

## Medical donations are not always free: an assessment of compliance of medicine and medical device donations with World Health Organization guidelines (2009–2017)

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Received 24 September 2018; revised 7 December 2018; editorial decision 17 January 2019; accepted 21 January 2019

Medicine and medical device donations have the potential to improve access to healthcare in some of the poorest parts of the world, but can do more harm than good. World Health Organization guidelines advise donors on how to make effective and useful donations. Our objective was to assess compliance of recent medicine or medical device donations with WHO guidelines from 2009 onwards. We searched media, academic and gray literature, including industry and organizational documents, to identify reports describing specific incidences of the donation of medicines or devices. We collected data on donation characteristics and guideline compliance. We identified 88 reports describing 53 donations. Most did not comply with at least some items in WHO guidelines and no reports provided sufficient information to assess compliance against all items. Donations that fail to comply with guidelines may be excessive, expired and/or burden recipient countries with storage and disposal costs. It was estimated that 40–70% of donated medical devices are not used as they are not functional, appropriate, or staff lack training. More effective donations involved needs assessments, training and the use of existing distribution networks. The donation of medicines and medical devices is frequently inadequately reported and at times inappropriate. Guidelines need to be enforced to ensure effective donations.

**Keywords:** device donation, donation program, drug donation, low and middle income countries, medicine donation, World Health Organization

### Introduction

Global inequities in health systems mean that many low and middle income countries experience shortages of necessary medicines and medical supplies. These disparities are sometimes remedied through donations made by external governments, pharmaceutical companies or non-government organizations (NGOs) to countries<sup>1</sup> or to individual health facilities.<sup>2</sup> Donations of medical aid may occur during emergency situations or as part of long-term programs, such as those targeting neglected tropical diseases (NTDs).<sup>3</sup>

Medicine and medical device donation programs have the potential to improve access to healthcare in some of the poorest parts of the world<sup>2</sup> when done well, such as medicine donations made following the 2001 earthquake in Gujarat, India, or Merck's Ivermectin donation program.<sup>4</sup> However, badly executed donations can cause harm and burden recipient countries.<sup>4</sup> For example, inappropriate and excessive medicine donations made to Bosnia and Herzegovina from 1992 to 1996 resulted in estimated disposal costs of US\$34 million, and were reported to include surplus medical supplies from World War II.<sup>5</sup> For pharmaceutical companies, medicine donation efforts may be a way to fulfill corporate social responsibility targets, 'dump' medicines they would otherwise have to pay to dispose of<sup>1</sup> and receive tax breaks.<sup>1,5,6</sup> In addition, there has been criticism that donation programs create new markets for products without consideration of how medicines will be purchased once the program ends.<sup>3,7</sup>

The WHO guidelines for medicine donations were created in 1996, then revised in 1999 and 2010.<sup>2</sup> The most recent review of medicine donations in 2009 found that a large proportion were not compliant with WHO guidelines because they were excessive, unnecessary, expired or otherwise inappropriate.<sup>4</sup> Emergency donations were less likely than long-term donations to comply with guidelines, and frequently had a short shelf life or inappropriate labeling.<sup>4</sup> This review found that the arrival of

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large donations in quick succession overwhelmed local services with excessive quantities of medicines that expired before they could be used.<sup>4</sup> Another study found that improper disposal may result in environmental pollution, such as the leaching of pharmaceuticals into soil and water.<sup>1</sup>

Donations of medical devices, including healthcare and diagnostic equipment, may also be poorly executed. Although WHO *Medical device donations: considerations for solicitation and provision* (2011)<sup>8</sup> and WHO *Guidelines for Health Care Equipment Donations* (2009)<sup>9</sup> exist, little is known about the compliance of medical device donations with guidelines and recommendations. The donation of medical devices poses unique challenges. Medical technology is often designed for use in developed countries, and may therefore be inappropriate for limited resource settings that often lack access to parts needed for repair and maintenance, or trained personnel to maintain equipment for long-term use.<sup>10</sup>

This paper aims to update the previous review of medicine donations<sup>4</sup> and expand it to include device donations. We assess the adherence of identified medicine and medical device donations to the WHO *Guidelines for Medicine Donations*<sup>2</sup> and/or the WHO *Medical device donations: considerations for solicitation and provision*<sup>8</sup> and WHO *Guidelines for Health Care Equipment Donations*.<sup>9</sup>

### Materials and methods

In January 2018, we searched media, academic and gray literature, including industry and NGO documents, to identify journal articles, reports and media stories that described the donation of medication or medical devices. We worked with a librarian to develop a search strategy for PubMed based on the concepts 'medicine donation(s)' and 'device donation(s)', and adapted this for Embase, Scopus, and Factiva, a news database. We then conducted a snowball search using Google and/or Google Scholar for companies, products, events or programs associated with medicine or medical device donations that were identified in our initial search, including websites of pharmaceutical companies and NGOs.

We included case studies, news reports, press releases, journal articles (peer-reviewed or not) and company reports published in English that described specific incidences of the donation of pharmaceutical agent(s), medical device(s), assistive technologies, personal protective equipment, or diagnostic or screening tests. We included descriptions of donations made from January 2009 onwards in order to capture reports not identified in the previous review, or long-term donation programs continuing through 2009, regardless of commencement date. We excluded reports that contained insufficient information to compare the donation against any of the items in the WHO guidelines,<sup>2,8,9</sup> and reports on the donation of funds designated for the purchase of pharmaceuticals or devices.

One investigator screened titles and/or abstracts of retrieved records for possible inclusion. Two investigators then assessed the full text for eligibility. From each report, we extracted data on donation characteristics and compliance with WHO guidelines using RedCap, a secure web-based application for the collection and management of data.<sup>11</sup> Collected data included information

on selection, quality assurance and shelf life, presentation, packaging and labeling, and information and management.

We assessed compliance against the WHO's guidelines for medicine donations,<sup>2</sup> for healthcare equipment donations<sup>9</sup> and for medical device donation considerations.<sup>8</sup> Reports of donations were stratified by donation type (disaster-related, longterm, one-off or repeated) and items donated. We created a list of items to assess compliance with guidelines. For medicine donations, we used all of the articles included in the WHO guidelines verbatim.<sup>2</sup> We created a list of 11 items to assess device donation compliance that incorporated the requirements from both the WHO guidelines for healthcare equipment donations<sup>9</sup> and the WHO medical device donation considerations<sup>8</sup> (see supplementary file 1). We calculated the percentage of donations in compliance with the items in the WHO guidelines. Commonly reported barriers and facilitators to donations were extracted from the included reports and summarized. We report case examples of both good and poor compliance with quidelines for medicines and devices. Examples were chosen if they provided sufficient information to assess most of the quideline items and if they presented a clear example of good or poor compliance across the assessed guideline items.

### Results

Eighty-eight reports describing 53 separate donations were included, as shown in Figure 1. Table 1 summarizes the characteristics of the included reports. We identified 15 disaster donations, 15 long-term donation programs and 23 one-off or repeated donations. There were 29 reported medicine donations, 18 device donations and 6 mixed donations.

Of the 88 included reports, 29 were media reports or press releases, 27 were from academic journals, 18 were publications from NGOs. 12 were from pharmaceutical company websites, one was from a multilateral agency and one was a book chapter. The majority of the reports from academic journals were case studies (n=14) or evaluations of donations (n=3).

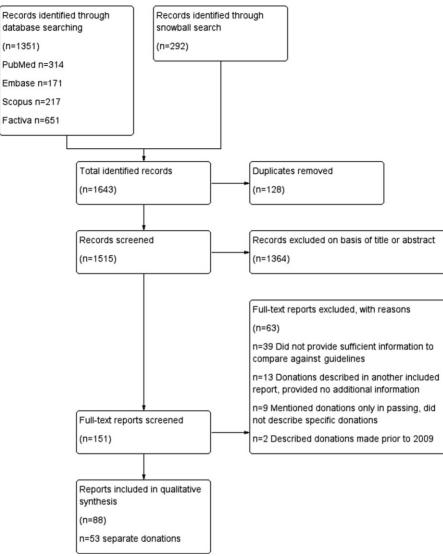
#### **Characteristics of donations**

#### Disaster-related donations

Table 2 summarizes the characteristics of the disaster-related donations. There were eight incidences of medicine donations, including one donation of a traditional Chinese medicine, two donations of medical devices, and a combination of medicines and supplies following five disasters.

#### Long-term donations

The characteristics of 15 long-term medicine donation programs are shown in Table 3. Program length ranged from 3 to 31 y. There was only one long-term medical device donation, that being equipment and consumables to Rwanda for screening women for HPV during 2013–2016.<sup>21</sup> This donation was made in response to the donation of Gardasil for Rwanda's HPV vaccination program, and based on agreement among the donor, QIAGEN and the Rwandan Ministry of Health as part of a national program to vaccinate, screen and treat women against



HPV and cervical cancer. Concessional pricing was offered following the end of the donation period.

#### One-off and repeated donations

Figure 1. Study flow diagram.

Table 4 summarizes the characteristics of 23 cases of one-off or repeated donations. 'Repeated donations' refers to multiple donations made by the same donor to the same recipient, but not as part of a specific long-term program. Fifteen donations were for medical devices, seven were for medications and one donation included both.

#### Compliance with donation guidelines

Most donations did not comply with at least some items in the WHO guidelines, and no reports provided sufficient information to assess compliance against all items. Tables 5 and 6 show the

percentage of donations compliant with WHO guideline items for medicine and medical device donations, respectively. Table 7 provides a summary of common problems demonstrating lack of compliance with WHO guidelines for medicine and device donations. For each main category, examples are provided below (see also supplementary file 2).

# Selection of donated medicines or devices prior to donation

'Selection of donated medicines or devices' refers to assessing the needs and distribution capacity of the recipient country. Excessive amounts of, or inappropriate, medicines were donated following disaster events. Some countries had to invest resources to store<sup>35</sup> or destroy medicines.<sup>27,31</sup> Following the 2010 earthquake in Haiti, the volume of donations overwhelmed the capabilities of Haitian hospitals and Programme

#### Table 1. Characteristics of included reports

Author	Year	Title	Publication type	Donation type	Donor	Recipient	Item donated
African News Agency <sup>12</sup>	2017	China donates medical equipment to SA hospital	Media report	One-off donation	Government, China	Steve Biko Academic Hospital, Pretoria, South Africa	Medical devices, equipment
African Press Organization <sup>13</sup>	2012	Tanzania/Merck To Intensify Support in the Fight Against Schistosomiasis in Tanzania	Media report	Long-term program	Merck, pharmaceutical company	Tanzania	Medicine, Praziquantel
All Africa <sup>14</sup>	2016	State Receives Record Drug Donation to Fight Worm Disease	Media report	Long-term program	Merck KGaA, pharmaceutical company	Abuja, Nigeria	Medicine, Praziquantel
American Medical Resources Foundation, Inc. <sup>15</sup>	2013	AMRF Equipment Donations Evaluated	Publication from NGO	One-off donation	American Medical Resources Foundation, NGO	ADENI hospital of Quetzaltenango; Santa Elena National Hospital of Santa Cruz del Quiche, Guatemala	Medical devices, equipment
Arie <sup>16</sup>	2010	Medical supplies are trapped in Haitian ports as NGOs struggle with paperwork and delays	Academic journal	Disaster-related donation	Bill Clinton Foundation, NGO	Haitian Society of Ophthalmology, Haiti	Medicine and medical devices, spectacles and eye drops
Arellano Maric et al. <sup>17</sup>	2015	-	Academic journal	One-off donation	Heinen und Löwenstein, medical device company	San José NIV centre, Chile	Medical devices
Bayer <sup>18</sup>	2011		Pharmaceutical company website	Long-term program	Bayer healthcare pharmaceuticals, pharmaceutical company	Countries in Latin America	Medicine, nifurtimox
Bauserman et al. <sup>19</sup>	2015	Determining the utility and durability of medical equipment donated to a rural clinic in a low-income country	Academic journal	One-off donation	Rice University	Takaya Health Centre, Democratic Republic of Congo	Medical devices
Berkrot <sup>20</sup>	2018	Biogen, Sobi pledge hemophilia drug donation in developing world	Media report	Long-term program	Biogen Idec Inc and partner Swedish Orphan Biovitrum AB, pharmaceutical companies	5	Medicine, Alprolix and Eloctate
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Table 1. Continued

Author	Year	Title	Publication type	Donation type	Donor	Recipient	Item donated
Binagwaho et al. <sup>21</sup>	2013	Integration of comprehensive women's health programmes into health systems: cervical cancer prevention, care and control in Rwanda	Academic journal	Long-term program	Merck & Co, pharmaceutical company Qiagen	Rwanda Ministry of Health, Rwanda	Medicine, Gardasil Medical devices, equipment and consumables for HPV screening
Boseley <sup>22</sup>	2010	GSK to donate a billion tablets a year for neglected diseases	Media report	Long-term program	GSK, pharmaceutical company	Africa	Medicine, Albendazole
Brack <sup>23</sup>	2015	Needed Donated Medicines Arrive in Nepal	Publication from NGO	Disaster-related donation	Project HOPE, NGO	Ministry of Health, Nepal	Medicine and medical devices
Bradley et al. <sup>24</sup>	2016	-		One-off donation	Canadian NGOs	Multiple hospitals, Ghana	Medical devices, equipment
BSR Healthcare <sup>25</sup>	2012		Pharmaceutical company website	Long-term program	Novartis, pharmaceutical company	Multiple	Medicine, multidrug therapy for the treatment of leprosy
Burpee <sup>26</sup>	2014	Why Uganda should regulate medical equipment	Media report	One-off donation	Donor not specified	Multiple hospitals, Uganda	Medical devices, equipment
Burns <sup>27</sup>	2010	Rx for Humanitarian relief	Media report	Disaster-related donation	Members of PQMD, pharmaceutical companies	Haiti	Medicine and medical devices
Bush & Hopkins <sup>28</sup>	2011	Public-private partnerships in neglected tropical disease control: The role of nongovernmental organizations	Academic journal	Long-term program	Merck, pharmaceutical company	Primarily west African countries	Medicine, Ivermectin
Cancer Weekly <sup>29</sup>	2015	-	Media report	One-off donation	Immune Therapeutics Inc., pharmaceutical company, and the Jack Brewer Foundation, NGO	Queen Elizabeth Central Hospital and clinics, Malawi	Medical devices, Wallach LLD100 Cryosurgical systems
Caribbean Media Corporation news agency website <sup>30</sup>	2012	Brazil makes drug donation to subregion	Media report	One-off donation	Government, Brazil	9 member countries of the sub-regional Organization of Eastern Caribbean States	Medicine, antiretroviral medicines

Table 1.	Continued
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Author	Year	Title	Publication type	Donation type	Donor	Recipient	Item donated
Claycomb <sup>31</sup>	2013	Issues in emergency pharmacy	Media report	Disaster-related donation	Donor not specified	Japan	Medicine, not specified
Cohen et al. <sup>32</sup>	2016	Progress Report on Neglected Tropical Disease Drug Donation Programs	Academic journal	Long-term program	Pharmaceutical companies that signed the 2012 London Declaration	Multiple	Medicine, not specified
Compton <sup>33</sup>	2012	Let's make donations more effective: don't waste these important efforts	Publication from NGO	One-off donation	Catholichealth care organizations, NGOs	Not specified	Medical devices, surplus
Cooper <sup>34</sup>	2017	Urgently needed hemophilia treatment drugs delivered to Puerto Rico pediatric hospital	Publication from NGO	Disaster-related donation	Bioverativ, pharmaceutical company	University Pediatric hospital, San Juan, Puerto Rico	Medicine, clotting factors
Cumming-Bruce <sup>35</sup>	2009	WHO takes lead on health as UN tackles crises	Academic journal	Disaster-related donation	'Governments and organizations'	Palestinian Ministry of Health, Gaza, Palestine	Medical devices, supplies
Crump et al. <sup>36</sup>	2012	The onchocerciasis chronicle: from the beginning to the end?	Academic journal	Long-term program	Merck & Co, pharmaceutical company	Multiple	Medicine, Ivermectin
de Ville de Goyet et al. <sup>37</sup>	2010	Health response to the earthquake in Haiti: Lessons to be learned for the next massive sudden- onset disaster	Report- multilateral agency	Disaster-related donation	Donor not specified	PROMESS, Haiti	Medicine and medical devices
Direct Relief <sup>38</sup>	2009	Direct Relief responding to dengue fever outbreak in Bolivia	Publication from NGO	Disaster-related donation	Direct relief, NGO	Bolivia	Medicine, including analgesics, antibiotics
Dzwonczyk & Riha <sup>39</sup>	2012	Medical equipment donations in Haiti: flaws in the donation process	Academic journal	Disaster-related donation	No specific donors mentioned	Hospitals, Haiti	Medical devices, supplies
Eisai <sup>40</sup>	2010	1	Pharmaceutical company website	Long-term program	Eisai, Pharmaceutical company	WHO	Medicine, diethylcarbamazine citrate (DEC) tablets
Eisai <sup>41</sup>	2013	Eisai Begins Free Supply of DEC Tablets to Eliminate Lymphatic Filariasis -First Shipment Sent from Eisai's Vizag Plant, India	Pharmaceutical company website	Long-term program	Eisai, pharmaceutical company	WHO, Papua New Guinea, Kiribati, Tuvalu, Fiji	Medicine, diethylcarbamazine citrate (DEC) tablets
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#### Table 1. Continued

Author	Year	Title	Publication type	Donation type	Donor	Recipient	Item donated
Eisai <sup>42</sup>	2016	Creating Leaflet for DEC Tablets in Local Languages for Endemic Countries	Pharmaceutical company website	Long-term program	Eisai, pharmaceutical company	Endemic countries	Medicine, diethylcarbamazine citrate (DEC) tablets
Eisai <sup>43</sup>	2016	DEC Project Managers' Efforts to Support Lymphatic Filariasis Elimination Activities in Indonesia	Pharmaceutical company website	Long-term program	Eisai, Pharmaceutical company	WHO and Indonesia/LF endemic countries (esp. Asia)	Medicine, diethylcarbamazine citrate (DEC) tablets.
Escandor <sup>44</sup>	2014	US-based NGO gives CamSur Php 172-M medical equipment	Media report	One-off donation	World Medical Relief, NGO	District hospitals, Camarines Sur Province, the Philippines	Medical devices, equipment
Finch et al. <sup>45</sup>	2014	Evaluation of a large-scale donation of Lifebox pulse oximeters to non-physician anaesthetists in Uganda	Academic journal	One-off donation	The Lifebox foundation, NGO	Uganda	Medical devices, oximeter
Friends of Disabled Adults and Children (FODAC) <sup>46</sup>	2010	FODAC is collecting supplies for shipment to Haiti	Publication from NGO	Disaster-related donation	Friends of Disabled Adults and Children, NGO	Haiti	Medical devices, supplie
Global Links <sup>47</sup>	2014	Global Links responds to cholera outbreak in Haiti	Press release	Disaster-related donation	Global Links, NGO	PAHO, Haiti	Medical devices, medica supplies and equipment
Gustavsen et al. <sup>48</sup>	2009	GlaxoSmithKline and Merck: private-sector collaboration for the elimination of lymphatic filariasis	Academic journal	Long-term program	Merck, GSK, pharmaceutical companies	>80 countries with endemic lymphatic filariasis	Medicine, Albendazole and Ivermectin
Hammerli <sup>49</sup>	2017	Children's Hospital in Cuba Receives 2nd Shipment of Medicines & Supplies	Publication from NGO	One-off donation	Heart to Heart International, NGO	William Soler Pediatric Hospital, Cuba	Medicine and medical devices
Health Partners International of Canada <sup>50</sup>	2009	World Vision, HPIC airlifts \$4 million cholera medications to Zimbabwe	Publication from NGO	Disaster-related donation	Health Partners International of Canada, NGO	Zimbabwe	Medicine, including rehydration solutions and antibiotics
Hoang <sup>51</sup>	2015	Vietnamese customs explains disposal of cancer drug	Media report	One-off donation	Novartis Pharma AG, pharmaceutical company	HCMC Hospital of Hematology and Blood Transfusion, Vietnam	Medicine, oncology

Continued

Table 1. Continued

Author	Year	Title	Publication type	Donation type	Donor	Recipient	Item donated
Hopkins <sup>52</sup>	2012	Beyond Providing Drugs: the Mectizan donation stimulates new strategies in service delivery and in strengthening health systems	Academic journal	Long-term program	Merck & Co Inc. (MSD), pharmaceutical company	Multiple	Medicine, Ivermectin
Hower & Garcia <sup>53</sup>	2010	2	Publication from NGO	Disaster-related donation	Global Links, NGO	Hospital Albert Schweitzer, Haiti	Medicine and medical devices, including antibiotics
International Health Partners <sup>54</sup>	2017	Thank you from Egypt	Publication from NGO	One-off donation	International Health Partners, NGO	Om El Masryen Hospital, Egypt	Medicine, including antibiotics, antifungal drugs, painkillers
International Organization for Migration <sup>55</sup>	2017	UN Migration Agency Supports Yemen's Struggling Health Care System	Press release	Disaster-related donation	UN Migration Agency, multilateral agency	Al-Jumhori Hospital in Sana'a, Yemen	Medicine and medical devices
Janssen <sup>56</sup>	2013	Janssen, the Pharmaceutical Companies of Johnson & Johnson, Announces First- of-its-Kind Drug Donation Program for HIV Treatment-Experienced Children	Press release	Long-term program	Janssen, pharmaceutical company	Ministry of Health in eligible countries, sub-Saharan Africa	Medicine, Darunavir and Etravirine
Jobe <sup>57</sup>	2010	Disaster relief in post- earthquake Haiti: unintended consequences of humanitarian volunteerism	Academic journal	Disaster-related donation	Donor not specified	Haiti	Medicine, not specified
Katabaazi Nakyanzi et al. <sup>58</sup>	2010	Expiry of medicines in supply outlets in Uganda	Academic journal	One-off donation	Donor not specified	Uganda	Medicine, not specified
Koporc et al. <sup>59</sup>	2015	Assessing 'First Mile' Supply Chain Factors Affecting Timeliness of School-Based Deworming Interventions: Supply and Logistics Performance Indicators	Academic journal	Long-term program	Johnson & Johnson, pharmaceutical company	Multiple	Medicine, Mebendazole
Ladner et al. <sup>60</sup>	2013		Academic journal	Long-term program	Boehringer Ingelheim, pharmaceutical company	Recipients in 60 countries	Medicine, Nevirapine

Table	1.	Continued

Author	Year	Title	Publication type	Donation type	Donor	Recipient	Item donated
Lauffenburger et al. <sup>61</sup>	2011	A public-health approach to site-specific formulary management: addressing deficient drug supplies in Malawi	Academic journal	One-off donation	Donor not specified	Outpatient medical clinic, Malawi	Medicine, not specified
Lyatuu <sup>62</sup>	2015	Coca-Cola, Medshare Give Kamuli Hospital Shs 1.4 Billion Equipment	Media report	One-off donation	Coca-Cola Beverages Africa in partnership with Medshare International, NGO	Hospitals in Uganda	Medical devices, medical supplies and consumables
Lynch <sup>63</sup>	2010	Haiti's humanitarian aid disaster	Media report	Disaster-related donation	Donor not specified	Haiti	Medicine, not specified
Mackenzie et al. <sup>64</sup>	2012	Elimination of onchocerciasis from Africa: Possible?	Academic journal	Long-term program	Merck & Co	Countries in Africa and Latin America (the paper mainly focuses on Africa)	Medicine, Ivermectin
Malaria Weekly <sup>65</sup>	2015	Investigators at Johnson & Johnson Discuss Findings in Tropical Medicine and Public Health (Assessing 'First Mile' Supply Chain Factors Affecting Timeliness of School-Based Deworming Interventions: Supply and Logistics Performance Indicator	Media report	Long-term program	Johnson & Johnson, pharmaceutical company	14 countries	Medicine, Mebendazole
Manne et al. <sup>66</sup>	2013	Barriers to Treatment Access for Chagas Disease in Mexico	Academic journal	Long-term program	Bayer, pharmaceutical company, and WHO, multilateral agency	National Program on Onchocerciasis, Leishmaniasis and Chagas Disease, Mexico	Medcine, Nifurtimox
Mectizan Donation Program <sup>67</sup>	2017	Guide for Donations of Mectizan <sup>®</sup> to Accelerate the Elimination of Lymphatic Filariasis in Countries where Onchocerciasis is not co- endemic	Pharmaceutical company website	Long-term program	Merck & Co Inc. (MSD), pharmaceutical company	,	Medicine, Ivermectin

Author	Year	Title	Publication type	Donation type	Donor	Recipient	Item donated
Mena Report <sup>68</sup>	2014	Fiji: Health sector receives timely donation from Turkish government	Media report	One-off donation	Government, Turkey	Ministry of Health and medical services, Fiji	Medical devices, equipment
Miesen <sup>69</sup>	2013	5	Media report	One-off donation	Donor not specified	Multiple hospitals, Uganda	Medical devices
Morain <sup>70</sup>	2015	Nepal Earthquake Response: Update 5/5	Publication from NGO	Disaster-related donation	Direct relief, NGO	Nepal	Medicine and medical devices
Morain <sup>71</sup>	2017	Direct Relief Airlifts 79,365 lbs of Emergency Medical Aid to Puerto Rico	Publication from NGO	Disaster-related donation	Direct relief, NGO	Department of Health, Puerto Rico	Medicine and medical devices
Mugini <sup>72</sup>	2015	Medical equipment donation to benefit Nyerere Hospital	Media report	One-off donation	MATTER, NGO	Nyerere District Designated Hospital, Tanzania	Medical devices
Nair <sup>73</sup>	2017	Novartis and The Max Foundation to provide cancer access programme in lower-income countries	Media report	Long-term program	Novartis, pharmaceutical company	Low-income countries	Medicine, Imatinib
Novartis <sup>74</sup>	2009	Novartis Delivers 250,000,000th Coartem <sup>®</sup> Treatment And Becomes First Healthcare Company To Join United Against Malaria Partnership	Pharmaceutical company website	Long-term program	Novartis, pharmaceutical company	Tanzania, other	Medicine, Artemisinin- based combination therapy
Novartis <sup>75</sup>	2017	Press release: Novartis and The Max Foundation transform pioneering cancer access program for people in lower-income countries	Press release	Long-term program	Novartis, pharmaceutical company	Lower income countries	Medicine, Imatinib, Nilotinib
Novartis <sup>76</sup>	2018	Novartis extends commitment to help achieve final elimination of leprosy	Press release	Long-term program	Novartis International AG, pharmaceutical company	Worldwide	Medicine, multidrug therapy for the treatment of leprosy
Parsons <sup>77</sup>	2013	30 Pallets of Essential Medicine for the Philippines on board Air Canada flight	Publication from NGO	Disaster-related donation	Health Partners International of Canada, NGO	Philippines	Medicine, not specified
Parsons <sup>78</sup>	2016	\$1.74 million Worth of Apotex Medicine Being Airlifted to Ecuador	Publication from NGO	Disaster-related donation	Apotex, pharmaceutical company	Ministry of Health, Ecuador	Medicine, including antibiotics, analgesics antifungals,
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Author	Year	Title	Publication type	Donation type	Donor	Recipient	Item donated
							antihypertensives – medicines for diabetes, antianxiety medications, eye drops, antihistamines
Partnow & Stuteville <sup>79</sup>	2014	Drug recycling: crime or compassion?	Media report	One-off donation	Salaam Cultural Museum, NGO	Jordan	Medicine, recycled
Pharmaceutical Journal <sup>80</sup>	2018	Janssen provides free courses of anti-TB drug bedaquiline	Media report	Long-term program	Janssen therapeutics, pharmaceutical company	National center for TB and lung diseases, Georgia	Medicine, Bedaquiline
Pharma business week <sup>81</sup>	2010	Sanomedics International Holdings; Sanomedics Supports Haiti Relief with Significant Medical Equipment Donation	Media report	Disaster-related donation	Sanomedics International Holdings, medical device company	Haiti	Medical devices, thermometers
The Philippine Star <sup>82</sup>	2014	Novartis, DOH vow to hasten progress in leprosy control	Media report	Long-term program	Novartis, pharmaceutical company	Department of Health	Medicine, multidrug therapy for the treatment of leprosy
Robles et al. <sup>83</sup>	2010	Customs stalling aid efforts in Haiti	Publication from NGO	Disaster-related donation	Granted wish foundation, NGO	Haiti	Medical devices, ambulance, mobile medical unit
Ryley <sup>84</sup>	2010	Haitian Hospitals Awash With Supplies, Struggle to Pay Staff (Part 2)	Media report	Disaster-related donation	Donor not specified	Hospitals, Haiti	Medical devices, supplie
Salenga et al. <sup>85</sup>	2015	Medicines management in the Philippine public sector during the response to Haiyan	Academic journal	Disaster-related donation	Donor not specified	Philippines	Medicine, not specified
Sanofi Espoir Foundation <sup>86</sup>	2011	Humanitarian emergencies in Côte d'Ivoire and Libya	Pharmaceutical company website	Disaster-related donation	Sanofi Espoir Foundation, pharmaceutical companies	Hospitals, Cote d'Ivoire and Libya	Medicine, not specified
Ganofi Espoir Foundation <sup>87</sup>	2011	Humanitarian emergencies in Pakistan, Thailand and Turkey	Pharmaceutical company website	Disaster-related donation	Sanofi Espoir Foundation, pharmaceutical companies charitable subsidiary	Ministry of Health, Pakistan	Medicine, Chloroquine
anofi Espoir foundation <sup>88</sup>	2012	Solidarity with the people of Haiti following the passage of cyclone Matthew	Pharmaceutical company website	Disaster-related donation	Sanofi and Zentiva, pharmaceutical companies	French Red Cross, Première Urgence Internationale, Haiti	Medicine, not specified

International Health

Author	Year	Title	Publication type	Donation type	Donor	Recipient	Item donated
Samsky <sup>89</sup>	2012	Scientific sovereignty: now international drug donation programs reshape health, disease, and the state	Academic journal	Long-term program	Merck, Pfizer, pharmaceutical companies	Tanzania	Medicine, Ivermectin, Zithromax
Samsky <sup>90</sup>	2015	The drug swallowers: Scientific sovereignty and pharmaceuticalization in two international drug donation programs	Book chapter	Long-term program	Merck, Pfizer, pharmaceutical companies	Tanzania	Medicine, Ivermectin, Zithromax
Savioli et al. <sup>91</sup>	2017		Academic journal	Long-term program	Merck, pharmaceutical company	Sub-Saharan Africa	Medicine, Praziquantel
Smith <sup>92</sup>	2017	Responding to devastation in Puerto Rico	Pharmaceutical company website	Disaster-related donation	Lilly, pharmaceutical company	Department of Health, Puerto Rico	Medicine and medical devices, including insulin
Sumner et al. <sup>93</sup>	2017	Wheelchair donation in a low- resources setting: Utilization, challenges and benefits of wheelchairs provided through a specialized setting programme in Haiti	Academic journal	One-off donation	Team Canada Healing Hands, NGO	Local rehabilitation program in northern Haiti	Medical devices, wheelchairs
Tekinturhan et al. <sup>94</sup>	2013	Improving access to care in low and middle-income countries: institutional factors related to enrollment and patient outcome in a cancer drug access program	Academic journal	Long-term program	Novartis, pharmaceutical company	47 institutions in 44 countries	Medicine, Imatinib
US Department of State <sup>95</sup>	2009	Project Hope and U.S. Government deliver medical assistance for Tajik hospitals	Publication from NGO	One-off donation	McNeil, GlaxoSmithKline, Alcon, Hospira, Abbott, Schering Plough and Johnson & Johnson, pharmaceutical companies	Health centers, Tajikistan	Medicine, including oncology, cardiovascular, antiviral and psychiatry drugs, ophthalmology and skin medicines and antibiotics
							Contin

Table 1. Continued							
Author	Year	Title	Publication type	Donation type	Donor	Recipient	Item donated
US Department of State <sup>96</sup>	2009	Tajikistan: Project HOPE delivers \$7.9 million of medical supplies to Tajik hospitals	Publication from NGO	One-off donation	Eli Lilly, Merck, GlaxoSmithKline, Alcon, Hospira and Janssen Cilaq, pharmaceutical companies	Hospitals and health centers, Tajikistan	Medicine, including insulin, antivirals, antibiotics, oncology medicines, cardiovascular medications, psychiatric medications and ophthalmology medicines
US Department of State <sup>97</sup>	2011	U.S. embassy delivers \$35 million in donated medicine to Tajikistan	Publication from NGO	One-off donation	GlaxoSmithKline, Abbott, Lundbeck, Merck, Hospira, Allergan and other pharmaceutical companies	Ministry of Health, clinics and hospitals, Tajikistan	Medicine, including antibiotics, and oncological, cardiological and psychiatric medication
Wan et al. <sup>98</sup>	2015	Global public health impact of recovered supplies from operating rooms: a critical analysis with national implications	Academic journal	One-off donation	SHARE, NGO	The Luis Vernaza Hospital and Damian House, Guayaquil, Ecuador	Medical devices, surgical equipment
Zhang et al. <sup>99</sup>	2015	Why West Africa rejected donation of Chinese medicine for treating Ebola recommended by Chinese government?	Academic journal	Disaster-related donation	Government, China	West African countries	Traditional Chinese medicine, Pien Tze Huang

Disaster	Medicine(s)/device(s)	Location	Year	Donor
Dengue fever outbreak <sup>38</sup> Cholera outbreak <sup>50</sup>	Medicines including analgesics and antibiotics Medicines for the management of cholera	Bolivia Zimbabwe	2009 2009	Direct Relief Health Partners International of Canada
Conflict <sup>35</sup>	Medical supplies	Gaza	2009	'Governments and organizations'
Earthquake <sup>16,27,37,39,46,53,57,63,81,83,84</sup>	Various medicines and medical supplies: - 483 091 kg of pharmaceutical supplies and 4990 kg of medical supplies were sent in the 2 weeks following the earthquake	Haiti	2010	Various <sup>a</sup>
Cholera outbreak <sup>47</sup>	Medical devices, including IV poles	Haiti	2010	Global Links
Flood <sup>87</sup>	Medicines - 3800 boxes of antimalarial medication (Nivaquine)	Pakistan	2011	Sanofi Espoir Foundation
Tsunami, earthquake <sup>31</sup>	Medicines	Japan	2011	Not specified
Conflict <sup>86</sup>	Healthcare kits Emergency medicine kits	Cote d'Ivoire Libya	2011	Sanofi Espoir Foundation
Typhoon <sup>77,85</sup>	Medicines - 30 pallets medicines - Unspecified medicines	Philippines	2013	Health Partners International of Canada, unspecified donor
Earthquake <sup>23,70</sup>	Medical supplies and medicines - X-ray units, ventilators, orthopedic supplies, IV solutions, medications and 5 'hospital modules' - unspecified supplies	Nepal	2015	Direct Relief, Project Hope
Ebola outbreak <sup>99</sup>	Pien Tze Huang (traditional Chinese medicine) for treatment of Ebola (rejected)	West Africa	2015	Chinese government
Earthquake <sup>78</sup>	Medicines	Ecuador	2016	Apotex
Hurricane <sup>88</sup>	Medicines	Haiti	2016	Sanofi
	Paracetamol			Zentiva
Hurricane <sup>34,71,92</sup>	Medicines, medical supplies - 79 365 lb medical aid (prescription medications, nutritionals and medical supplies)	Puerto Rico	2017	Direct Relief
Conflict <sup>55</sup>	Medicines, medical supplies	Yemen	2017	UN migration agency

**Table 2.** Characteristics of disaster-related donations (n=15)

<sup>a</sup>Global Links, members of Partnership for Quality Medical Donations (PQMD), Bill Clinton Foundation, Friends of Disabled Adults and Children, Granted Wish Foundation, Sandomedics International Holdings.

de Médicaments Essentiels (PROMESS),<sup>57</sup> a medicines distribution agency managed by the Pan American Health Organization (PAHO). PROMESS distributed 345 000 boxes of essential medicines in the first 45 d following the earthquake.<sup>37</sup>

Some pharmaceutical donations following disasters were matched to recipients' needs. Some donors reached agreement with the recipient prior to making the donation,<sup>78</sup> or responded to direct requests for specific medications.<sup>34,90,91</sup> In one-off non-disaster-related donations, some medication and device donations were also in response to expressed needs.<sup>17,19,49,69,78,95</sup> Donations that involved communication between donor and recipient, or collaboration with experienced NGOs,<sup>33</sup> were more compliant with the WHO guidelines, appeared more useful and were more likely to suit the recipient's needs. However, medical device donations were commonly inappropriate for resource-limited settings, particularly in relation to energy requirements.<sup>16,39</sup>

Long-term programs generally required applications from recipients and were prioritized for areas endemic for the targeted disease. Applications required evidence that the recipient had the resources to distribute the medication.

#### Quality assurance and shelf life

Medicines were donated that were therapeutic classes or formulations uncommon in the recipient country,<sup>61</sup> arrived without labeling, had expired<sup>52,59</sup> or had a short shelf life on arrival.<sup>51,85</sup> The source of some medicines was unclear, making it difficult to determine if they were counterfeit.<sup>31</sup> Excessive donations made sorting and quality assurance a challenge.<sup>57,85</sup> Medicines for long-term programs were more compliant with quality assurance and shelf-life guidelines because they were often manufactured specifically for these donations. In response to the

#### Table 3. Characteristics of long-term medicine donation programs (n=5)

Generic medicine	Brand name	Disease	Donor
HPV <sup>21</sup>	Gardasil	Vaccination against HPV infection	Merck
Ivermectin <sup>28,32,36,52,64,67,89,90</sup>	Mectizan	Onchocerciasis Lymphatic filariasis	Merck
Darunavir Etravirine <sup>56</sup>	Prezista Intelence	HIV (second- and third-line treatment)	Janssen
artemisinin-based combination therapy (ACT) <sup>74</sup>	Coartem	Malaria	Novartis
diethylcarbamazine citrate (DEC) <sup>32,40-43</sup>		Lymphatic filariasis	Eisai
Imatinib	Glivec	Chronic myeloid leukaemia (CML), gastrointestinal	Novartis
Nilotinib (second-line treatment) <sup>64,66,73</sup>	Tasigna	stromal tumors (GIST) and other rare cancers	
Albendazole <sup>46,49,55</sup>		Intestinal worms/soil-transmitted helminthiasis, lymphatic filiariasis	GSK
Mebendazole <sup>49,58,61</sup>	Vermox	Soil-transmitted helminthiasis	Johnson & Johnson
Nevirapine <sup>60</sup>	Viramune	Prevention of mother-to-child transmission of HIV	Johnson & Johnson
MDT <sup>a25,32,76,82</sup>		Leprosy	Novartis
Nifurtimox <sup>18,66</sup>	Lampit	Chagas disease	Bayer
Praziquantel <sup>13,14,91</sup>	Biltricide	Schistosomiasis	Merck
Azithromycin <sup>32,89,90</sup>	Zithromax	Trachoma	Pfizer
Bedaquiline <sup>80</sup>	Sirturo	Multidrug-resistant TB	Janssen
Coagulation factor IX <sup>20</sup>	Alprolix	Haemophilia B	Biogen and Sobi
Antihemophilic factor (recombinant)	Eloctate	Haemophilia A	2

<sup>a</sup>MDT, multidrug therapy (rifampicin, clofazimine and dapsone).

Ebola outbreak in West Africa in 2015, the Chinese government offered donations of Pien Tze Huang, a traditional Chinese medicine,<sup>99</sup> which was rejected due to insufficient evidence of an antiviral effect, reported adverse events and ingredients from an endangered species.

Surplus supplies were a common source of medical device donations. Devices that were non-functional, or posed an environmental or health hazard, were donated.<sup>39</sup> Donations commonly arrived without all required parts to operate or repair devices, recipients were unable to access consumables or spare parts locally for obsolete equipment<sup>26,39</sup> and lacked maintenance or instruction manuals in local languages.<sup>33,38,58</sup>

#### Presentation, packaging and labeling

No information was available about the language of labeling for most donations. The active ingredients of some medications donated to Japan in 2011 could not be determined as the packaging was in unfamiliar languages.<sup>31</sup> In compliance with one guideline item Eisai produces brochures on diethylcarbamazine citrate for health professionals in languages common in endemic countries.<sup>42</sup> Multidrug therapy donations by Novartis for the treatment of Leprosy are packaged in fixeddose blister packages,<sup>32</sup> while Nevirapine (Johnson & Johnson), is provided in individual take-home packages for patients, reducing the potential for wastage.<sup>60</sup>

#### Information and management of the donation process

'Information and management' refers to the shipment of donations and management afterwards. Generally, shipment to recipient countries was arranged by the donor. Within-country distribution and logistics were in some cases facilitated by NGOs or multilateral agencies following disasters<sup>27,57,77,97</sup> and in long-term programs,<sup>32,52,89</sup> but otherwise were the responsibility of the recipient.

Transportation to landlocked countries was challenging as donations had to move through two or more countries' customs clearances to get from port to recipient.<sup>59</sup> Delays in customs clearance occurred due to incorrect paperwork, or failure by donors to prove tax-free status.<sup>16</sup> Medical device donations rarely involved training for healthcare workers, which resulted in devices remaining unused,<sup>39,69</sup> and non-functional devices created storage challenges for the recipients.<sup>33</sup>

# Case example: good compliance with medicine donation guidelines<sup>59</sup>

Johnson & Johnson have donated mebendazole for the control of soil-transmitted helminthiasis since 2007. Distribution and technical support were facilitated by Children without Worms (CWW) from 2007 to 2012. From 2013 onwards, overview of the donation program was transferred to the WHO with continued involvement from CWW. Applications for the program included information about disease burden, proposed medicine distribution, training, and monitoring and evaluation, to ensure endemic areas were

#### Table 4. Characteristics of one-time or repeated donations of medicine or devices (n=23)

Medicine/device	Recipient	Year	Donor
Medicine			
Antiviral medicines (for the treatment of HIV) <sup>30</sup>	Organization of Eastern Caribbean States	2012	Brazil
Three donations of medicines (antiviral, psychiatric medicines, cardiovascular medicines, antibiotics, insulin) <sup>95-97</sup>	Tajikistan	2009, 2011	Project Hope, US Department of State
Medicines, including antibiotics, antifungals, painkillers, diabetic medications <sup>54</sup> Cancer medicines <sup>51</sup>	Egypt	2017	International Health Partners
	Vietnam	2015	Novartis
Medicines close to expiry, recycled medications <sup>79</sup>	Refugee camps in Jordan	2014	Salaam Cultural Museum
Unspecified medicines <sup>58</sup>	Uganda	2010	Various <sup>a</sup>
Unspecified medicines <sup>61</sup>	Outpatient clinic in Malawi	Not specified	Various <sup>a</sup>
Devices and medicine			
Medicines and medical devices <sup>49</sup>	William Soler Pediatric Hospital, Cuba	2015, 2017	Heart to Heart International
Medical devices			
Medical devices, including consumables, imaging equipment, dental devices, life-support equipment and other medical supplies <sup>24</sup>	Health facilities in Ghana	Not specified	Various <sup>a</sup>
Medical devices, including 5 bed central station ICU monitoring system, microscopes, centrifuges and sterilizer <sup>15</sup>	Guatemala	2013	American Medical Resources Foundation
Second-hand ventilators, masks and tubing systems <sup>17</sup>	Chile	2014	Heinen und Löwenstein
Diagnostic equipment <sup>19</sup>	Democratic Republic of Congo	2012	Rice University
Medical devices, including X-ray endoscopy, oxygen concentrator, C-Arm fluoroscopy machine, dialysis machines and two 'slightly used' ambulances <sup>44</sup>	Camarines Sur, Philippines	2014	World Medical Relief
Medical devices including imaging equipment, patient monitors, ventilators and an anesthesia workstation <sup>12</sup>	Steve Biko Academic Hospital, Pretoria	2017	China
Medical surplus <sup>33</sup>	CHA member hospitals	Not specified	СНА
5 ECG machines, 5 vital-signs monitors and 12 scales worth US\$25 000 <sup>68</sup>	Fiji	2014	Turkey
Handheld pulse oximeters 45	Uganda	2011	The LifeBox Foundation
Medical devices and consumables, including Intensive Care Unit beds, ultrasound machine, incubators, delivery sets, oxygen concentrators and anesthetics unit <sup>62</sup>	Uganda	2016	Coca-Cola Beverages Africa, in partnership with Medshare International
Wallach LL100 Cryosurgical systems for the treatment of cervical cancer <sup>29</sup>	Malawi	2010	Jack Brewer
Medical devices including ultrasound machines, microscopes and beds <sup>72</sup>	Nyerere	2015	MATTER
Wheelchairs <sup>93</sup>	Haiti	2014	Team Canada Healing Hands
Medical devices, including incubators and anesthetic machines <sup>26,69</sup>	Hospitals in Uganda	2014, prior to 2013	Various <sup>a</sup>
Recovered supplies <sup>98</sup>	Ecuador	2010-2013	SHARE

<sup>a</sup>Specific donors not stated.

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Table 5. Percentage of medicine donations compliant with guideline items

Guideline item	Number of donations that met guideline item	Number that reported on compliance	Percentage (%) compliant with guideline item
1.1. Is the donation based on an expressed need from the recipient?	25	29	86.2
1.2 Is the donation relevant to the disease pattern of the recipient country?	27	28	96.4
1.3 Were the donation quantities agreed upon between the donor and recipient?	12	17	70.6
2.1 Are the donated medicines or their generic equivalents approved for use in the recipient country?	7	10	70.0
2.2 Do the donated medicines or their generic equivalents appear on the national list of essential medicines, national standard treatment guidelines or the WHO model lists of essential medicines if no national list is available?	2	4	50.0
2.3. If 'no' to question 2.2, was the donation specifically requested by the recipient?	1	1	100.0
3.1 Is the presentation, strength, and formulation of the donation similar to those of medicines commonly used in the recipient country?	0	3	0.0
4.1 Was the donation obtained from a quality-ensured source?	26	28	92.9
4.2 Does the donation comply with quality standards of the donor country?	0	1	0.0
4.3 Does the donation comply with quality standards of the recipient country?	1	4	25.0
4.4 Was the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce used?	0	0	0.0
5.1 Was the donation free from returned/recycled medications, or free samples given to health professionals?	20	21	95.2
6.1 Did the donated medicines have a remaining shelf life of at least 1 y on arrival at the recipient country?	1	6	16.7
6.2 Do the donated quantities match the recipient countries' consumption needs before they are expired?	2	5	40.0
7.1 Are the medicines labeled in a language easily understood by healthcare workers in the recipient country?	1	3	33.3
7.2 Did the label of each container contain the International Non-proprietary Name (INN) or generic name of the medicine?	0	1	0.0
7.3 Did the label include batch number, dosage form and strength, name of manufacturer, country of manufacture, quantity in the container, storage conditions and expiry date?	0	1	0.0
8.1 Were the donated medicines provided in appropriate pack sizes?	3	4	75.0
<ul><li>9.1 Was the donation packed in accordance with international shipping standards, accompanied by a detailed packing list and not mixed with other supplies (unless shipped as kits with predetermined contents)?</li></ul>	3	6	50.0
10.1 Were medicines sent with prior consent of the recipient?	24	26	92.3
11.1 Was the declared value of the donation based on the wholesale price of the generic equivalent in the recipient country, or world-market price?	4	4	100.0
12.1 Were the associated costs of transport, storage, port clearance, handling, disposal, etc. paid for by the donor (unless agreed upon with the recipient in advance)?	27	27	100.0

prioritized and resources were in place to distribute the medicine. Once the donation was approved, production and shipment were scheduled. The donor arranged shipment to government medical stores, which were responsible for within-country distribution. CWW ensured that critical paperwork for customs clearance was available prior to the shipments being loaded onto a vessel. Delayed or missed medicine administration was evaluated.<sup>59</sup> In-country delays were the most common, due to lack of local resources or coordination by recipients. Shipping and customs issues occurred, including delays in arranging secondary overland transport, difficulty in transporting to landlocked countries or insufficient budget in the recipient program for customs costs. To reduce production delays, recipients completed applications 1 y prior to the planned medicine administration.

## Case example: poor compliance with medicine donation guidelines<sup>79</sup>

A Seattle-based NGO, Salaam Cultural Museum, distributed medicines in 2014 to Syrian refugees in Jordan on seven separate Table 6. Percentage of medical device donations compliant with guideline items

Guideline item	Number of donations that met guideline item	Number that reported on	Percentage (%) compliant with guideline item
			galactine iterri
<ul><li>1.1 Is the donation based on an expressed need from the recipient?</li><li>1.2. Was the donation based on agreement between the donor and recipient regarding the device(s) to be donated, shipping and customs arrangements, and whether donare result?</li></ul>	14 5	16 8	87.5 62.5
whether donor or recipient covers any costs? 2.1. Does the recipient country have the resources to install, operate, maintain and dispose of the equipment?	8	10	80.0
<ul><li>2.2. Does the recipient have the available facilities, including physical space, stable electrical supply, water supply, heating or air-conditioning, to operate the equipment/device(s)?</li></ul>	5	7	71.4
2.3. Is the device(s) capable of being operated in a limited-resource setting?	8	9	88.9
2.4. Does the device(s) have low energy consumption?	2	2	100.0
2.5. For device(s) requiring an energy source, has it been confirmed that one is	4	6	66.7
available, or has an alternative power source been provided as appropriate?	1	0	00.7
<ul><li>2.6. If the device requires a power source, does the device have the correct plug adaptor for the recipient country?</li></ul>	1	4	25.0
<ul><li>3.1. Does the donation comply with national or organizational policy, or national guidelines, of the donor country?</li></ul>	1	2	50.0
<ul><li>3.2. Does the donation comply with national or organizational policy, or national guidelines, of the recipient country?</li></ul>	1	1	100.0
4.1. Is the device(s) fully operational on arrival to the recipient country?	7	11	63.6
4.1. Is the device(s) fully operational on annual to the recipient country? 4.2. Has sterilization/disinfection of the device(s) been considered and accounted for?	1		100.0
		1	
4.3. For refurbished device(s), were they restored to the manufacturer's original specifications?	2	2	100.0
4.4. Is the device(s) free from environmentally hazardous substances?	0	1	0.0
4.5. Does the recipient have the resources to appropriately dispose of waste from the device(s)?	0	0	0.0
5.1 Is the device affordable to transport to the recipient?	5	5	100.0
5.2 Is it affordable to install?	6	6	100.0
5.3 Are transport and customs costs covered by the donor?	9	9	100.0
5.4 Is it affordable to maintain and service?	0	1	0.0
5.5 Are staffing costs affordable?	3	3	100.0
5.6 Is it affordable to dispose of safely?	0	0	0.0
6.1 Does the recipient country have personnel trained in operating donated	7	10	70.0
equipment/device(s)?			
6.2 Is there appropriate training available to personnel for use and/or maintenance of the device(s)?	7	11	63.6
7.1 Are legends or labeling on the device(s) such as on instrument controls, in a language common in the recipient country?	0	1	0.0
7.2 Are user manuals, service or maintenance manuals, disposal instructions and software available as required in a language commonly used in the recipient country?	1	2	50.0
8.1 Has the donor completed a checklist and provided it for the recipient to ensure that all components, accessories and supplies for initial operation are included?	0	1	0.0
<ul><li>8.2 Are installation requirements specified and detailed installation instructions made available by the donor?</li></ul>	2	2	100.0
8.3 Are all essential accessories and supplies available on arrival to the recipient country?	3	7	42.9
8.4 Does the donation include any auxiliary equipment required, e.g. X-ray film or medical gases?	4	6	66.7
			Continued

#### Table 6. Continued

Guideline item	Number of donations that met guideline item	Number that reported on compliance	Percentage (%) compliant with guideline item
8.5 Is auxiliary equipment included with the donation sufficient to enable reasonable use of the device(s) for the required time span (e.g. minimum of 6 months from arrival in the recipient country)?	5	7	71.4
8.6 If 'no' to above, is it confirmed that auxiliary equipment is available locally and that the recipient has the means to acquire them?	2	5	40.0
9.1 Does the device have a minimum of 6 months shelf life from arrival in the recipient country?	3	6	50.0
9.2 Is maintenance for the device(s) required?	5	5	100.0
9.3 Is manufacturer sales support, such as repair and maintenance assistance, available for a minimum of 2 y?	1	2	50.0
9.4 Are maintenance materials provided or available for a minimum of 1 y of operation?	3	4	75.0
10.1 Is the donation distributed through existing distribution channels?	6	7	85.7
10.2 Was the device(s) safely and appropriately packaged prior to transport as per manufacturer's specifications?	1	2	50.0
10.3 Was the device(s) decontaminated prior to shipping if required?	1	1	100.0
10.4 Do shipping documents list everything inside the shipment and specify that the shipment is a donation?	0	0	0.0
10.5 Is shipping documentation provided in a language common in the recipient country?	0	0	0.0
10.6 Has any special documentation required for customs clearance been provided by the recipient?	2	3	66.7
10.7 Did the donor cover any costs for the release of donations from customs or any taxes?	2	3	66.7
10.8 Has provision been made for the cost of transport within the recipient country, either by the recipient or by the donor?	4	4	100.0
10.9 On arrival, was the donation inspected to confirm contents are intact and undamaged?	0	0	0.0
10.10 If the device(s) had cold chain requirements, were these followed?	0	0	0.0

occasions. Therapeutic indications included chronic diseases, of which many were not on the WHO essential medicines list. While some medicines were within 6 months of expiry and obtained legally via medicine recycling collaborations, others were leftover prescribed medicines from the general public, the distribution of which is illegal within the USA. A health professional donated medicines that had been discarded by a US hospital. These medicines had been disposed of due to concerns about the quality of the products. Donated medicines were distributed without appropriate packaging or labeling, some in a Ziploc bag labeled only with the medicine name and dose. Medicines were distributed by health professionals who travel independently to the country. No information is available about what happened to the medicines following arrival in the recipient country.

## Case example: good compliance with medical device donation guidelines<sup>19</sup>

In 2012, researchers donated diagnostic devices to Takaya Health Centre in the Democratic Republic of Congo (DRC). The

donation was chosen based on consultation with physicians who had experience of working in the area and taking into consideration available resources. Devices were low-cost, durable and battery- or solar-powered. Rechargeable batteries and a solar-powered recharging system were included. To minimize importation challenges into the DRC, the donation was transported as luggage by healthcare workers visiting the region. The durability and functionality of the devices were evaluated quarterly following donation. A small portion of the devices was underutilized due to a lack of familiarity or training. Auxiliary devices were sufficient for approximately 6 months. Supplies that were depleted during the year following donation were mostly replaced by the recipient, with the exception of glucometer test strips that could not be obtained locally.

## Case example: poor compliance with medical device donation guidelines<sup>26,69</sup>

Two reports discussed the medical equipment available in health facilities in Uganda, in  $2013^{69}$  and 2014,<sup>26</sup> respectively. Many of

Guideline item	Identified problems		
Selection of medicines or devices	<ul> <li>Poor communication between donor and recipient</li> <li>Donated amounts exceed recipient's needs, or was not needed</li> <li>Medicines were not approved for use or were not commonly used in the recipient country</li> <li>Medicines were not on WHO or country Essential Medicines List</li> <li>Donations were not appropriate for a resource-limited setting</li> <li>Devices did not use an appropriate power voltage</li> </ul>		
Quality assurance and shelf life	<ul> <li>Devices did not use an appropriate power voltage</li> <li>Expired or short shelf life</li> <li>Unknown source, therefore unclear if counterfeit</li> <li>Devices were not functional</li> <li>Devices were donated without all required parts or consumables</li> <li>Spare parts or consumables not available locally</li> <li>No instruction manuals or manuals in inappropriate language</li> </ul>		
Presentation, packaging and labeling	<ul> <li>Labeling in a language not commonly used in the recipient country</li> <li>Medicines not properly packaged</li> <li>Mixtures of medical supplies sent that required sorting</li> </ul>		
Information and management	<ul> <li>Costs of transportation within recipient country not covered by donors</li> <li>Customs delays due to incomplete paperwork</li> <li>Recipients required to arrange customs clearance, cover storage or product disposal costs</li> <li>Training not provided for the use or maintenance of devices</li> <li>Negative environmental impact when donations disposed of inappropriately</li> </ul>		

Table 7. Common problems identified with medicine and medical device donations

the devices were donated, primarily by NGOs or other donors such as church aroups. Recipients reported that donors appeared to 'dump' healthcare equipment,<sup>69</sup> donations appeared to be made to meet corporate responsibility targets,<sup>26</sup> and were often problematic. Devices were donated that were not functional or broke soon after arrival and could not be repaired due to a lack of training or locally available spare parts.<sup>69</sup> For example, one donated anesthesia machine was used once before it stopped working, and 13 of 20 incubators in one hospital were nonfunctional. Equipment was also often donated without all required parts, for example an infant warmer sent without a patient probe, which was therefore unsafe to use.<sup>26</sup> Donations often required a different power voltage to that used in Uganda. Ugandan Ministry of Health policy states that donors should ensure that electrical needs can be met, but this was not enforced.<sup>26</sup> Healthcare workers often did not receive training or instructions on how to use devices,<sup>26</sup> or instructions were provided in languages not commonly spoken in Uganda.<sup>69</sup> Lack of communication was an issue, and few donor organizations conducted needs assessments prior to donations (IMEC, Project C.U. R.E. and Samaritan's Purse).<sup>6</sup>

### Discussion

We found that the majority of donations were inadequately reported and at times did not comply with WHO guidelines.<sup>2,8,9</sup> Despite updated guidelines, we found that there is still poor compliance across all types of donations, unchanged from the results of a similar review of medicine donations conducted almost a decade ago.<sup>4</sup> Although our findings suggest there has

been little improvement in compliance, it is important to note that reporting of donations remains poor, which hinders the assessment of compliance. An identified barrier to guideline compliance was poor communication among stakeholders, which results in unsuitable or excessive donations. Donors often have limited involvement once the donation arrives in the recipient country, and the recipient bears the responsibility and costs for sorting, distributing and disposing of donations, creating financial and logistical burdens.

Following disaster events, there were often limited control mechanisms for the acceptance and distribution of medicines, and damage to existing distribution networks and infrastructure. Donations of medicines made following the 2010 Haiti earthquake were reported to have better compliance with guidelines than the response to previous disaster events.<sup>37</sup> This may be attributed to PROMESS, which was already established at the time of the earthquake.

Donations reported in peer-reviewed publications tended to provide more information concerning guideline compliance. These reports more commonly evaluated long-term medicine donation programs by pharmaceutical companies, and tended to reflect better guideline compliance. Donations for the management of NTDs were more likely to be on the WHO essential medicines list.<sup>32</sup> Long-term donation programs were characterized by more communication among stakeholders, application processes that prioritized endemic areas and involvement of experienced NGOs or multilateral agencies. They also incorporated community involvement, which makes programs more cost-effective and sustainable, particularly if multiple programs are combined.<sup>100</sup> Combining programs does, however, create a higher burden for community medicine distributors, who often receive little compensation for their time. Moreover, withdrawal of external funding, lack of resources, political will, or capacity to distribute donations or implement mass drug administration programs in recipient countries, were challenges in long-term programs.

Donations can be made more effective by conducting needs assessments that facilitate communication among donors, recipients and local stakeholders, and using existing distribution networks such as community distribution networks or national health systems. Additionally, donors can engage qualified logistics personnel (e.g. pharmacists and logisticians), experienced NGOs or multilateral agencies, or utilize structured international control efforts with multiple donors such as horizontal donation programs, in which multiple programs utilize the same community workers for distribution. Ensuring local availability of spare parts and consumables, appropriate resources for operation and training for healthcare workers in the use and maintenance of devices is essential prior to the donation of medical devices. The development of checklists for both donors and recipients to evaluate compliance against WHO guideline items may help improve donations. Financial donations would allow recipients to purchase medical supplies that suit their needs, while stimulating local markets. Countries should have the capacity to reject donations that do not meet their needs and donors should be required to bear the costs of disposing of inappropriate donations. Efforts should also be focused on reducing bottlenecks in the supply chain, such as customs clearance, and the sorting and distribution of donations.

We acknowledge that currently there are other efforts that aim to improve medical Donations, such as the Partnership for Quality Medical donations (PQMD) and the Access to Medicines Index, although these were not the focus of this study.

This study has several limitations. Information sources were limited to publicly available media reports, company or NGO documents and journal articles in English. Many of these sources were written by affiliates of donors, and therefore may be biased towards the donor, whereas lay press reports may focus on donations with which problems occur. None of the reports for medicine donations provided sufficient information to assess compliance with all items in the WHO guidelines for either medicine or medical device donations. Percentages reported in the results must be interpreted with caution due to limited reporting on the details of each donation. More structured, transparent and in-depth reporting of donations, particularly following disaster events, would be beneficial for determining compliance with guidelines.

#### Conclusion

The donation of medicines and medical devices can have a positive impact on providing or improving access to healthcare in low and middle income countries, but can cause a large burden to recipients to sort and store items, and dispose of inappropriate donations. Our findings suggest that improved compliance with WHO guidelines for medicine and device donations is urgently needed. The existing guidelines, if fully implemented, could achieve a positive health impact and limit the burden on already disadvantaged healthcare systems. Communication with recipients prior to making donations is essential to ensure that recipient needs are met, and to reduce wastage. Partnerships with experienced NGOs or agencies and use of existing distribution networks would also make donations more effective.

### Supplementary data

Supplementary data are available at *International Health* online (http://inthealth.oxfordjournals.org/).

**Authors' contributions:** SM developed the protocol, wrote the search strategy and undertook the literature search, conducted title and abstract and full text screening for final inclusion, collected and analyzed data, and drafted the manuscript. AF, LP and JW contributed to development of the protocol, conducted full text screening for final inclusion, extracted data and provided critical revision of drafts of the manuscript. LB devised the study, contributed to development of the protocol and analysis and full text screening for final inclusion, and provided critical revision of drafts of the manuscript. SM and LB are guarantors of the paper.

**Acknowledgements:** We thank Lisa Hedman and Suzanne Hill, the World Health Organization, and Quinn Grundy and Barbara Mintzes, the University of Sydney, for their comments on the study.

Funding: This work was supported by the World Health Organization.

**Competing interests:** None declared.

Ethical approval: Not required.

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