1 Review Paper

Assessment of Blood donation safety by People Diagnosed with Diabetes, Hypertension, Malaria and Cancer

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5 ABSTRACT

6 The present review aims to assess the blood donation safety by people suffered from diabetes, 7 hypertension, malaria and cancer. Diabetes, hypertension, malaria and cancer have become common 8 health problems in human society. Cases of blood transfusion-transmitted malaria, hypertension, cancer 9 and the safety of blood donation by diabetic people have been described around the world and highlighted 10 in some studies. Diabetes is generally associated with complications and people with diabetes usually take 11 different medications and may already have anaemia secondary to renal impairment, B12 deficiency. As 12 for the recipient safety, a blood from a person with hyperglycaemia but otherwise healthy i.e. satisfy 13 blood donation safety standards (no record of HIV, Hepatitis B or C) would be quite safe to receive as the 14 extra glucose would simply be regulated and utilised by the recipient's body. Hypoglycemia is as bad as 15 hyperglycemia and could be fatal and hence, generally, it is not desired that diabetics give blood donations. Diabetic patients taking bovine or porcine insulin may develop antibodies and it is not 16 17 recommended that the antibody contaminated blood to be given to any other person. A person with 18 hypertension can donate blood, as long as the blood pressure is normal at the time of blood 19 donation and there's no fluctuation. Malaria is also readily transmitted by blood transfusion through 20 donations collected from asymptomatic, parasitaemic donors. The parasite is released into the 21 bloodstream during its lifecycle and will, therefore, be present in blood donated by infected individuals. 22 The presence of total anti-*Plasmodium* spp. antibodies in the bloodstream of individuals many years after exposure, with no history of malaria in the meantime, is important to highlight. Regarding donors with 23 24 cancer blood donations should not be taken from people with recently active malignancies, except in the 25 case of basal cell carcinoma or cervical carcinoma in situ.

- 26 Keywords: Blood Transfusion, Diabetes Mellitus, Hypertension, Malaria and Cancer
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28 **1. INTRODUCTION**

Diabetes has become endemic to human society, and over 400 million people live with this syndrome across the world. It is natural that there will be questions regarding the safety of blood donation in persons with diabetes, as well as about the viability of blood taken from them. There may be further questions about the safety of blood component transfusion in persons with

diabetes. Unfortunately, strong evidence-based knowledge for any of these questions is lacking 33 [1]. No evidence raised baseline blood pressure, treated hypertension or low blood pressure are 34 predictive of increased adverse reactions to blood donation, although the level of evidence is 35 limited [1]. In addition, there is no evidence of harm to recipients of blood from donors taking 36 anti-hypertensive medication. Individuals whose blood pressure is well-controlled by medication 37 and meet other donor selection criteria can be accepted as blood donors. Donors who have 38 recently started taking anti-hypertensive medication or for whom the dose of anti-hypertensive 39 medication has been adjusted should be deferred for 28 days after the blood pressure has been 40 stabilised [1]. 41

42 Cases of transfusion-transmitted malaria have been described around the world and highlighted in some studies. Semi-immune individuals are more likely to transmit malaria as they may be 43 44 asymptomatic. Some countries allow blood donations only based on epidemiological criteria while others reinforce their criteria with serological tests. However, little is known about the 45 46 longevity of anti-*Plasmodium* spp. antibodies and its meaning in blood donation [2,3]. Acceptance criteria for prospective donors with a history of treated solid tumours vary widely. 47 Some **Blood Transfusion Service (BTS)** accept donors who are disease-free for a specified 48 period, while others permanently defer on the basis that there is a theoretical possibility of 49 50 transfusion-transmission of tumour cells or oncogenic viruses, although these policies are currently under review [3]. 51

A large retrospective cohort study of cancer incidence among patients who received blood from 52 donors deemed to have subclinical cancer at the time of donation (diagnosed with cancer within 53 five years of the donation) showed no excess risk of cancer among recipients of blood from pre-54 cancerous donors compared with recipients of blood from non-cancerous donors. However, the 55 transmission of donor melanoma by organ transplantation has been reported. Transfusion-56 transmitted cancers have never been convincingly demonstrated, but most BTS continue to take a 57 58 precautionary approach and do not accept blood from people who have had a malignancy as 59 many malignancies spread through the bloodstream and by invading surrounding tissues. Blood donations should not be taken from people with recently active malignancies, except in the case 60 61 of basal cell carcinoma or cervical carcinoma in situ.

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64 **2. Blood donation by diabetic people**

Are persons with diabetes eligible to donate blood? In general, if well controlled, persons with 65 diabetes can do so safely. The guidelines of the National AIDS Control Organization (NACO) 66 advise that prospective donors be screened for any serious illness, primarily to safeguard donors. 67 Patient advisories by the American Diabetes Association clearly mention that statements as 68 69 persons with diabetes cannot donate blood are a myth. However, opinion varies about whether all persons with diabetes are eligible for donation. The World Health Organization (WHO) British 70 and European Guidelines have only included persons with diabetes well controlled on diet or oral 71 medications as eligible donors, while the American Red Cross Society has deemed even persons 72 well controlled on insulin as eligible [4]. It should also be noted that persons with diabetes who 73 had injected bovine insulin sourced from the UK after 1980 are not eligible for donation even 74 under the American Red Cross guidelines [1]. 75

Modern diabetes care, however, does not use animal insulin, and only recombinant human 76 77 insulin and insulin analogues are available today. The published evidence of the safety of blood donation in insulin-dependent diabetes is scant. One published study which gives the donor 78 79 reaction rate in type 1 diabetic autologous blood donors showed a donor reaction rate of 4.8% as compared to 2.7 % for normal donors. Therefore, it is advisable to avoid blood donation by 80 81 individuals with type 1 diabetes, as per the WHO criteria, until further studies clearly demonstrate safety [5]. Even for type 2 diabetes, published evidence about the safety of blood 82 83 donation is sparse. Though the WHO, British and European guidelines have included non-insulin requiring persons with type 2 diabetes as eligible donors, a systematic review found no data 84 85 relating to blood donor safety in type 2 diabetes controlled on oral hypoglycemic agents. Few studies have observed that repeated blood donations may increase insulin sensitivity both in 86 87 persons with type 2 diabetes as well as non-diabetics. Therefore, blood donation may have the potential to prevent the development of diabetes in normal persons by preventing iron overload. 88 This, however, needs confirmation through well-designed studies [4, 5]. 89

Type 2 DM can donate safely for Type 1 it is clinically unsafe and if should be done for any
reason you need to do that after being sure that the patient is at optimal conditions for donating
blood + a blood glucose and clinical follow up for at least 8-12 hours after donation (speaking
about Type 1 DM) [1].

94 Those with Type 2 diabetes need not be excluded if they are on diet alone, metformin alone or95 thiazolidinediones or insulin to control their blood

96 glucose. One should be cautious with those on sulphonylureas as residual concentrations of thes

97 e in the blood might cause hypoglycaemia in the recipient, however, this is a theoretical

possibility and no evidence to suggest that this would be a serious risk. It is likely that the risk (ifany) from suphonylureas would only exist for a few hours following ingestion.

100 It is suggested that for the sulphonylurea gliclazide, plasma concentrations around 101 1.5 mg/l cause hypoglycaemic effects. It is estimated that a unit of whole blood from a donor 102 taking gliclazide is likely to contain 10- to 100-fold less than a single daily therapeutic dose,

and is very unlikely to produce hypoglycaemia. It is recommended that individuals with non-103 insulin dependent diabetes should be accepted as whole blood or component donors, provided 104 105 that treatment is stable (i.e. not altered within the past 4 weeks) and the donor as well, with no history suggestive of cardiovascular or cerebrovascular, disease, renal impairment or peripheral 106 vascular disease [6]. What are the transfusion guidelines for persons with diabetes? By and large, 107 the only potential problem is that blood bag solution contains a small amount of glucose 108 109 (approximately 2.5 g of dextrose monohydrate in 100 ml of Citrate Phosphate Dextrose (CPD) solution; one blood bag of 450 ml contains about 69 ml of CPD), and therefore, in serious 110 111 conditions, when a large number of transfusions have to be given, the patient needs to be closely monitored. The long-term effect of one-time transfusion on glycaemic control has not been 112 113 studied. In the short term, HbA1C may be lowered due to the mixing of normal red blood cells (RBCs) with RBCs of the person with diabetes. HbA1C has been deemed an unreliable marker 114 115 for glycaemic control in diabetic blood recipients even in autologous donors [1].

In the United States, the Food and Drug Administration does not have any regulatory restrictions 116 117 against diabetics donating blood other than if the individual has received bovine source insulin 118 since 1980. The concern here is not diabetes but rather the bovine spongiform encephalopathy. As bovine source insulins were not widely available in the US, the diabetic would have had to 119 specifically import it from Europe. (Of note, the FDA regulations require that is the donor 120 answers that they are not certain whether they received bovine source insulin, they are deferred. 121 Many donors answer "I do not know" and are therefore deferred when in reality they have not 122 been exposed as it was not available in the US.) Donors may mistake this deferral as being due to 123 124 their having diabetes. Here is the FDA guidance [7].

125 The only instance where diabetes would have a negative effect on blood product and therefore an adverse effect on the patient would be in the rare instances where we collect granulocytes. If the 126 127 donor had poor glucose control, this could impair neutrophil function. Since granulocyte donors are usually stimulated with corticosteroids, which would worsen glucose control, diabetics are 128 deferred from granulocyte donation at my institution so this is not an issue. However diabetes is 129 generally associated with complications and people with diabetes usually take different 130 medications and may already have anaemia secondary to renal impairment, B12 deficiency. As 131 for the recipient safety, a blood from a person with hyperglycaemia but otherwise healthy i.e. 132 satisfy blood donation safety standards (does not have HIV, Hep B or C) would be quite safe to 133 receive as the extra glucose would simply be regulated and utilised by the recipient's body. 134

135 Diabetic people when they donate blood may become, hypotensive or hypoglycemic. Hypoglycemia is as bad as hyperglycemia and could be fatal and hence, generally, it is not 136 137 desired that diabetics give blood donations. Diabetic patients taking bovine or porcine insulins may develop antibodies and it is not recommended that the antibody contaminated blood to be 138 139 given to any other person. Each country and each hospital may have its own rules and regulations which are quite strict. There is indeed no necessity to have a uniform policy for a 140 141 generally objectionable practice. In those urgent life-saving circumstances, if the blood from normal healthy volunteers is absolutely not available, then perhaps blood from carefully drawn 142 from diabetics may be transfused under the supervision of hospital authorities. Diabetic patients 143 are actually apparently likely to benefit from donating blood/ bloodletting, , in view of the fact 144 that about 10% of Americans and 25% of the Irish, are carriers for hemochromatosis, a 145 hereditary iron overload disease and excess iron appears to induce insulin resistance, and many 146 people in the Western world particularly, eat lots of red meat, (Loyola University Medical Center 147 http://www.biomedcentral.com/1741-7015/10/54). 148

149 **3. Blood donation by hypertensive people**

150 'A 2002 study of 72,059 whole blood donations at the American Red Cross (ARC) showed no 151 statistical association between low pre-donation systolic or diastolic blood pressure and adverse 152 reaction [8]. In addition, ARC reviewed pre-donation blood pressure on all donors with adverse 153 reactions that resulted in hospitalization from January 1999 to December 2002. This review 154 showed no over-representation of low blood pressure or antihypertensive use in those donors. Health Canada's decision (to accept donors taking antihypertensive medication) is based on the f act that there is no known link between reactions from giving blood and the use of medication to control high blood pressure.

Donors who take antihypertensive medication are no more at risk than other donors 158 [6]. It would be medically safe to accept donations from donors on antihypertensive medication ot 159 her than diuretics. None of the antihypertensive agents in regular use should compromise a patie 160 nt's ability to compensate for a 1 unit donation. Regarding possible direct toxicity to the 161 recipient, his view was that 'that unit of blood will have the very little active drug in it by the 162 time it reaches the recipient.' It would not be unreasonable to consider allowing blood donation 163 in patients with stable cardiovascular disease or those taking cardioactive medications, provided 164 that they do not suffer from symptoms of postural hypotension generally [6]. They have not 165 166 suffered any adverse effects of raised blood pressure (BP) such as heart disease (angina, heart attack or heart failure), stroke, transient ischaemic attack (TIA or mini-stroke), or peripheral 167 168 vascular disease (intermittent claudication, gangrene). They are taking only a Beta(b)-blocker and/or diuretic as their treatment for the raised BP. The list below shows the proper and trade 169 170 names of allowed drugs. It is important to note that this list is not exclusive and that these drugs may be used to treat other conditions such as heart failure and abnormal heart rhythms 171 172 (arrhythmia); both of which would mean the donor must not donate. Other medication should be assessed independently. Treatment is stable and this requires: That the donor as well and not 173 174 having any problems with feeling faint, fainting or Giddines [6].

There is no evidence that raised baseline blood pressure, treated hypertension or low blood 175 pressure are predictive of increased adverse reactions to blood donation, although the level of 176 177 evidence is limited. In addition, there is no evidence of harm to recipients of blood from donors taking anti-hypertensive medication. Individuals whose blood pressure is well-controlled by 178 medication and meet other donor selection criteria can be accepted as blood donors. Donors who 179 180 have recently started taking anti-hypertensive medication or for whom the dose of anti-181 hypertensive medication has been adjusted should be deferred for a period of 28 days after the 182 blood pressure has been stabilised.

183 A person with hypertension can donate blood, as long as the blood pressure is normal at the 184 time of blood donation and there's no fluctuation. Acceptable blood pressure rate for blood

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donation is below 180 systolic (first number) and below 100 diastolic (second number) at the time of donation. Even though the donor is on regular medications, one must understand that medications for high blood pressure do not disqualify you from donating blood. Provided, you don't have side effects related to your medication. Also, the person shouldn't be suffering from other co-morbid diseases associated with hypertension. People who have fluctuating blood pressure with irregular treatment must stay away from donating

Routine ambulatory BP monitoring may identify a large number of individuals with white-coat hypertension and a smaller but significant number of individuals with masked hypertension, ensuring adequate protection of potential donors and the accurate assessment of donor risk. Differences in baseline characteristics are small and are not clinically useful in distinguishing individuals with masked hypertension from individuals with sustained normotension or individuals with white-coat hypertension from individuals with sustained hypertension, demonstrating the importance of ambulatory BP monitoring in this population [9].

4. Blood donation by people with malaria

A number of Chinese workers also travel as labourers to Africa, where many countries are 199 200 endemic for malaria; this trend has further increased the number of potential malaria-infected 201 donors in China. No autochthonous cases of malaria have been reported in the Jiangsu province since 1998 sporadic cases of imported malaria, mostly from Africa and Southeast Asia, have 202 203 been reported in recent years. This has led to an increase in the proportion of blood donors at risk for malaria. In August 2013, transfusion-transmitted malaria (TTM) case caused by P. 204 falciparum was reported in Jiangsu Province Blood Center for the first time. The blood donor 205 206 was a worker who recently returned from Kenya and once had malaria. He later admitted to 207 concealing his medical history in order to know whether he had recovered enough to donate blood. Malaria antibodies were detected in 2.13% of the 704 plasma samples studied. The 208 prevalence of malaria antibodies was not significantly correlated with gender, occupation and 209 frequency of donation, but it increased with age. No Plasmodium was observed in red blood cells 210 and no *Plasmodium* DNA was detected in any of the antibody-positive samples (10-12). 211

The study prevalence of malaria antibodies was not higher than expected, even in donors from regions where malaria is endemic. Additionally, parasitemia was not detected even once, and 214 none tested positive for *Plasmodium* DNA in the PCR assay. The number of blood donors is estimated to be less than 1% of the total national population. Donor deferral will further reduce 215 216 repeat donations and universal serological screening is impossible. In this study, follow-up investigations were not conducted, and none of the donors was deferred. Hence, the deferral of 217 malaria-risk donors still relies on the deferral guidelines, and, for a long time, this has been the 218 219 only method to prevent TTM in China. Donors may give inaccurate information intentionally or unintentionally because they misunderstand the questions or are unaware or have forgotten that 220 221 they have previously had contact with malaria (10-12).

222 Some factors that may influence the longevity of total anti-Plasmodium spp. antibodies over time 223 were identified: (a) had been born in endemic areas and (b) the previous history of malaria. On the other hand, living in endemic areas during childhood does not seem to be related to the 224 225 longevity of total anti-*Plasmodium* spp. antibodies, as well as the number of travels to endemic 226 areas or the length of time spent in endemic areas, for the population studied. Although the 227 length of time since the last stay in endemic areas was not statistically significant, the presence of total anti-Plasmodium spp. antibodies in the bloodstream of individuals many years after 228 229 exposure, with no history of malaria in the meantime, is important to highlight [13].

230 Asymptomatic malaria parasitaemia and anaemia were observed to be higher among commercial blood donors than voluntary donors. Malaria parasite-infected blood transfused to a non- the 231 232 immune individual is associated with fatal outcomes. Mandatory screening of blood donors for malaria parasite is advocated to curb transfusion-transmitted malaria and associated squeal. A 233 234 voluntary donation of blood should be encouraged. When malaria is transmitted through a blood 235 transfusion to a non-immune recipient, it can be rapidly fatal. Although reports show that a good 236 number of recipients of blood transfusion living in malaria-endemic areas in sub- Saharan Africa 237 are semi-immune to malaria, the degree of protection that this immunity confers against 238 transfusion-transmitted malaria is unknown. Malaria due to Plasmodium falciparum can be acquired even with transfusion of a small number of infected red blood cells. Children and 239 240 pregnant women, who form the bulk of recipients of blood in sub-Saharan Africa, are more likely to be immunologically compromised, thus exposing them to complications of transfusion-241 242 transmitted malaria. Haemoglobin assessment is an important criterion for blood donor selection. This is critical for the safety of blood donor and recipient. A number of African studies have 243

reported that low haemoglobin concentration is frequent in most blood donors. This has great
implication for the rate of recovery of patients transfused with blood [14].

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Malaria is also readily transmitted by blood transfusion through donations collected from asymptomatic, parasitaemic donors. The parasite is released into the bloodstream during its lifecycle and will, therefore, be present in blood donated by infected individuals. The parasites are stable in plasma and whole blood for at least 18 days when stored at +4°C and for extended periods in a frozen state criteria to exclude collecting blood from individuals with current or past history of malaria infection and at risk of transmitting malaria through transfusion, should be based on local epidemiological evidence and endemicity of the infection [15].

254 Malaria is transmitted by the bite of mosquitoes found in certain countries and may be 255 transmitted to patients through blood transfusion. Blood donations are not tested for malaria because there is no sensitive blood test available for malaria. If you have travelled or lived in a 256 257 malaria-risk country, it requires a waiting period before you can donate blood. Wait 3 years after completing treatment for malaria, wait 12 months after returning from a trip to an area where 258 259 malaria is found, wait 3 years after living more than 5 years in a country or countries where malaria is found. An additional waiting period of 3 years may be required if you have travelled to 260 261 an area where malaria is found if you have not lived a consecutive 3 years in a country or countries where malaria is not found. If you have travelled outside of the United States and 262 Canada, your travel destinations will be reviewed at the time of donation (American Red cross, 263 Medications and Vaccinations) [8]. 264

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4. Blood donation by people with Cancer

Acceptance criteria for prospective donors with a past history of treated solid tumours vary widely. Some BTS accept donors who are disease-free for a specified period, while others permanently defer on the basis that there is a theoretical possibility of transfusion-transmission of tumour cells or oncogenic viruses. 271 A large retrospective cohort study of cancer incidence among patients who received blood from 272 donors deemed to have subclinical cancer at the time of donation (diagnosed with cancer within 273 five years of the donation) showed no excess risk of cancer among recipients of blood from pre-274 cancerous donors compared with recipients of blood from non-cancerous donors. However, the transmission of donor melanoma by organ transplantation has been reported. Transfusion-275 transmitted cancers have never been convincingly demonstrated, but most BTS continue to take a 276 precautionary approach and do not accept blood from people who have had a malignancy as 277 many malignancies spread through the bloodstream and by invading surrounding tissues. Blood 278 279 donations should not be taken from people with recently active malignancies, except in the case 280 of basal cell carcinoma or cervical carcinoma in situ [15, 16].

A recent literature review concluded that there is now ample evidence to consider accepting selected donors with a history of malignant disease (except for those where there are specific safety concerns, such as haematological malignancy and melanoma) on the basis of a minimum (suggested 5-year) interval after the completion of successful curative treatment. Healthy adults with a remote history of treated malignant conditions from which they can be regarded as cured may be able to donate under certain well-monitored circumstances. Further studies in this field are indicated.

- For individuals with a past history of solid malignant tumour, BTS may consider
 acceptance if 5 years or more since completion of successful curative treatment.
- Individuals with a history of "in situ" malignant disease such as basal cell carcinoma or cervical carcinoma in situ, if regularly monitored and considered successfully treated and in good health.
- Individuals with a current diagnosis of malignancy. Individuals with past history of the solid malignant tumour if less than 5 years since completion of treatment. Individuals with a history of malignant melanoma and Individuals with current or past haematological malignancy, including Leukaemia: i.e. lymphoproliferative and myeloproliferative disorders-Lymphomas, Clonal haematological disorders such as: Polycythaemia rubra vera and essential thrombocythaemia ,Paroxysmal nocturnal haemoglobinuria and Myelodysplastic syndromes [15, 17].

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300 Conclusions

It is advisable to avoid blood donation by individuals with type 1 diabetes, as per the WHO 301 302 criteria, until further studies clearly demonstrate safety. Even for type 2 diabetes, published evidence about the safety of blood donation is sparse. A person with hypertension can donate 303 304 blood, as long as the blood pressure is normal at the time of blood donation and there's no fluctuation. Acceptable blood pressure rate for blood donation is below 180 systolic (first 305 306 number) and below 100 diastolic (second number) at the time of donation [18]. Malaria is also readily transmitted by blood transfusion through donations collected from asymptomatic, 307 308 parasitaemic donors. The parasite is released into the bloodstream during its lifecycle and will, therefore, be present in blood donated by infected individuals. The presence of total anti-309 310 Plasmodium spp. antibodies in the bloodstream of individuals many years after exposure, with no history of malaria in the meantime, is important to highlight. Regarding donors with cancer 311 Blood donations should not be taken from people with recently active malignancies, except in 312 the case of basal cell carcinoma or cervical carcinoma in situ. 313

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