

## References by Category, Figures, and Search Strategy

In this supplemental file, we present additional tables, figures, and the search strategy for the paper “The Drug Shortage Era: A Scoping Review of the Literature 2001-2019.” In Section S1, for each category, we present a table of the references associated with each sub-category. In Section S2, the figures present the journals of included articles and the number of papers by therapeutic or practice area. In Section S3, we report an example of the database search strategy.

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## Section S1. References by category

Table S1. Types of papers

Category		References	n
Overviews		(1–33)	33
Perspectives, editorials, viewpoints, and commentaries		(16,20,24,26,29,34–94)	66
Major reports		AMA (27,95–102); ASPE (103); ASTHO (104); FDA (32,105–110); GAO (111–115); Pew-ISPE (116); Premier Healthcare Alliance (117,118)	26
Reviews*		(17,22,23,27,95–102,119–133)	27
Specific provider types	Nurse	(25,134)	2
	Pharmacist/technician	(74,127,135)	3
	Providers	(40,136,137)	3
Databases		(138,139)	2
Events (e.g., summits, workshops)		(31,140–145)	7
Surveys or interviews, by type of respondent	Patients/general population	(146,147)	2
	Pharmacy/pharmacists	(117,130,148–171)	26
	Pharmaceutical industry	(116,172–174)	4
	Providers	(118,175)	2
	Specialists	(59,176–184)	10
	Other	(161,185–193)	10
Surveys, by organizational sponsor	ASA	(176,177)	2
	ASHP	(154,165,166,192)	4
	ASPEN	(158,175,188)	3
	IDSA EIN	(181,182,184)	3
	ISMP	(149–153,187,189)	7
	ISPE	(116,173)	2
	Premier Healthcare Alliance	(117,118)	2
	Other	ACEP (194); AHA (193); ASGE (59); HOPA (157); OIG (160); Vizient (163)	6
Therapeutic/practice areas	Ambulatory/outpatient	(74,195–197)	4
	Anesthesia, anesthetics, and analgesics	(4,22,35,43,44,60,71,80,81,87,120,147,155,162,166,176,177,198–214)	34
	Anti-infectives	(49,54,64,79,92,93,123,124,181,182,184–186,190,215–233)	33
	Cardiovascular	(125,126,234–239)	8
	Controlled substances	(114,115)	2
	Critical care	(7,24,53,169,240–255)	20
	Emergency medicine	(20,73,104,252,256–258)	7
	Gastroenterology	(59,69,259,260)	4
	Hormones	(29,48,261)	3
	Medical toxicology	(89,262–268)	8
	Neurology	(169,248,269,270)	4
	Oncology	(8,16,18,26,41,45,47,50,55,70,85,86,119,132,134–137,146,157,161,170,178–180,183,197,202,271–310)	68
	Ophthalmology	(311,312)	2

Category		References	<i>n</i>
	Orphan drugs	(266,267,313–315)	5
	Parenteral Nutrition	(17,23,42,77,122,129,152,158,175,188,251,316–346)	42
	Sterile solutions	(62,76,84,90,91,165,166,189,347–352)	14
Shortage prevalence and characteristics	Over time	(14,17,23,30,32,44,60,74,103,106–113,115,124–126,129,131,137,144,145,156,179,196,221,225,230,240,247,250,252,256,259,268,270,272,277,284,293,313,314,349,353–361)	56
	Single point in time or surveyed experience	(4,19,20,22,27,47,59,95–102,105,149,154,155,157,158,161,163–167,170,171,173,176,177,180–186,188,192–194,216,257,362–364)	48

\* Reviews of alternative medications are presented in Table S6.

ACEP = American College of Emergency Physicians; AHA = American Hospital Association; AMA = American Medical Association; ASA = American Society of Anesthesiologists; ASGE = American Society for Gastrointestinal Endoscopy; ASPE = Assistance Secretary for Planning and Evaluation; ASPEN = American Society for Parenteral and Enteral Nutrition; ASHP = American Society of Health-System Pharmacists; ASTHO = Association of State and Territorial Health Officials; FDA = Food and Drug Administration; GAO = Government Accountability Office; HOPA = Hematology/Oncology Pharmacy Association; IDSA EIN = Infectious Diseases Society of America Emerging Infections Network; ISMP = Institute for Safe Medication Practices; ISPE = International Society for Pharmaceutical Engineering; OIG = Office of Inspector General; UUDIS = University of Utah Drug Information Service

Table S2. Causes

Category		References	n
Proximate Causes*	Discontinuations	(1,3,6,10,11,15,20–22,27,89,93,111,112,116,117,125,126,132,145,199,266,269,274,365,366)	26
	Disruptions	(9,103,112,113,358,367)	6
	Facility closures	(77,111,120,141,274,368)	6
	Manufacturing issues	(2,10–12,18,20,21,27,30,96,111,112,125,142,144,145,173,265,365,369,370)	21
	Natural disasters	(6,11,20,21,62,82,84,108,112,144,199,335,365)	13
	Quality issues	(1,14,30,52,55,56,81,98,103,111–113,116,141,144,173,367,371)	18
	Raw materials	(2,3,6,10–12,18,20–22,27,30,92,111,112,116,117,126,142,173,186,199,356,365)	24
	Recalls	(11,21,22,56,60,98,120,352,365,369,371)	11
	Stockpiling or hoarding	(21,369)	2
	Unpredictable demand	(10,22,28,92,111,112,116,124,125,141,185,199,269,296,297,358,365,369,372) Dissent (142)	19, 1
Economic Factors	Aging facilities/quality issues	(2,14,30,55,111,367)	6
	Consolidated bargaining power or GPOs	(15,75,88,120,199,203,287,309,370,373–375) Dissent (111)	12, 1
	Distribution/allocation policies or gray market	(2,16,21,151,365,369) Dissent (32,103,376–378) Solicitations (153,170)	6, 5, 2
	Economics, general	(10,14–16,18,21,30,60,93,111,126,141,144,145,203,359,365,370,376,379)	20
	Inelastic demand	(2,9,10,15,95,103,126)	7
	Liability, increased outsourcing, or anti-trust laws	(21,71,120,368,370) Dissent (10,315)	5, 2
	Little to no penalties for not meeting production target	(103,367,375)	3
	Low demand	(92,103,355)	3
	Low prices	(15,103,111,195,376,380) Evidence against (113)	6, 1
	Low profit margins	(15,16,18,21,45,56,60,64,93,95,111,113,120,134,203,304,370,374,376,377,379) Dissent (112,142)	21, 2
	Medicare profit or pricing issues	(10,15,16,55,111,132,134,199,287,370,374,376–378) Evidence against (5,367,381) or dissent (140)	14, 3, 1
	New drugs	(12,45,64,367,375) Dissent (16)	5, 1
	Patent expiration/age of drug	(10,11,293,358)	4
	Recession and global market	(367,375)	2
340B program	(370,375) Dissent (5)	2, 1	

Category		References	n
Capacity and inventory	Concentrated market or single or few suppliers	(1,2,5,11,12,14,15,18,20,21,27,28,30,32,55,57,60,71,72,89,96,111–113,142,144,199,269,293,315,355,358,365,367,368,373–375,382,383) Dissent (14,103,370,378)	40, 4
	Difficulty ramping up production	(1,12,14,21,32,70,112,368,372)	9
	Drugs require specialized facilities or complex production processes	(14,32,103,112,367)	5
	International supply chains	(28,57,112,144,199,379,384)	7
	Lack of redundancy	(14,30,62,116,126,367)	6
	Limited capacity or high utilization	(1,2,10,12,15,28,30,32,96,103,111,141,144,199,358,368,374,375)	18
	Low levels of inventory held	(2,3,20–22,32,57,60,103,111,112,142,199,203,365,367)	16
Regulation	Low levels of enforcement	(126)	1
	Regulatory issues <sup>†</sup>	(5,6,10,15,18,27,64,81,87,111,114–117,132,142,145,172,173,199,359,365,368,370,374,376,382,384) Dissent (14,32)	28, 2
	Unapproved Drug Initiative	(10,21,142,144,355–357) Dissent (14,32)	7, 2

\* Papers that report the distribution of shortages by proximate cause can be found in Table S1 under “Shortage Prevalence and Characteristics”

<sup>†</sup> Including communication, review, more stringency, warning letters

GAO = Government Accountability Office; GPO = Group Purchasing Organization

Table S3. Examples of impact on care

Category		References	<i>n</i>
Treatment	Changed or affected*	(4,59,66,68–70,81,82,87,115,123,125,129,130,134,141,145,148–150,152,154,157–159,161,163–171,175–184,186,189,191–194,197,205,207,208,210,211,213,214,220,223,225,229,233,235–237,241,246,248,249,251,260,271,276,278,281,290–292,294,295,298–301,303,307,311,312,318–320,322,324–326,330,331,333–335,342–344,348,354,385–391)	114
	Decrease in use of short drug	(69,79,90,149,179,202,211,212,215,218,219,221–224,228,239,243,244,250,269,280,288,327,331,335,342,387,392)	29, 3
	Increase in use or mixed effects	(272,289,310)	
	Delayed or cancelled	(59,115,117,149,151,152,157,159,163,167,170,176,177,180–183,186,189,190,192–194,246,263,266,267,276,281,299,335,354,369,393)	34
	Drug rationed	(68–70,79,87,117,120,123,129,141,149,151,152,154,157,158,163,165,166,171,180,183,186,191,193,225,226,249,289,297,318,320,324,331,335,354,369,385,390)	39
	Substitute not available	(115,151,247,251,256,274,281,301,307,344,354)	11
	Increased monitoring	(159,187,208,266,320)	5
Patient referred or transferred to another institution	(151,157,159,170,171,180,181,191,192,369)	10	
Clinical trials	Affected†	(151,157,161,183)	4
Effects on people	Patient response or behavior	Reported by patients or patient groups (115,147) Reported by providers or researchers (155,159,162,176,177,263)	2, 6
	Provider dynamics	(7,130,149,151,154,162,169,175,193)	9

\* Including substitutions, dosing, and delivery

† Including limited, delayed, or cancelled patient participation

Table S4. Health outcomes

Category		References	n
Retrospective/ observational studies	Health outcomes worse	(202,209,213,215,221,224,244,260,273,291,295,299,318,387)	14
	Health outcomes similar	(205,210–212,217,218,220,223,226,228,241,243,249,292,294,300,301,303,307,320,330,333,348,386,388,389,391)	27
	Health outcomes improved	(214,228,325)	3
	Baseline not reported	(229,236,276,278,285,394)	7
Other	Case report	(122,204,207,208,233,235,251,271,298,308,311,312,316,319,322,324,326,343,344,395)	20
	Survey	(59,117,149–151,154,156–159,167,168,170,175–177,179,181–183,190,192,194)	23
	Other	(4,69,87,115,145,219,232,257,266,267,334,396)	12
Medication errors		(22,66,145,149–152,157,159,161,163,167,168,200,257,395,397) No increase (255,345) Risk (80,111,115,126,145,149,156,170,342,354,385)	17, 2, 11

Table S5. Labor and costs

Category		References	n
Labor and time to manage		(4,59,80,111,115,130,144,145,149,151,154,157,159,163,166–171,175,183,191,194,285)	25
Total or general costs		(59,144,151,157,159,167,170,175,191,269,318,398)	12
Drug costs	General	Increased (117,193) Mixed effects (354)	2, 1
	Short drugs	(59,69,168,191,323,355,360,392,399–404) Mixed (405)	14, 1
	Substitutes	More expensive substitutes (4,45,117,125,132,149,157,166,169,170,179,181,182,186,193,214,274,280,282,310) Similar (391) Less expensive (69,218,223,348)	20, 1, 4
	Imported drugs	(152,285)	2
	Gray markets	(9,118,144,149,153,157,406)	7
	Pass-through to patients or out-of-pocket costs	(115,274,280,369,377)	5
	Treatment costs and delivery costs	Increased	(208,232,266,278,279,320,387)
Rare, minimal change or decreased		(68,214,217,237,331)	5

Table S6. Management strategies

Category		References	n	
Guidance and tools	General	(2,21,33,121,365,385)	6	
	Specific	Alternatives*	(81,201,206,234,238,245,407)	7
		Cardiovascular	(125,126)	2
		Critical care	(247,257)	2
		Emergency medicine	(73,104)	2
		Oncology	(26,134,137,275,305)	5
		Opioids	(80,87,198)	3
		Parenteral nutrition	(23,122,129,317,321,328,332,336–341)	13
	Other	Antimicrobial (123); dermatology (366); medical toxicology (265); pediatrics (408); sterile solutions (351); transplant (131)	6	
	Component of broader guidance statement		(135,409)	2
Ethics	Overview	(2,38,203)	3	
	Framework/guidance	(119,136,275,297,305,306,390,410)	8, 7	
	Response or model	(34,36,37,39,40,94,302)		
	Liability or obligation	(9,44,46,257,397)	5	
Disclosure	(2,43,44,123,410)	5		
Tools		(156,231,258,352,392,411–413) Improve EHRs (31,346)	8, 2	
Examples	Communication	Communicate with and educate staff and students	(20,68,87,90,117,123,130,148,149,154,164,167,168,170,187,193,208,215,219,223,258,266,283,331,335,385,386,390,411) Evaluate competencies (347)	29, 1
		Coordinate with manufacturer/distributor	(68,117,130,164,168,170,208)	7
	Conservation of suppliers	Guidelines for treatment and alternatives	(68,87,90,117,123,141,161,170,171,180,181,192,215,223,228,266,301,307,308,331,335,369,386,407) Adherence to guidelines (197,220)	24, 2
		Prioritize access	(20,68,69,82,87,117,120,123,129,141,148,149,154,157,163,165,166,170,171,180,186,191–193,226,249,297,307,318,320,324,331,335,369,385,390,401)	37
		Reduce waste	(161,163,166,168,170,237,242,276,306,323,324,350,390,401)	14
	Drug acquisition	Add alternatives to formulary or use non-formulary drugs	(117,165,181,193,218)	5
		Compound	(130,149,158,160,166,167,175,181,192,320,390,393–396)	15
		Import	(152,158,273,285,294)	5
		Other sources	(68,123,130,149,153,157,158,161,167,168,170,171,181,276,324)	15
		Other suppliers	(69,123,130,148,149,160,164,167,170,171,186,192,193)	13
	General	Management plan	(117,148,154,156,169,178,187,335)	8
		Increase staff support	(149,154,157,159,167,168,170,171,191)	9
		Task force or committee	(68,87,129,130,148,163,171,191,223,266,276,283,297,306,390,401)	16
		Track shortages	(45,168)	2
Ethics	General	(123,171,178,369,390)	5	



Category		References	<i>n</i>
		Disclosure (283) Not common (171) Hypothetical survey (146,147)	1, 1, 2
	Inventory	Do not hoard (68) Reports of hoarding (149,151,157,171,369)	1, 5
		Inventory management (4,68,117,149,163,164,168,170,171,192,193,198,223,414)	14
		Monitor inventory (130,154,223)	3
Case example	(4,68,90,223,226,235,237,285,331,335,347,390,401,411)	14	

\* Papers that evaluated the effects of potential alternatives are presented in Table S4

EHR: Electronic health records

Table S7. Prevention strategies

Category	References*	n	
Decreasing risk	Demand forecasts	(140,145,358)	3
	Economic incentives	(14,18,30,31,62,79,110,116,140,142,144,145,274,376,384,415)	16
	Evaluate risk of shortages	(110,111,124,140,142,144,358)	7
	External quality measures <sup>†</sup>	(14,15,18,31,57,58,110,126,140,141,168,174,203,349,367,416,417)	17
	Increase manufacturing transparency	(8,15,31,62,79,101,102,126,128,144,145,349,353,376)	14
	Internal quality improvements, including quality control	(14,15,30,52,61,96,98,100–102,116,126,128,140,141,145,173,384,417–420) Plan or tool (419,420)	22, 2
	Prioritize submissions if meet production goals consistently or add redundancy	(3,15,55,58,274,382) Dissent (10)	6, 1
	Revoke licenses for if production goals not met	(15,18,55,58)	4
Increasing supply chain resiliency	Add capacity or redundancy	(8,10,14,15,30,32,55,56,61,62,95,97,98,100–102,110,126,128,140–142,144,157,170,304,314,315,419,420)	30
	Add shortages as a performance metric	(10,140,173,420)	4
	Collaborate with regulators internationally/harmonize standards	(28,30,65,72,141,370,382)	7
	Decrease time to complete FDA review	(3,15,16,59,115,136,141,142,376,382)	10
	Encourage competition	(46,144,195,382,383,421,422)	7
	Fee waivers, reimbursements, or restructure user fees	(10,15,18,28,47,144,357,382,403) Dissent (140)	9, 1
	National stockpile	(13,47,54,58,61,93,96,145,186,315) Hold at hospitals (80) Dissent (10,45,370) Not in short-term (3)	10, 1, 3, 1
	Safety stock	(110,128,140,144,145,304,314) Purchasers rather than manufacturers (63)	7, 1
	Strengthen failure-to-supply clauses	(10,13,18,103,110,126,141,286,304,370,375,378)	12
Tax credits or financial incentives	(3,8,10,15,18,28,47,64,101,110,120,140–142,144,145,157,257,274,353,370,379,415)	23	
Increasing attractiveness to produce drug	Exclusivity	(3,13,15,18,55,67,141,257,261,353)	10
	Long-term contracts	(67,116,144,353,382,422)	6
	Pricing	General (8,13,15,16,18,45,61,98,101,136,140,144,195,286,304,380) Medicare (5,10,18,55,95,96,140,257,274,287,353,370,374,376–378) Dissent (141,375)	16, 16, 2
	Purchase requirements or guaranteed order quantities	(116,141,423) Dissent(370)	3, 1
	Other	(5,10,15,18,22,31,45,47,67,136,373)	11

Category	References*	<i>n</i>	
Reducing impact of disruptions or potential shortages	Allocation or distribution	(8,11,12,21,27,29,32,46,63,97,98,100–102,142,144,145,369)	18
	Communication between stakeholders	(3,8,12,15,17,27,29,30,32,46,48,64,95–97,102,105–110,114–116,140–142,144,145,181,191,199,269,364,374,419,420,424,425)	40
	Databases and other means to track shortages	(32,64,97,105,106,109–112,126,145,425)	12
	Early warning systems <sup>‡</sup>	(3,10,27,32,46,58,65,141,186,287,358,424) Dissent (369)	12, 1
	Expedited reviews or inspections	(1,3,12,14,16,21,28,48,55,56,61,95,97,98,100–103,105–110,112,115,140–142,144,145,173,261,357,370,403,425,426)	38
	Extend expiration dates	(262,264,267,427,428)	5
	Identify other sources for drug	(12,15,46,59,145,280)	6
	Importation	(5,6,12,14,15,17,21,29,51,54,60,62,93,107,108,112,141,186,274,285,344,372,421,422,427) Dissent (376)	25, 1
	Increase FDA resources	(28,32,126,140,142,145,382)	7
	Increase production by other manufacturers	(12,14,21,59,105–110,112,141,173)	13
	Mandatory reporting	(3,6,8,10,16,27,29–32,46,95,97,124,142,145,186,230,425,426) Dissent (5,370,376)	20, 3
	Non-profit manufacturer or produce drugs in-house	(47,72,83,144,422,429)	6
	Reduce gray market/online drug sales	(6,86,110,153,287,364,369) Dissent (370)	7
	Reduce hospital hoarding	(21,262)	2

\* In these papers, authors may have recommended these strategies or proposed they be considered. Inclusion does not necessarily imply endorsement.

<sup>†</sup> Including quality metrics, recognition of high quality, and inclusion in contracts

<sup>‡</sup> Including prediction of shortages or volume volatility

FDA = Food and Drug Administration

Table S8. Federal government response to shortages

Category		References	<i>n</i>
Overviews		(3,9,11,12,14,15,18,21,23,30,32,106,110–112,257)	16
Created new agency or task force		(415,430)	2
Executive order		(426)	1
FDASIA		(425)	1
Reports	Annual reports	(106–109)	4
	GAO reports	(111–115)	5
	Other reports	(32,110)	2

FDASIA = Food and Drug Administration Safety and Innovation Act; GAO = Government Accountability Office

## Section S2. Additional Figures

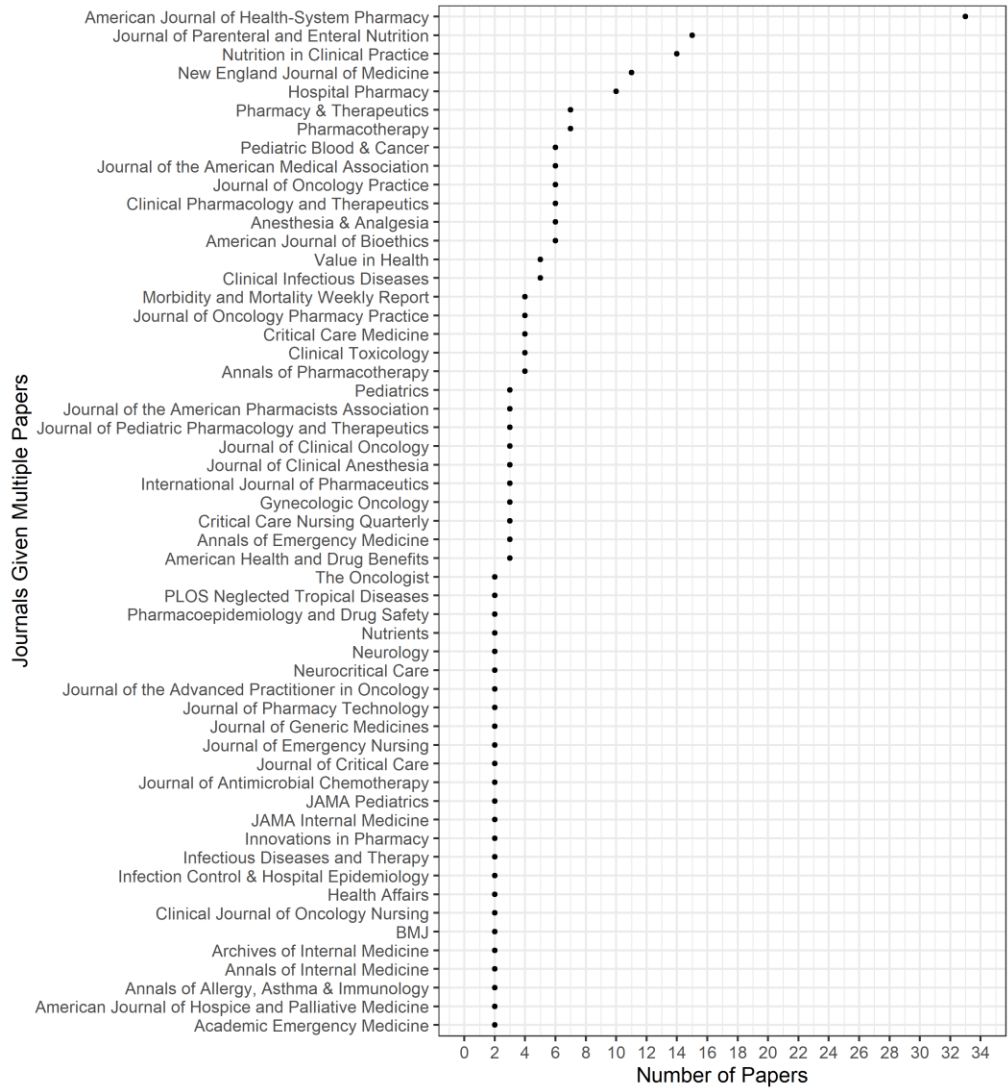


Figure S1. Journals with multiple papers included in the analysis

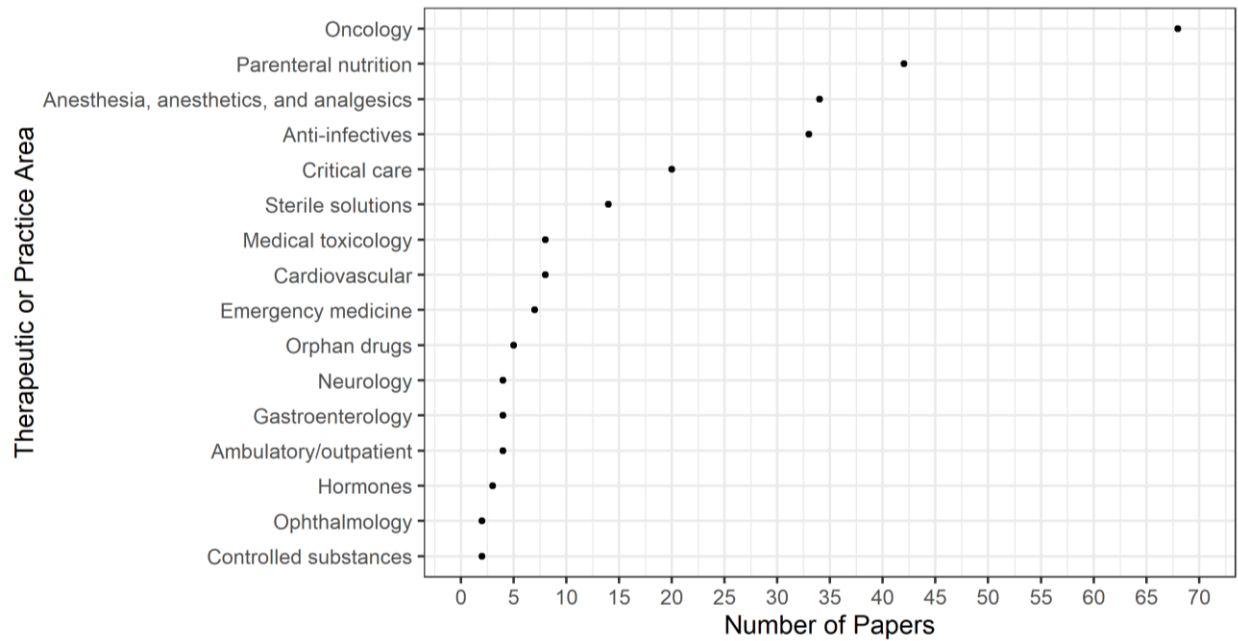


Figure S2. Number of papers associated with particular practice or therapeutic areas

### Section S3. Example Search Strategy

Below is the full query used to search to search Pubmed when the literature was refreshed on May 7, 2019:

User query: ((drug AND shortage)) OR (medicine AND shortage) AND (("2019/01/01"[PDat] : "3000/12/31"[PDat]))

Query translation: (drug[All Fields] AND shortage[All Fields]) OR ("medicine"[MeSH Terms] OR "medicine"[All Fields]) AND shortage[All Fields]) AND ("2019/01/01"[PDAT] : "3000/12/31"[PDAT])

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