabi	Active	–

	4%, 10mg/ACT			Canada	Ethical	7/22/1998
	2%			Hong Kong	Pharmacy[c]	7/24/2003
	1.75%			Namibia	–	11/17/1970
Lidocaine / Prilocaine	2.5% / 2.5%	Cream	–	Abu Dhabi	Active	–
				Hong Kong	Pharmacy[c]	11/20/1986
				Ireland	Prescription, non-renewable	9/8/2017
				Latvia	Prescription	5/28/2018
			Cutaneous	Belgium	Prescription	8/5/1996
			Topical	Australia	Schedule 2	8/13/1991
				New Zealand	Pharmacy[c]	9/18/1986
				Saudi Arabia	Prescription	–
				UK	Pharmacy[c]	5/16/1996
	2.5% / 2.5%, 42.5mg / 42.5mg	Gel	Dental	Australia	Schedule 4	7/22/2005
	2.5% / 2.5%			Belgium	Prescription	11/19/2006
				New Zealand		4/24/2008
Lidocaine / Tetracaine	7% / 7%	Cream	Topical	Canada	Prescription	09/28/2015

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

[a]Medicine registers of national regulatory agencies were searched if they met the following criteria: freely accessible; able to search and retrieve results in English language; and desired information (product trade name, active ingredient, strength, form, route of administration and approval status) provided in a useable format. Information was recorded only for products with strengths, forms and/or routes of administration similar to those requested in the nominations. .

[b]If multiple approval dates and/or multiple strengths, then earliest date provided.

[c]Pharmacy-only medications may only be sold in a pharmacy, and a pharmacist must make or supervise the sale.

Summary of literature review

- Total number of studies included: 22 studies (13 descriptive, 8 experimental, and 1 observational).
- Most of the studies were from the US (17).
- The most common indication for the use of lidocaine in the US was anesthesia. The most common indication from the non-US studies was for anal fissures.
- Compounded products were identified from US studies, all of which were utilized in the nominated formulations.

Table 5. Types of studies

Types of Studies	Number of Studies
Descriptive[1–13]	13
Experimental[14–21]	8
Observational[22]	1

Table 6. Number of studies by country

Country	Number of Studies
Brazil[22]	1
Italy[14,18]	2
Sweden[9]	1
Turkey[21]	1
US[1,2,12,13,15–17,19,20,3–8,10,11]	17
	Total US: 17 Total Non-US Countries: 5

Table 7. Number of studies by combinations

	Combination Formula	Number of Studies
Nominated	Lidocaine 1% / Hydrocortisone 2.5%	0
	Lidocaine 23% / Prilocaine 5%	0
	Lidocaine 6-23% / Tetracaine 6-7%[1,10,17]	3
	Lidocaine 8-10% / Benzocaine 20% / Tetracaine 4-10%	0
	Lidocaine 5% / Cimetidine 10% / Salicylic Acid 40%	0
	Lidocaine 15% / Phenylephrine 0.25% / Prilocaine 5%	0
	Lidocaine 20% / Phenylephrine 0.05% / Tetracaine 10%	0
	Lidocaine 10-15% / Dibucaine 0.5% / Phenylephrine 1% / Prilocaine 2.5-5%	0
	Lidocaine 2% / Mupirocin 2% / Tranilast 1% / Aloe Vera 0.2%	0
	Lidocaine 5% / Cimetidine 10% / Deoxy D Glucose 0.2% / Ibuprofen 2% / Salicylic Acid 15%	0
Others found in literature	Lidocaine 1-1.5% / Hydrocortisone 1%[14,18]	2
	Lidocaine 2.5% / Prilocaine 3.5% – gel[13]	1
	Lidocaine 5% / Prilocaine 5% – cream, emulsion[9,15,21]	3
	Lidocaine 7% / Prilocaine 7% – cream[22]	1
	Lidocaine 20% / Prilocaine 5% – topical[7]	1
	Lidocaine 8% / Tetracaine 8% – cream[8]	1
	Lidocaine 6% / Benzocaine 10% / Tetracaine 4% – cream[4]	1

	Lidocaine 6% / Benzocaine 20% / Tetracaine 4% – gel, cream, ointment[2,5,11,12,16]	5
	Lidocaine 6% / Benzocaine 20% / Tetracaine 5% – topical[6]	1
	Lidocaine 6% / Benzocaine 20% / Tetracaine 6% – vaginal[3]	1
	Lidocaine 1% / Phenylephrine 2.5% / Tetracaine 1% – topical[19,20]	2
	Lidocaine 6% / Benzocaine 20% / Diphenhydramine 2% / Tetracaine 4% – cream[5]	1

Table 8. Dosage by indication – US

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Anesthesia[1,2,12,13,15–17,19,20,3–8,10,11]	–	5-8%	Cream	Topical	Once pre-procedure
		6%	Gel	Topical	
		2.5%		Vaginal	
		6%	Ointment	Topical	
		1-23%	–	Topical	
		6%		Vaginal	

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

Table 9. Dosage by indication – non-US countries

Indication	Dose	Concentration	Dosage Form	ROA	Duration of Treatment
Anesthesia[22]	–	7%	Cream	Topical	Once pre-procedure
Hyperhidrosis[9]	–	5%	Emulsion	Topical	Once
Anal fissure[14,18,21]	–	1.5-10%	Ointment	Rectal	6-8 weeks
		5%	–		

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

Table 10. Compounded products – US

Indication	Publication Year	Compounding Method	Dosage Form	Final Strength
Anesthesia[2,5,6,12,15,17]	2003-2018	• Compounded in combination with benzocaine 20% / tetracaine 4%	Ointment	6%
			Gel	6%
		• Compounded in combination with prilocaine 5%	Cream	5%
		• Compounded in combination with benzocaine 20% / tetracaine 6%	–	6-23%
		• Compounded in combination with tetracaine 7%	–	23%
		• Compounded in combination with benzocaine 20% / tetracaine 4%	Cream	6%
		• Compounded in combination with benzocaine 20% / tetracaine 4% / diphenhydramine 2%	Cream	6%

Abbreviations: "–", not mentioned.

Table 11. Compounded products – non-US countries

No compounded products from reported studies

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

Two (2) interviews were conducted. One (1) interview was conducted with two (2) interviewees.

Table 12. Overview of interviewee

Interviewee	Level of Training	Specialty	Current Practice Setting	Experience with Lidocaine	Interview Summary Response
DER_06	MD	Dermatology / Immunology	Consulting	Yes	• Expressed a need for compounded "caine" products in the office. • Some practitioners like to mix different "caine"s due to different onset and duration of effects.
ANE_01	MD	Anesthesiology	Trauma center	Not specified	• Interested in having access to compounded "caine" products.
ANE_02	NP	None	Trauma center	Not specified	• Interested in having access to compounded "caine" products.

Abbreviations: MD, Doctor of Medicine, NP, Nurse Practitioner.

Indications for use

- One interviewee stated that there is a need for lidocaine in the office for use prior to cosmetic procedures. Procedures are done in the office so does not make sense to write prescription for it.
- One interviewee stated that compounded LET (lidocaine, epinephrine, tetracaine) is the preferred product for skin grafts.
- Additionally, lidocaine can be infused into the wound bed.
- Post-op topical lidocaine can be used on intact skin for centralized neuropathic pain. The interviewee stated there is a need for topical lidocaine due to the increase in abuse of gabapentin.

Use in combination

- Use with phenylephrine via injection for local anesthesia prior to procedures.
- Some practitioners like to mix different "caine"s because some of them are fast onset and some are longer acting.
- One (1) interviewee indicated that EMLA [lidocaine/prilocaine topical cream] does not eliminate the need for various compounded "caines" because EMLA is only available in one concentration.

- One (1) interviewee stated an interest in using in combination with a non-steroidal anti-inflammatory drug (NSAID) and gabapentin or a gabapentinoid to treat peripheral neuropathy.

Safety

- One (1) interviewee expressed concerns about central nervous system adverse events or developing allergy to topical "caines", but also stated that physicians who use them are well-trained, skilled, and cognizant of the adverse events.

Availability

- Two (2) interviewees stated a lack of access to compounded preparations at their practice site so use of compounded products is limited. One interviewee stated "caine" products are useful for wellness/caring and can be continued for long periods of time.

Summary of survey results

Table 13. Characteristics of survey respondents [11 people responded to the survey[a]]

Board Certification	MD	PhD	No response
Anesthesiology	1	0	0
Dermatology	2	0	0
Neurology	1	0	0
Pain Medicine	3	0	0
No Board certification	0	1	1
No response	0	0	4

Abbreviations: MD, Doctor of Medicine; PhD, Doctor of Philosophy.
[a]Some respondents reported more than one terminal clinical degree or board certification.

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

Types of Products	Respondents, n (N=8[a])
Compounded	0
FDA-approved	4
Over-the-counter	1
Dietary	0
Unsure	1
No response	3

[a]Out of 11 respondents, 8 reported using, prescribing, or recommending multiple types of lidocaine product.

Table 15. Compounded use of lidocaine in practice

No survey respondents provided this information

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

Indication	Standard Therapy			
	Compounded, n (N=0)	**Non-compounded, n (N=4)**	**Unsure, n (N=1)**	**No response, n (N=3)**
Only as an anesthetic for procedures	0	1	0	0
Other	0	1	1	0
Neuropathic, visceral and MSK pain	0	1	0	0
No response	0	1	0	3

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

No survey respondents provided this information

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

No survey respondents provided this information

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

No survey respondents provided this information

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

No survey respondents provided this information

CONCLUSION

Lidocaine (UNII code: 98PI200987) was nominated for inclusion on the 503B Bulks List by OFA, Sincerus, AnazaoHealth, and David Smith for pain associated with wounds, neuropathy, warts, and to provide a topical anesthetic prior to various procedures. The nominated ROA and dosage forms include topical creams, gels, emulsions, ointments, solutions and suspensions. Lidocaine is available in the nominated formulations in Abu Dhabi, Australia, Belgium, Canada, Hong Kong, Ireland, Latvia, Namibia, New Zealand, Saudi Arabia, UK, and US.

From the literature review conducted, the most common indication in the US was anesthesia. The most common indication from the non-US studies was for anal fissures. Compounded products were identified from US studies, all of which were utilized in the nominated formulations.

From the interviews, one (1) interviewee stated there is a need for lidocaine in the office and the other two (2) interviewees expressed interest in having access to compounded "caine" products. One (1) interviewee stated that the commercially available product may not meet the needs of different procedures, stating that there is a need for various compounded combinations of "caine"s in the office.

From the survey responses, eight (8) out of eleven (11) respondents used lidocaine, but none used compounded lidocaine.

APPENDICES

Appendix 1. References

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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 **lidocaine**. 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: Lidocaine

Q1. What type(s) of product(s) do you use, prescribe, or recommend for **lidocaine**? 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 lidocaine? Please check all th... != Compounded drug product

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

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Display This Question:

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

Q2. Please list any conditions or diseases for which you use compounded **lidocaine** 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 **lidocaine** 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 lidocaine as a single agent active ingredient, or as one active ingredient... != Combination

Display This Question:

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

Q4. In which combination(s) do you use compounded **lidocaine**? Please check all that apply.

- ☐ Lidocaine 1% / Hydrocortisone 2.5%
- ☐ Lidocaine 2% / Aloe vera 0.2% / Mupirocin 2% / Tranilast 1%
- ☐ Lidocaine 5% / Cimetidine 10% / Salicylic acid 40%
- ☐ Lidocaine 5% / Cimetidine 10% / Deoxy-d-glucose 0.2% / Ibuprofen 2% / Salicylic acid 15%
- ☐ Lidocaine 8-10% / Benzocaine 20% / Tetracaine 4-10%
- ☐ Lidocaine 10-15% / Dibucaine HCl 0.5% / Phenylephrine HCl 1% / Prilocaine 2.5-5%
- ☐ Lidocaine 15% / Phenylephrine HCl 0.25% / Prilocaine 5%
- ☐ Lidocaine 20% / Phenylephrine HCl 0.05% / Tetracaine 10%
- ☐ Lidocaine 23% / Prilocaine 5%
- ☐ Lidocaine 6-23% / Tetracaine 6-7%
- ☐ Other (please describe) _____

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

_____

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

_____

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

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

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

_____

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

- o Yes
- o No

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

Display This Question:

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

Q10. In what practice location(s) do you stock non-patient-specific compounded **lidocaine**? 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 **[substance]**? 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 **lidocaine**? 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 lidocaine? Please check all that apply. = Convenience

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

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

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

_____

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

_____

End of Block: Lidocaine

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